2777

COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

RECEIVED
IRRC
2010 NOV 22 A 11: 32

November 22, 2010

Independent Regulatory Review Commission
ATTN: Kim Kaufman, Executive Director
333 Market Street, 14th Floor
Harrisburg, PA 17120

RE: NOTICE OF FINAL RULEMAKING
Report Resubmitting Disapproved Final-Form Regulation with Revisions
Department of Agriculture
7 Pa. Code Chapters 59 and 59a
Milk Sanitation
I.D. No. 2-160
Proposed Rulemaking: 39 *Pa. Bulletin 4677* (August 1, 2009)

Dear Mr. Kaufman:

The Independent Regulatory Review Commission voted to *disapprove* the above-referenced final-form regulation at its October 7, 2010 public meeting. Section 7 of the Regulatory Review Act (71 P.S. § 745.7) provides an administrative agency such as the Department of Agriculture (Department) with several options when IRRC issues a Disapproval Order with respect to a final-form regulation. Of these, the Department has elected to prepare and file the report described in Section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)). A copy of that Report is enclosed, and is submitted to you in accordance with the referenced statutory provision.

The enclosed Report has been delivered to the majority and minority chairpersons of the House and Senate Committees for Agriculture and Rural Affairs on this date, as well. A copy of a signed transmittal sheet confirming this delivery is enclosed.

I respectfully request the Commission's approval of this Report. The Department will provide any assistance you may require to facilitate a thorough review of this document. Thank you.

Sincerely,

Dwight-Jared Smith
Assistant Counsel

Enclosures

OFFICE OF CHIEF COUNSEL | PENNSYLVANIA DEPARTMENT OF AGRICULTURE
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pennsylvania
DEPARTMENT OF AGRICULTURE

CDL-1

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(Pursuant to Commonwealth Documents Law)

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

By:
(Deputy Attorney General)

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 11/12/10

BY Russell C. Redding
RUSSELL C. REDDING

TITLE
SECRETARY
Pennsylvania Department of Agriculture

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

BY Andrew C. Clark

DATE OF APPROVAL
NOV 22 2010
(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 Final Rulemaking:

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

Milk Sanitation

Report of the Pennsylvania Department of Agriculture to the Independent Regulatory Review Commission, the House Committee for Agriculture and Rural Affairs, and the Senate Committee for Agriculture and Rural Affairs

Report: Disapproved Regulation Submitted with Revisions

NOTICE OF FINAL RULEMAKING

TITLE 7 – AGRICULTURE
7 Pa. Code Chapters 59 and 59a
Milk Sanitation

A. *Introduction.*

This document is a report from the Department of Agriculture (Department) to the Independent Regulatory Review Commission (IRRC), the House Committee for Agriculture and Rural Affairs and the Senate Committee for Agriculture and Rural Affairs. It is submitted pursuant to Section 7(c) of the Regulatory Review Act (71 P.S. § 745.7(c)), and in accordance with IRRC's regulatory requirements at 1 Pa. Code Chapter 311 (relating to procedures for review of disapproved final regulations).

This document relates to IRRC's disapproval of the Department's final-form regulation titled *Milk Sanitation*. That document bears Department Regulation Identification No. 2-160 and IRRC Identification No. 2777.

B. *IRRC Disapproval Order.*

IRRC disapproved the subject final-form regulation (by a vote of three Commissioners favoring disapproval and two Commissioners favoring approval) at a public meeting held on October 7, 2010. IRRC's written Disapproval Order was delivered to the Department on October 15, 2010.

A true and correct copy of the subject Disapproval Order is appended to this report as "Attachment 1" and is incorporated herein. The inclusion of the Disapproval Order is in accordance with Section 7(c) of the Regulatory Review Act and IRRC's regulation at 1 Pa. Code § 311.4(2) (relating to report for disapproved regulation submitted with revisions).

In summary, the subject Disapproval Order concluded that although the final-form regulation was consistent with statutory authority and the intention of the General Assembly, Subchapter F of the final-form regulation (relating to raw milk for human consumption) was not in the public interest. IRRC stated two reasons in support of its conclusion:

> First, we believe that Subchapter F will have a negative fiscal impact on raw milk producers. (71 P.S. § 745.5b(b)(1)). In our comments on the proposed rulemaking, we asked the Department to quantify the costs the rulemaking will have on raw milk producers. The Department quantified the costs related to

testing requirements for raw milk. However, the regulated community, through written comments and statements made at the October 7, 2010 public meeting of this Commission, believes Subchapter F will impose a much greater cost than what was estimated by the Department. Of particular concern are the provisions related to mechanical capping of bottles and the need for separate rooms to perform certain tasks associated with the production of raw milk.

Second, the Department has failed to explain the need for the provisions contained in § 59a.410, relating to raw milk packaging. In addition, we find that section of the regulation to be unclear. (71 P.S. § 745b(b)(3)(ii) and (iii)). Of particular concern is why separate rooms are needed to perform certain tasks associated with production of raw milk, when separate rooms would be needed and why some customer-owned containers must be mechanically capped and others do not.

C. *Revised Final-Form Regulation.*

A true and correct copy of the revised final-form regulation is appended to this report as "Attachment 2" and is incorporated herein. The inclusion of the revised final-form regulation is in accordance with Section 7(c) of the Regulatory Review Act and IRRC's regulation at 1 Pa. Code § 311.4(1). *Although the entire final-form regulation is attached, the only changes to the final-form regulation appear on pages 6, 71 and 72.*

D. *Department's Response and Recommendations with respect to the Disapproval Order.*

The Department offers the following as its response and recommendations with respect to the subject Disapproval Order. This is offered in accordance with Section 7(c) of the Regulatory Review Act and IRRC's regulation at 1 Pa. Code § 311.4(3).

IRRC's first major concern was that it believed the final-form regulation would have imposed greater costs on the regulated community than were estimated by the Department. In particular, IRRC identified: (1) costs related to the mechanical filling and capping of raw milk containers; and (2) costs related to the need for separate rooms to perform certain tasks associated with the production of raw milk.

The Department has revised the final-form regulation to address the concerns expressed in the Disapproval Order. With respect to any new costs related to mechanical filling and capping equipment, the Department has revised § 59a.410 (relating to raw milk packaging) so that it imposes *no new costs related to mechanical filling and capping equipment* on the regulated community. In addition, the revised final-form regulation will effectively do away with the current regulatory requirement that raw milk that is prepackaged *for on-farm sale* be packaged using mechanical filling and capping equipment.

For at least 25 years, the current regulation at § 59.302(b)(7) (relating to raw milk) has required that the holder of a permit allowing the sale of raw milk for human consumption

(raw milk permit) use mechanical means of filling and capping bottles for "prepackaging" raw milk. The term "prepackaging" refers to packaging raw milk for later sales to customers – whether these sales occur on-farm or off-farm.

The revised final-form regulation (at § 59a.410(a)) will require mechanical filling and capping only when packaging is being done for off-farm sales. This regulatory requirement is less restrictive than the current regulatory requirement, in that a raw milk permit holder who packages raw milk only for on-farm sales would not have to acquire and use mechanical filling and capping equipment. In light of this change, the revised final-form regulation does not add any new costs with respect to mechanical filling and capping equipment – and eliminates any such costs for those raw milk permit holders who package raw milk only for on-farm sales.

The revised final-form regulation preserves a long-standing traditional practice (likely dating from 1935, when the Milk Sanitation Law was enacted) of allowing raw milk permit holders to fill customer-owned containers on-farm, directly from the milk tank, without having to use mechanical filling and capping equipment or adhere to other sanitation practices. The revised final-form regulation actually expands that tradition slightly, by allowing a raw milk permit holder to prepackage raw milk for on-farm sale without having to use mechanical filling and capping equipment. When raw milk for human consumption *travels from the farm to be sold off-site* (such as at a grocery store or farmers market), the revised final-form regulation requires the raw milk permit holder to employ filling, capping and sanitation practices that are more consistent with modern milk sanitation. The Department believes this is a reasonable line, in that it preserves a long-standing tradition for raw milk permit holders who offer raw milk for sale on-farm, while providing consumers who purchase raw milk from locations other than the farm at which it was produced with a product that has been packaged using mechanical filling and capping equipment.

IRRC's Disapproval Order also expressed concern over the costs involved with the separate rooms that would be required for different activities associated with the production of raw milk.

The revised final-form regulation would eliminate proposed language (at § 59a.410(a)) requiring "... separate rooms for bottling, single-service container storage, and bottle washing, as applicable." Revised § 59a.410 will require that: (1) the mechanical filling and capping of raw milk containers that are being filled for off-farm sale occur "in a room separate from the milk room" and (2) the washing of returnable (reusable) containers occur in a room that is separate from any room that is devoted to bottling or the filling of other containers.

With respect to the revised final-form regulation's requirement that mechanical filling and capping of containers for off-farm sale occur in a room that is separate from the milk room, the Department is aware that this would be a new regulatory requirement for raw milk permit holders. There are currently 139 raw milk permit holders. Of these, 12 only produce cheese made from raw milk, and do not sell or package raw milk for human

consumption. Of the remaining 127 raw milk permit holders (those who actually sell raw milk for human consumption), 111 (87%) *also* produce milk for pasteurization. For these 111 producers, the presence of filling and capping equipment in the milk room would violate long-standing regulatory requirements relating to the production of milk for pasteurization. In particular, these include requirements that the milk house or room "be used for no other purpose than milkhouse operations" (§ 59.105(10), relating to milk house or room – construction and facilities) and that equipment and operations be located within the milk house "as to prevent overcrowding and contamination of sanitized containers, equipment and utensils by splash, condensation or manual contact" (§ 59.116(1), relating to protection from contamination). These same requirements are prescribed by the Grade "A" Pasteurized Milk Ordinance, in Item 5r (relating to milkhouse – construction and facilities), 6r (relating to milkhouse – cleanliness), and 14r (relating to protection from contamination). These Grade "A" Pasteurized Milk Ordinance standards are adopted in the final-form regulation, at § 59a.19 (relating to standards for Grade "A" milk for pasteurization, ultrapasteurization or aseptic processing).

Given that the revised final-form regulation does not expand the universe of raw milk permit holders who are required to have mechanical filling and capping equipment beyond those who are already required to have it under the current, long-standing regulation, and given that approximately 111 (87%) of the 127 raw milk permit holders who produce raw milk for human consumption also produce milk for pasteurization and have long been required to locate mechanical filling and capping equipment away from the milk room, the Department believes very few, if any, raw milk permit holders will have to move mechanical filling and capping equipment from the milk room. Of these few, even fewer would actually have to build a new, separate room for mechanical filling and capping. In addition, for those raw milk producers that do not also produce milk for pasteurization, and who wish to only sell raw milk on-farm, mechanical filling and capping could occur in the milk room.

The Department cannot offer an estimate of the numbers of raw milk permit holders who would be required to move filling and capping equipment from the milk room and/or construct a room – separate from the milk room – for mechanical filling and capping required by the revised final-form regulation, or the total cost the regulated community would incur in meeting this requirement. The Department maintains that this separate room requirement is reasonable, in that it will lessen the chance that contaminants will be introduced to raw milk in the filling and capping process, and will lessen the chance of contamination in the milk room.

With respect to the revised final-form regulation's requirement that washing of returnable bottles occur in a room that is separate from any room that is devoted to bottling, the Department believes this provision lessens the prospect that contaminants on dirty returnable containers will find their way into containers that are being filled.

For at least 25 years, the current regulation (at § 59.302(b)(4)) has required that if: "... the containers of the producers are to be used, an additional room shall be provided for

bottle washing." A raw milk producer that fills and caps its own containers has been required to have a separate room for bottle washing.

The revised final-form regulation does away with any distinction based upon ownership of the container and, instead, requires (at § 59a.410(c)) that any *reusable* container be washed in a room that is separate from any room that is devoted to bottling or the filling of other containers. The impact of this revision will be as follows:

> For a raw milk permit holder that refills its own reusable containers, that permit holder already has (or is required to have) a separate room for bottle washing – so no new rooms are required by the revised final-form regulation.
>
> For a raw milk permit holder that refills reusable containers that are owned by its customers, and also fills its own reusable containers, that permit holder already has (or is required to have) a separate room for washing the reusable containers it owns – so no new rooms are required by the revised final-form regulation.
>
> For a raw milk permit holder that only refills reusable containers that are owned by its customers, and does not also fill its own reusable containers, the revised final-form regulation will require that permit holder to have and use a separate room for bottle washing.

The Department cannot offer an estimate of the numbers of raw milk permit holders who would be impacted by the revised final-form regulation by either having to: (1) move equipment among existing rooms such that the washing of reusable bottles and the refilling of returnable containers occurs in separate rooms; or (2) construct a new room and move equipment such that the washing of reusable bottles and the refilling of returnable containers occurs in separate rooms.

A reusable container that is returned to a raw milk permit holder to be refilled may contain contaminants. The process of washing-out reusable containers presents an opportunity to spread these contaminants (whether through spraying, splashing, run-off, misting or other means) to nearby articles. For this reason, the Department maintains that it is reasonable to require that this refilling activity occur in a room other than the room in which filling and capping (bottling) occurs.

To the extent that IRRC's concerns regarding the need for separate rooms to perform certain tasks associated with the production of raw milk might relate to the production of *cheese* from raw milk (a subject that was addressed by various commentators at IRRC's October 7, 2010 public meeting), the Department offers that for at least 25 years, the current regulation at § 59.771 (relating to rooms and compartments) has prescribed the specific rooms or areas that are required for the manufacturing of cheese. Section 59a.371 (relating to rooms and compartments) of the final-form regulation is a *verbatim* restatement of the current requirements set forth in § 59.771. The final-form regulation does not add any new requirements with respect to the manufacturing of cheese, does not require a person who is producing cheese (whether from raw milk or other milk) to build,

construct or use any new room or area in the cheese-making process, and imposes no new costs upon the regulated community.

IRRC's Disapproval Order also concluded that the Department failed to explain the need for the provisions contained in § 59a.410 of the final-form regulation and that the provision was unclear. In response, and as detailed above, that section has been rewritten in the revised final-form regulation to: (1) make it *less-restrictive than the current regulation* with respect to the need for mechanical filling and capping equipment; (2) allow raw milk permit holders to sell raw milk on-farm without having to use mechanical filling and capping equipment to fill the containers; and (3) require that any washing of reusable containers occur in a room other than the room in which bottling occurs.

With respect to IRRC's concern as to why separate rooms are needed to perform certain tasks associated with the production of raw milk, the Department offers that the revised final-form regulation imposes a reasonable requirement that the washing of reusable containers not occur in the same room where filling and capping (bottling) occurs. There are legitimate food safety risks associated with washing dirty containers in the same room where food is being packaged.

The revised final-form regulation also requires the mechanical filling and capping of raw milk containers for off-farm sales, and that filling and capping for off-farm sales occur outside of the milk room. The Department believes this is reasonable, and will have virtually no impact on the vast majority of raw milk permit holders (particularly, those raw milk permit holders who also produce milk for pasteurization from the same dairy operations where they produce raw milk for human consumption).

IRRC's Disapproval Order also expressed concern as to "why some customer-owned containers must be mechanically capped and others do not." As stated, the revised final-form regulation refocuses raw milk packaging requirements on whether the raw milk is being sold *on-farm* or *off-farm*, rather than on who owns the container in which the raw milk is packaged for sale.

E. *Conclusion.*

The Department respectfully submits that it has addressed the concerns expressed by the Independent Regulatory Review Commission in its Disapproval Order. The Department made substantive changes to the revised final-form regulation to address IRRC's concerns, and has explained the basis for the changes in this Report.

The Department respectfully request the Commission's approval of this Report, in accordance with Section 7(c.1) of the Regulatory Review Act (71 P.S. § 745.7(c.1)).

Attachment "1"

Disapproval Order

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http://www.irrc.state.pa.us

INDEPENDENT REGULATORY REVIEW COMMISSION

333 MARKET STREET, 14TH FLOOR, HARRISBURG, PA 17101

October 15, 2010

Honorable Russell Redding, Secretary
Department of Agriculture
211 Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17110

Re: Regulation #2-160 (IRRC #2777)
Department of Agriculture
Milk Sanitation

Dear Secretary Redding:

The Independent Regulatory Review Commission disapproved your regulation on October 7, 2010. Our order is enclosed and will be available on our website at www.irrc.state.pa.us.

Within 40 days of receipt of our order, Section 7(a) of the Regulatory Review Act requires you to select one of the following options: (1) proceed with promulgation under Section 7(b); (2) proceed with promulgation under Section 7(c); or (3) withdraw the regulation. If you do not take any action within this period, the regulation is deemed withdrawn.

If you or your staff have any questions, please contact me, at 783-5506.

Sincerely,

Kim Kaufman /kjew

Kim Kaufman
Executive Director
wbg
Enclosure
cc: Honorable Michael W. Brubaker, Majority Chairman, Senate Agriculture and Rural Affairs Committee
Honorable Michael A. O'Pake, Minority Chairman, Senate Agriculture and Rural Affairs Committee
Honorable Michael K. Hanna, Sr., Majority Chairman, House Agriculture and Rural Affairs Committee
Honorable John A. Maher, Minority Chairman, House Agriculture and Rural Affairs Committee

INDEPENDENT REGULATORY REVIEW COMMISSION
DISAPPROVAL ORDER

Commissioners Voting:

Arthur Coccodrilli, Chairman
George D. Bedwick, Vice Chairman
S. David Fineman, Esq., by Phone, Dissenting
Silvan B. Lutkewitte, III, Dissenting
John F. Mizner, Esq., by Phone

Public Meeting Held October 7, 2010

Regulation No. 2-160 (#2777)
Department of Agriculture
Milk Sanitation

On July 21, 2009, the Independent Regulatory Review Commission (Commission) received this proposed regulation from the Department of Agriculture (Department). This rulemaking rescinds 7 Pa. Code Chapter 59 and replaces it with a new Chapter 59a. The proposed regulation was published in the August 1, 2009 *Pennsylvania Bulletin* with a 60-day public comment period. The final-form regulation was submitted to the Commission on September 3, 2010.

This final-form rulemaking reflects developments in the dairy industry, brings Pennsylvania's sanitation standards into alignment with federal standards and requirements, and consolidates and updates provisions addressing the production of raw milk for human consumption. After review of the rulemaking, we find that Subchapter F of Chapter 59a, pertaining to raw milk for human consumption, is not in the public interest for the following reasons.

First, we believe that Subchapter F will have a negative fiscal impact on raw milk producers. (71 P.S. § 745.5b(b)(1)). In our comments on the proposed rulemaking, we asked the Department to quantify the costs the rulemaking will have on raw milk producers. The Department quantified the costs related to testing requirements for raw milk. However, the regulated community, through written comments and statements made at the October 7, 2010 public meeting of this Commission, believes Subchapter F will impose a much greater cost than what was estimated by the Department. Of particular concern are the provisions related to mechanical capping of bottles and the need for separate rooms to perform certain tasks associated with the production of raw milk.

Second, the Department has failed to explain the need for the provisions contained in § 59a.410, relating to raw milk packaging. In addition, we find that section of the regulation to be unclear. (71 P.S. § 745b(b)(3)(ii) and (iii)). Of particular concern is why separate rooms are needed to perform certain tasks associated with production of raw milk, when separate rooms would be needed and why some customer-owned containers must be mechanically capped and others do not.

We have determined that this regulation is consistent with the statutory authority of the Department (31 P.S. § 660(c) and 31 P.S. § 20.13) and the intention of the General Assembly. However, after considering all of the other criteria of the Regulatory Review Act discussed above, we find promulgation of this regulation is not in the public interest.

BY ORDER OF THE COMMISSION:

The regulation # 2-160 (IRRC # 2777) from the Department of Agriculture:

Milk Sanitation

was disapproved on October 7, 2010.

Arthur Coccodrilli. Chairman

Attachment "2"

Revised Final-Form Regulation

FINAL RULEMAKING

Title 7 – AGRICULTURE
DEPARTMENT OF AGRICULTURE
[7 PA. CODE CHS. 59 AND 59a]
Milk Sanitation

The Department of Agriculture (Department) hereby deletes the current regulation at 7 Pa. Code Chapters 59 and establishes 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 Pennsylvania 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 of the Final-Form Regulation

The protection of the health and safety of persons who consume milk, milk products and manufactured dairy products is the primary purpose of the final-form regulation. The secondary purpose is to provide the regulated community – persons who produce milk, milk products and manufactured dairy products within Pennsylvania 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 final-form regulation will 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 final-form regulation will 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 final-form regulation will help bring Pennsylvania's standards into alignment with the current state of the science.

In addition, the final-form regulation will 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 final-form regulation will 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 it Production and Processing – Recommended Requirements* (USDA Recommended Requirements) document issued by the U.S. Department of Agriculture, Agricultural Marketing Service, Dairy Program.

The final-form regulation will also consolidate and update provisions relating to the production of raw milk for human consumption.

The final-form regulation will 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.

Summary

The final form regulation serves the objectives set forth above. In the extensive comment-and-response section below, the Department details many of the changes and improvements accomplished by the final-form regulation. As part of its extensive comments, the Independent Regulatory Review Commission requested an explanation of the Department's rationale for the changes accomplished by the final-form regulation. The Department offers this preamble, including the statement of purpose, this summary section, and the extensive comment-and-response section below, in support of its position that the final-form regulation is in the public interest.

In general, the adoption of Grade "A" PMO standards and the references to specific applicable portions of the Grade "A" PMO throughout the final-form regulation are significant steps forward, in that they bring Pennsylvania's milk sanitation standards into alignment with nationally-used milk sanitation standards that embody the current state of dairy science. The current milk sanitation regulation (which is being supplanted by the final-form regulations) is premised on the *1978* version of the Grade "A" PMO.

Section 59a.2 (relating to definitions) establishes a common terminology, borrowing language from the current regulation at Chapter 59 (relating to milk sanitation), the Act, the Food Act, the Grade "A" PMO and the USDA Recommended Requirements.

Section 59a.4 (relating to approved inspectors) clarifies the requirements that must be met in order for a person to be eligible to become an approved inspector (authorized to inspect dairy farms).

Section 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) adds detailed language as to the standards and procedures by which a person may become a Pennsylvania-approved dairy laboratory director.

Section 59a.12 (relating to permits) provides substantially more detail on milk permit requirements than does the current regulation (at § 59.12 (relating to permits)). The new provision details exceptions to permit requirements, provides an explanation of the process by which a permit can be obtained, and addresses ownership, refusal, suspension and revocation in detail.

Section 59a.16 (relating to markings, sealing and documentation for vehicles containing milk and milk products) provides new regulatory guidance, using standards and language from the Grade "A" PMO.

Section 59a.17 (relating to inspection of dairy farms and milk plants) supplants the current provision at § 59.31 (relating to inspection of dairy farms), and provides clearer regulatory guidance.

Section 59a.18 (relating to sampling and examination) clearly identifies the types of laboratories that may conduct regulatory testing and sampling.

Sections 59a.19 (relating to standards for Grade "A" raw milk for pasteurization, ultrapasteurization or aseptic processing), 59a.20 (relating to standards for Grade "A" pasteurized, ultrapasteurized and aseptically processed milk and milk products) and 59a.21 (relating to standards) incorporate specific Grade "A" PMO standards. These provisions accomplish a major regulatory change, and go a long way toward bringing Pennsylvania's dairy industry into compliance with these well-regarded national milk sanitation standards.

Section 59a.25 (relating to milk and milk products from outside this Commonwealth) of Pennsylvania) supplants the current provision at § 59.304 (relating to milk and milk products from beyond the limits of routine inspection). The final-form regulation provides more specific guidance as to the standards that must be met by other jurisdictions from which milk is shipped into Pennsylvania, and adds applicable references to the Grade "A" PMO.

Section 59a.27 (relating to personnel health) supplants vague regulatory language from the current provision at § 59.306 (relating to personnel health) and provides a reference to the provisions of the Grade "A" PMO that address this subject matter.

In Subchapter C (relating to production and processing of milk for manufacturing purposes) of the final-form regulation, the Department adopts the USDA Recommended Requirements and restates a number of current regulatory requirements.

Section 59a.109 (relating to bacterial estimate classification) supplants the current provision at § 59.504 (relating to bacterial estimate classification), and establishes a uniform 500,000 bacteria per milliliter standard as a bacterial count beyond which warnings and exclusion of milk from market may occur. This revision should promote good sanitation practices.

Section 59a.110 (relating to somatic cell count) effectively lowers the acceptable somatic cell count from a maximum of 1,000,000 per milliliter to a maximum of 750,000 per milliliter (with a higher permissible count for goat milk). Somatic cell count is a general indicator of sanitation practices and quality of milk. This change is significant, and will help improve the overall quality and safety of the milk supply.

Section 59a.113 (relating to suspended milk for manufacturing) expands upon the list of circumstances under which a milk plant may not accept milk, by adding situations where milk has repeated excessively high somatic cell counts or contains added water to that list.

Subchapter D (relating to farms producing milk for manufacturing) repeats current regulatory requirements. Section 59a.201 (relating to farm inspection) adds clarification as to how an approved inspector is to determine a particular farm should receive a passing score on a required inspections. Section 59a.207 (relating to water supply) provides a specific reference to the Grade "A" PMO requirements for water sources.

Subchapter E (relating to manufacturing plants) brings the regulations addressing milk for manufacturing into closer alignment with the USDA Recommended Requirements. This new subchapter borrows basic format and language from the *current* regulations at §§ 59.701 (relating to surroundings) through 59.792 (relating to operations and operating procedures). These current regulations were promulgated in 1985; and much of the language was borrowed directly from the then-current USDA Recommended Requirements. For this reason, there are comparatively fewer changes or new requirements imposed on the regulatory community by Subchapter E.

Section 59a.302(f)(5) (relating to buildings) contains a more specific reference to the appropriate laboratory standards to be followed should a permitholder establish its own testing laboratory. These standards are as prescribed in the current *Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration* and FDA 2400 Laboratory Series forms.

Section 59a.311(c) (relating to cleaning and sanitizing treatment) provides better guidance as to how milk transport tanks are to be cleaned and sanitized, and adopts a requirement (from the USDA Recommended Requirements) that a tank that has been cleaned and sanitized be cleaned and sanitized again if 96 hours or more elapse between uses of the tank.

Subchapter F (relating to raw milk for human consumption) seeks to present the major provisions that relate to the production of raw milk for human consumption in a single chapter. Under the current milk sanitation regulation at Chapter 59, provisions relating to the production of raw milk for human consumption are scattered throughout that chapter. The Department believes this has been inconvenient for the regulated community and has been the cause of some confusion. In 2008, the Department issued a Guidance Document titled *Permits allowing the Sale of Raw milk for Human Consumption.* The Guidance Document was distributed to all raw milk permitholders, with the objective of providing them a single document that referenced those statutory and regulatory provisions that most impacted their raw milk production businesses. This Guidance Document was used in drafting Subchapter F of the final-form regulation. Subchapter F also reflects the experience the Department has gained as it has assisted dairy producers through the raw milk permit application process, encountered problems and pathogenic bacteria in raw milk, and been involved in investigations of food borne human illness where raw milk has been implicated as a source.

Section 59a.402 (relating to raw milk; prohibitions) is significant in that it clearly states the extent of a raw milk permitholder's authority. Such a permitholder may produce raw milk for human consumption and – under certain circumstances – aged cheese manufactured from raw milk.

Section 59a.404 (relating to requirements for the issuance of a raw milk permit) provides a detailed statement of the standards that must be met in order to obtain a raw milk permit, and varies these requirements based upon whether the permit sought is a *new* raw milk permit or a *successor* permit to a raw milk permit that has expired.

Section 59a.406 (relating to animal health) requires that animals used in the production of raw milk be brucellosis-free, tuberculosis-free and in apparent good general health. Good animal health is essential to the production of safe raw milk for human consumption.

Section 59a.408 (relating to regular testing of raw milk for human consumption) provides a chart explaining the routine testing that must be performed by raw milk permitholders. This includes a requirement that milk temperatures be monitored and that regular testing for bacterial count, coliform count, somatic cell count and the presence of drugs and specific pathogenic bacteria occur at regular intervals.

Section 59a.411 (relating to label content review by the Department) requires raw milk permitholders to submit their proposed label information for review by the Department – just as other milk permit holders are required to do. Given that milk is a potentially

hazardous food, and that raw milk – in particular – presents risks to certain consumers, the provision requires a label statement much as is required with respect to other potentially hazardous foods (such as raw shellfish, raw or undercooked meat, and similar foods).

Sections 59a.412 (relating to inspection, sampling and testing by the Department) through 59a.416 (relating to enforcement: seizure, condemnation, denaturing or destruction of raw milk; exclusion from sale) provide the raw milk permitholder with a comprehensive summary of actions the Department or the Office of Attorney General might take with respect to the permit. This includes references to the Department's authority to conduct reasonable inspections, permit suspension or revocation actions, permit denials, suspensions or revocations, summary criminal prosecutions, injunctive relief and the seizure or detention of unsafe raw milk. As stated above, one of the Department's objectives with respect to Subchapter F is to consolidated provisions relating to raw milk permits in a single subchapter.

Comments and Responses

A notice of proposed rulemaking was published at 39 *Pennsylvania Bulletin* 4677 (August 1, 2009), affording the public, the Legislature and IRRC the opportunity to offer comments. The comment period was extended an additional thirty days (through September 30, 2009), by notice published at 39 *Pennsylvania Bulletin* 5131 (August 29, 2009).

Comments were received from IRRC, the United States Department of Agriculture Agricultural Marketing Service Dairy Grading Branch (USDA), QC Laboratories, the Pennsylvania Independent Consumers and Farmers Association (PICFA), the Pennsylvania Association for Sustainable Agriculture (PASA), the Farm-to-Consumer Legal Defense Fund (FTCLDF) (from Virginia), the Penn State Dairy Herd Health Educator for Southeastern Pennsylvania (PSU) and over 100 additional commentators.

In addition, the Department has reviewed and considered – and in this document offers a response to – approximately 12 comment letters that were submitted *after* the close of the formal public comment period. The Department appreciates the time and thought that went into these various comments, and treated each as it would a timely comment.

A summary of comments described in the two preceding paragraphs, as well as the Department's responses to these comments, follows.

Comment 1: PASA and 11 other commentators asked that the comment period for the proposed regulation be extended to allow additional time for input from the regulated community. PASA and several other commentators recommended the comment period be extended to run through the end of October 2009.

Response: The Department extended the comment period for the proposed regulation so that it ran for 60 days, rather than the 30-day period originally proposed. The

comment period ran through September 30, 2009. The Department has also considered the comments that were received *after* the expiration of this extended comment period. These late comments are addressed in this document as if they were received within the 60-day window. Given the 60-day comment window, the large number of comments received, and the fact that the Department has considered all of these comments - even those comments that were received after the September 30, 2009 submittal deadline – the Department is satisfied that all interested commentators had adequate opportunity to offer comments.

Comment 2: IRRC noted that § 5.2 of the Regulatory Review Act (71 P.S. § 745.5b) directs it to determine whether a regulation is in the public interest. When making this determination, IRRC considers criteria such as economic or fiscal impact and reasonableness. To make that determination, IRRC must analyze the text of the Preamble and proposed regulation and the reasons for the new or amended language. IRRC also considers the information a promulgating agency is required to provide under § 5 of the Regulatory Review Act (§ 745.5(a)) in the Regulatory Analysis Form (RAF). IRRC noted the proposed rulemaking is a comprehensive rewrite of the Department's milk sanitation regulation that includes seven subchapters, but that the Preamble to this proposed rulemaking only provided an "overview of the major provisions of the proposed rulemaking." IRRC offered that this overview did not provide an adequate description of the numerous sections of the rulemaking and the rationale behind the language. IRRC believes that without this information it is unable to determine if the regulation is in the public interest. IRRC recommended the Preamble to the final-form regulation provide more detailed information, including a description of the language proposed for each section of the regulation and why the language is required.

Response: The Department accepts this comment, and believes the summary set forth above, and the detailed responses to the many comments received with respect to the proposed regulation, provide the requested description and rationale to support a conclusion that the final-form regulation is in the public interest.

Comment 3: IRRC noted that according to the Regulatory Analysis Form, some dairy producers may be required to incur new testing costs as a result of this rulemaking. The costs are estimated at $85,200 for fiscal year 2009-2010 and then at $55,200 per year after that. IRRC believes that *raw milk producers* will incur additional costs related to testing of their products, and that these tests were not quantified in the Regulatory Analysis form. IRRC asked the Department to provide an analysis of the costs this rulemaking will impose on the raw milk producer community.

Response: The Regulatory Analysis Form has been revised to reflect the costs described in this response. The *current* regulations (at §§ 59.302(b)(8) and 59.32(d)) require raw milk permitholders to test raw milk somatic cell count once each month. Section 59a.408 (relating to regular testing of raw milk for human consumption) of the final-form regulation requires that somatic cell count be tested *twice* each month. A somatic cell count test costs approximately $25, and the final-form regulation requires 12 more such tests each year than does the current regulation. This change will add

approximately $300 (12 tests x $25/test) to a raw milk permitholder's testing costs each year.

Section 59a.408 of the final-form regulation will also require testing for the presence of pathogenic bacteria at least twice annually. These tests typically cost between $120 to $220, and the final-form regulation requires 2 such tests each year. This change will add up to $440 to a raw milk permitholder's testing costs each year.

In total, new testing costs will be approximately $740/year.

Comment 4: PASA noted that the preamble to the proposed rulemaking reflected that the regulation would have no fiscal impact on the general public. The commentator added:

> This statement seems inadvisable at best and totally inaccurate at worst. If the other public and private costs reported in this section of the proposal are indeed incurred, along with the costs to farmers of additional testing that will be necessary, it is unreasonable to assume that consumers would see no impact on state taxes owed or the retail price of milk and other dairy products, including prices related to sales directly from the farms involved.

Another commentator quoted and joined PASA's comment.

Response: The Department assumes the comment refers exclusively to those members of the general public who acquire raw milk for human consumption from dairy operations as described in Subchapter F (relating to raw milk for human consumption). The Department cannot confirm or quantify any additional costs that would be passed-along to this segment of the general public. As described in the response to Comment No. 3, additional testing costs would be approximately $740 per year. When sold as raw milk for human consumption, raw milk is typically sold at a price several times higher than a consumer would pay for the same quantity of pasteurized milk. There is room in the current market pricing of raw milk for human consumption for the permitholder to absorb the increase in testing costs without passing these costs along to the consumer. If the permitholder passes these costs along to the raw milk purchaser, though, the impact on the consumer costs would be negligible.

Comment 5: IRRC noted that § 59a.11 (relating to the adoption of Grade "A" PMO) establishes the standards of the Grade "A" PMO as those of the Department. In addition, Subchapter C, relating to the production and processing of milk for manufacturing purposes, adopts the United States Department of Agriculture's document titled "*Milk for Manufacturing Purposes and its Production and Processing – Recommended Requirements*" as the Department's regulatory standards with respect to milk manufacturing. IRRC asks – given the detail contained in these two documents - what the need is for the various sections of this rulemaking to address the same topics.

Response: The Department considered this same question as it drafted the proposed regulation. On balance, the Department favors a final-form regulation that contains as much detail for the regulated community as is consistent with the Act, the Food Act and additional standards that are incorporated by reference. Although the final-form

regulation establishes a new regulatory chapter, it makes extensive use of language from the current milk sanitation regulation – at Chapter 59. For much of the regulated community, the layout and language of the final-form regulation will be familiar.

Comment 6: A commentator from New Jersey recommended that the final-form regulation prohibit "Rbgh" (recombinant bovine growth hormone) in milk.

Response: The Department declines to implement this comment. Bovine growth hormone is present in all cow milk; and there is currently no way to differentiate analytically (nor are there any measurable compositional differences) between milk from cows that receive recombinant bovine growth hormone and those that do not.

Comment 7: A commentator notes that the Milk Sanitation Law states that milk is "milk from cows." The commentator raises goats. The commentator offers the opinion that he is participating in the milk permitting system voluntarily, and that the goat milk production operation is not subject of the Milk Sanitation law. The commentator believes the proposed regulation violates the Milk Sanitation Law, to the extent it includes milk from all hooved animals, instead of just "milk from cows."

Response: The commentator is correct to the extent that the Milk Sanitation Law references milk as being milk *from cows*, but is incorrect in the statement that a goat milk dairy operation participates in the milk permit process described in the final-form regulation on a voluntary basis.

The final-form regulation is promulgated under authority of both the Milk Sanitation Law and the Food Act. The Food Act does not define "milk," but categorizes it as a "potentially hazardous food," considers food (including milk) to be "adulterated" if it contains any diseased, contaminated, filthy, putrid or decomposed substance or is "produced, prepared, packed or held under unsanitary conditions so that it may have become contaminated with filth or may have been rendered diseased" (31 P.S. § 20.8), and charges the Department to promulgate regulations as necessary for the proper enforcement of that statute (31 P.S. § 20.13).

Given that the concerns for the safety of milk are basically the same, regardless of the species of mammal from which the milk was produced, the final-form regulation treats all milk essentially the same way (although there are some provisions that relate specifically to goat milk). With respect to milk from cows, the authority for this regulation derives from both the Milk Sanitation Law and the Food Act. With respect to milk from other species, the authority for this regulation derives from the Food Act.

In response to this comment, the Department has revised § 59a.2 (relating to definitions) by adding language to the definition of "milk" to clarify that it pertains to milk from any hooved mammal species.

The Department notes that this general topic is also addressed in Comment No. 11.

Comment 8: PASA offered the recommendation that for those dairy producers who market directly to the public, with appropriate labeling, and where their operations are "certified by independent third parties," the dairy producers be relieved from "costly

extra testing or unnecessary repetitive procedures." Another commentator joined this comment.

Response: The Department declines to revise the final-form regulation to allow for third-party certification of milk quality with respect to dairy operations that sell directly to the consumer. Neither the Milk Sanitation Law nor the Food Act provide for such third-party certifications, or provide a basis for the Department to treat the same food differently, based on whether it is sold directly to the consumer or to a milk processor. There is no identifiable lessening-of-risk that attaches to direct dairy-to-consumer sales.

Comment 9: A commentator offered the following comment:

> Would like to propose a 2 days suspension in a 3 out of 5 situation with no accelerated testing, with a good follow up sample. (Basic system now in practice). The accelerated testing would be or could be very costly. If lab could not get the 2 weekly samples, I'm 60 miles away from approved, affordable lab. Do not want to see a 2-day suspension with accelerated testing.

The Department notes that a similar comment was offered by industry participants from a liaison committee between the Department and the Pennsylvania Association of Milk, Food, and Environmental Sanitarians (PAMFES), outside of the formal comment process.

Response: The final-form regulation adopts the Grade "A" PMO to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO). Section 6 of the Grade "A" PMO (titled *The Examination of Milk and Milk Products*) addresses the circumstances and process under which problematic milk is to be excluded from market. Although there is cost associated with accelerated testing to demonstrate that problematic milk is no longer problematic, the producer should realize overall savings by virtue of being able to return excluded milk to market more quickly than is allowed under the current regulation (at § 59.33(a) (relating to problems)).

Comment 10: A commentator who is also an approved inspector offered that somatic cell counts and bacteria counts from samples that are drawn from multiple tanks on the same day should be averaged for regulatory purposes; and that this should be a "weighted average."

Response: The Department considered this suggestion, but declines to implement it in the final-form regulation since the referenced calculation would introduce a level of complexity that exceeds the requirements of the Grade "A" PMO.

Comment 11: With respect to § 59a.1 (relating to Scope – Clarity), IRRC noted that a commentator asked whether this regulation applies to other milk producing animals, such as goats or sheep, and recommended that – to the extent that the regulation *does* apply to these other animals - appropriate language be included in this section.

Response: The Department accepts this comment and agrees that the proposed regulation could have been clearer on this point. The regulation applies to milk from any hooved mammal species (as does the Grade "A" PMO). As described in the response to Comment No. 7, the Department has revised § 59a.2 (relating to definitions) by adding language to the definition of "milk" to clarify that it pertains to milk from any hooved mammal species

Comment 12: With respect to § 59a.1, IRRC noted this section does not make any reference to the regulation of raw milk. IRRC understands that "raw milk" is wholly included within the definition of "milk," but offered "... we believe that adding raw milk to this section would improve the clarity of the rulemaking."

Response: The Department accepts this comment, and has revised § 59a.1 in the final-form regulation to clarify that the regulation pertains to raw milk, as well.

Comment 13: With respect to the definition of "3-A Sanitary Standards" in § 59a.2 (relating to definitions), IRRC offered the following:

> ... This definition references the latest standards jointly promulgated by certain parties. It concludes with the following phrase, "...or as otherwise defined in the Grade "A" PMO." This would appear to create two sets of standards that may or may not be consistent. Since regulations create binding standards and have the full force and effect of law, the Department must clearly indicate which standards will take precedence. We have similar concerns with the phrase as used in the definition of "*PMO – defined milk products*."

This comment relates to a similar comment IRRC offered with respect to the definition of "PMO-defined milk products" in this same section.

Response: The Department agrees with IRRC on this point, and has deleted the reference to the Grade "A" PMO from the definition of "3-A Sanitary Standards."

With respect to the portion of the comment addressing the proposed definition of "PMO-defined milk products," the Department has deleted that term and definition, and references its response to Comment No. 31.

Comment 14: PSU reviewed the definition of "3-A Sanitary Standards" in § 59a.2 and suggested the word "promulgated" be changed to "prepared."

Response: The Department declines to implement this suggestion in the final-form regulation, since the exact language of the proposed definition is used in the Grade "A" PMO (in the notes provided under Items 9r (titled *Utensils and Equipment – Construction*) and 11p (titled *Construction and Repair of Containers and Equipment*). The Department believes the term "promulgated" is more descriptive than "prepared," and would prefer that the definition mirror the Grade "A" PMO.

Comment 15: With respect to the definition of "Adulterated" in § 59a.2, IRRC offered the following:

> ... Several definitions found in this section are either direct quotes or paraphrases of statutory definitions found in the Milk Sanitation Law (31 P.S. §§ 645—660g) (Act) or the Food Act (31 P.S. §§ 20.1—20.18) (Food Act). Why is this definition a cross-reference to a statutory definition when other definitions are a quote or paraphrase? We have a similar concern with the definition of "misbranded." We recommend that the Department be consistent with the way it defines terms.

Response: The Department's general approach to defining terms is to set forth a complete definition, rather than a cross-reference. The Department believes that it is reasonable to vary from this approach with respect to the definitions of "adulterated" and "misbranded," though. The Food Act contains detailed and lengthy descriptions of what constitutes "adulteration" of food or "misbranding" of food (at 31 P.S. §§ 20.8 and 20.9, respectively). These descriptions also contain cross-references to other provisions of that statute. Rather than repeat these lengthy descriptions *verbatim*, the Department believes it is preferable for the final-form regulation to simply provide a cross-reference to where each term is described in the Food Act.

Comment 16: With respect to the definition of "Canned milk" in § 59a.2, PSU offered that the term seemed out-of-place and asked why it is defined as a separate term. The commentator offered that the term is not used in Chapter 59 or the Grade "A" PMO, and asked: "Is there something special or confusing about this term that it needs to be included in the PA regulations?"

Response: The Department accepts this comment, and has deleted the definition of this term from the final-form regulation. Although the term is defined in the Milk Sanitation Law, it is not used in the final-form regulation.

Comment 17: PSU noted the definition of "Certified industry inspector" in § 59a.2, and offered that the last sentence of that definition does not make sense. The sentence at issue reads: "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."

Response: The Department agrees with the commentator. The proposed definition contained a typographical error that has been corrected in the final-form regulation. A "certified industry inspector" is the equivalent of a "designated inspector" for purposes of conducting certified industry inspections as described in the Grade "A" PMO.

Comment 18: With respect to the definition of "Dairy farm" in § 59a.2, IRRC noted that another commentator asked whether this term includes only farms with cows, and requested this be clarified in the final-form regulation.

PSU raised the same question.

Another commentator that raises dairy goats asked whether the place where the goats are kept is a "dairy farm" and recommended the definition be broadened to include all dairy animals.

PSU expressed a preference for the more expansive and inclusive definition of "dairy farm" that is found in the Grade "A" PMO.

Response: The proposed definition of a "dairy farm" comes *verbatim* from the Milk Sanitation Law (at 31 P.S. § 645). Since the final-form regulation is also promulgated under authority of the Food Act (the Department references its response to Comment No. 7), and since that statute takes a broader view of what constitutes "milk" than the Milk Sanitation Law does, the Department believes the definition can (and should) be expanded in the final-form regulation. The definition has been broadened to reference "lactating hooved mammals," rather than only "cows."

Comment 19: PSU suggested a grammatical change to the definition of "Dairy farm" in § 59a.2, recommending that the word "of" be changed to "or."

Response: The Department agrees the suggested change would add clarification. The Milk Sanitation Law (at 31 P.S. § 645) uses the word "of" in this definition, but the proposed change would not contradict the meaning of the term, would add clarity, and would be supported under the Food Act – the other statute upon which the final-form regulation is premised. The change has been made in the final-form regulation.

Comment 20: PSU reviewed the definition of "Department" in § 59a.2 and offered a preference for the way that word is defined in Chapter 59.

Response: The Department declines to make the suggested change. The proposed definition is clear, and mirrors the statutory definition of "Department" in the Agriculture Code (at 3 Pa.C.S.A. § 102).

Comment 21: With respect to the definition of "Food Act" in § 59a.2, IRRC offered the following:

> *Food Act* – This definition simply states, "31 P.S. §§ 20.1—20.18." We recommend that it be amended to mirror the format used for the definition of "Act", which states "The act of July 2, 1935 (P.L. 589, No. 210) (31 P.S. §§ 645—660g), known as the Milk Sanitation Law."

Response: Unlike the Food Act, the statute that has come to be known as the "Milk Sanitation Law" (which was enacted in 1935) does not have a formal title. Although the Department's drafting objective was to help provide some information to account for the unofficial name that has been associated with this statute, the Department appreciates the commentator's desire for brevity and a more consistent description of statutes. The definition has been revised in accordance with IRRC's recommendation.

In reviewing its response to this comment, the Department noted the defined term "food establishment" was used only once in the proposed regulation – at § 59a.15(a) (relating to

labeling: milk dating) – and that the defined term is unnecessary. It has been deleted from the final-form regulation, and the single use of that term in § 59a.15(a) has been supplanted by a general reference to "similar food facilities."

Comment 22: PSU reviewed the definition of "Grade 'A' PMO" in § 59a.2 and recommended that the website link offered in that definition be made more specific than the general link to the Department's website.

Response: Although the Department would prefer to provide a very specific link to the location on the Department's website where a copy of the Grade "A" PMO may be found, it has concern as to whether a specific website address would remain constant over the years the final-form regulation is expected to remain in effect. The Department's website is revised frequently. On balance, the Department is satisfied that a person who can access the Department's website should be able to navigate to the copy of the Grade "A" PMO with a minimum of difficulty. In addition, an interested person can bypass the Department and quickly access a copy of the Grade "A" PMO through any on-line search engine, such as the Google® search engine.

Comment 23: With respect to the definition of "Growth inhibitor" in § 59a.2, a commentator asked whether growth inhibitor testing and *beta lactam* testing are equivalent, and whether *beta lactam* testing is included within growth inhibitor testing.

Response: *Beta lactam* testing is a subset of growth inhibitor testing. The term "growth inhibitor" includes a variety of antimicrobial adulterants that would include *beta lactam* drug residues.

In response to this comment, the Department considered the use of the term "growth inhibitor" throughout the final-form regulation and has – where appropriate – changed that term to "drugs."

Comment 24: PSU offered a grammatical correction to the definition of "Growth inhibitor" in § 59a.2. The commentator recommended the word "a" be changed to "any" or "an."

Response: The recommendation has been implemented in the final-form regulation.

Comment 25: With respect to the definition of "HACCP" in § 59a.2, PSU suggested inserting a reference to the Grade "A" PMO definitions to provide greater detail.

Response: The suggestion has been implemented in the final-form regulation. A reference to Appendix K of the Grade "A" PMO – which addresses the HACCP Program - has been added to the definition, along with a reference to the HACCP-related terms and definitions set forth in Section 1, definition "R" of the Grade "A" PMO.

Comment 26: PSU reviewed the definition of "HTST" in § 59a.2 and offered:

> I question whether 'High Temperature short time' is actually a definition and there is no further explanation within the Grade "A" PMO ('07); if no definition is considered needed, should it be included?

Response: The referenced definition has been deleted from the final-form regulation.

Comment 27: With respect to the definition of "Manufactured dairy products" in § 59a.2, IRRC offered the following:

> *Manufactured dairy products* – This definition lists specific products and concludes with the phrase "...and other products for human consumption, as may be designated by the Secretary." We recognize that this definition is a verbatim quotation from the Act. However, it is vague and does not set a binding standard. How will the regulated community know if a product was designated as a manufactured dairy product? We recommend that the final-form regulation provide greater clarity as to what is or is not a manufactured dairy product.

Response: As IRRC notes, the definition comes from the Milk Sanitation Law. Subchapter E (relating to manufacturing plants) prescribes a number of "supplemental requirements" for plants that manufacture certain designated products. Each of these designated products is a "manufactured dairy product." The Department has compared these manufactured dairy products to those listed in the proposed definition, and has added a sentence to the final-form regulation, identifying those manufactured dairy products that were not already in the referenced definition. These include instant nonfat dry milk and other dry milk products, pasteurized process cheese and related products, sterilized milk products, and butter-related products.

Comment 28: PSU reviewed the definition of "Milk" in § 59a.2 and offered the observation that this definition appears to be different from the 2007 version of the Grade "A" PMO, which defines "goat milk" and "sheep milk" – but not "milk." The commentator offered the following:

> The new definition for MILK seems confusing to me despite understanding the PMO is regulation [sic] for Pasteurized Milk and PA regulations include regulations for Raw milk for human consumption as well.

Response: Although the proposed definition of "milk" comes *verbatim* from the Milk Sanitation Law (at 31 P.S. § 645), the Department understands the confusion the proposed definition causes. Since the Food Act is also the basis for this final-form regulation, though, the Department believes it is reasonable to revise this definition in the final-form regulation by adding a sentence to clarify that the term includes milk "from hooved mammals." This term is used in the Grade "A" PMO (at Section 1, definition S). The Department references its responses to Comment Nos. 7 and 11.

Comment 29: With respect to the definition of "Milk plant or plant" in § 59a.2, IRRC offered the following:

Milk plant or *plant* – Most of the language in this definition is from the same definition found in the Act. However, the regulatory definition adds the phrase "milk for manufacturing purposes or milk for pasteurization." Why is the new language being added?

Response: In response to this comment the Department has revised this definition in the final-form regulation to mirror the definition of "Milk plant" that appears in the Milk Sanitation Law.

Comment 30: PSU reviewed the definition of "Milk plant or plant" in § 59a.2 and asked whether the definition applies only to a place where milk is "sold," or whether it also applies to locations where milk is "transferred" or "distributed" (without being sold).

Response: As related in the response to Comment No. 29, the definition of "Milk plant" has been revised in the final-form regulation. As revised, the term would include a transfer station (because milk is collected there) but would not include a warehouse or other distribution facility.

Comment 31: With respect to the definition of "Milk products" in § 59a.2, IRRC asked what the need is for this definition *and* the definition of "*PMO-defined milk products*"

Response: The commentator makes a valid point. The Department has revised the definition of "milk products" in the final-form regulation to include those products that are "milk products" under the Grade "A" PMO. Since this ends any need for the separately-defined term "PMO-defined milk products" in the final-form regulation, that term has been deleted.

Comment 32: USDA noted the proposed definition of "Milk products," and observed that in other sections of the proposed regulation the term "seems to be used to apply to other dairy products such as butter, cheese, etc..."

The commentator noted the use of this term in §§ 59a.12(b)(3) and 59a.12(b)(4) (relating to permits), and asked whether the phrase "and manufactured dairy products" should be added at the end of each of these paragraphs.

The commentator raised the same issue with respect to the use of the term "milk products" in §§ 59a.14(d) and 59a.14(d)(3) (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products). The commentator believes the requirements imposed by these provisions should apply to manufactured dairy products such as butter, cheese, and the like.

Response: The commentator's point is well-taken. The Department has revised §§ 59a.12(b)(3) (relating to permits), 59a.12(b)(4) and 59a.14(d) (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products) to address the commentator's concerns.

Comment 33: With respect to the definition of "Official laboratory" in § 59a.2, PSU asked whether the phrase "under the direct supervision" of the Department should be further clarified.

Response: The Department has clarified this definition in the final-form regulation. The Department's intent is to distinguish an "Official laboratory" from a "Pennsylvania-approved dairy laboratory." The former is a laboratory that is either part of the Department (such as the dairy laboratory that is physically located at the Department's headquarters in Harrisburg) or might be another dairy laboratory (such as a University's dairy laboratory) that performs dairy analysis under contract with the Department or with Department personnel otherwise involved in the testing performed by that laboratory. The latter has been approved and certified by the Department, but these are typically private sector businesses and the Department does not guide, direct or prescribe the work to be done by such a laboratory.

Comment 34: PSU reviewed the definition of "PMO-defined milk products" in § 59a.2 and expressed confusion as to the distinction between "milk," "milk products" and "PMO-defined milk products."

Response: As related and explained in greater detail in the response to Comment No. 31, the Department has deleted all references to the term "PMO-defined milk products" in the final-form regulation.

Comment 35: IRRC offered two comments with respect to the definition of "Pennsylvania-approved dairy laboratory director" in § 59a.2. First, it noted a reference to "written examinations" and asked what examinations this phrase refers to. Second, it asks how an individual would demonstrate the "necessary experience" referenced in that definition.

Response: The Milk Sanitation Law (at 31 P.S. § 660) requires that bacteriological analysis of milk, milk products and manufactured dairy products be made by a laboratory "... the equipment and director of which have been approved by the Secretary of Agriculture." The Department has added new language to § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) to describe the standards and procedures for certification of a person who seeks to be a Pennsylvania-approved dairy laboratory director.

Comment 36: With respect to the definition of "Permitholder" in § 59a.2, IRRC asked whether producers of *raw milk* who hold permits would be considered permitholders and, if so, recommended this definition should be amended to reflect this.

Response: A person who holds a raw milk permit is a "Permitholder." The Department does not believe the proposed definition will cause any confusion in the regulated community. The *current* regulatory definition of this term is at § 59.1 (relating to definitions), is substantively the same as the proposed definition, and has not created any confusion in the years it has been in effect. Also, the repeated use of the term throughout

Subchapter F (relating to raw milk for human consumption) helps avoid any ambiguity as to whether holders of raw milk permits are "Permitholders."

Comment 37: With respect to the definition of "raw milk" in § 59a.2, IRRC noted that this definition references "relevant provisions of this chapter," and recommended that the specific relevant provisions be cross-referenced in this definition.

Response: The recommendation has been implemented in the final-form regulation.

Comment 38: IRRC offered the comment that while the Act explains what raw milk is, it only defines "milk;" and that where the Act references "milk, milk products or manufactured dairy products," it is unclear if this language encompasses raw milk. IRRC believes clarification of this phrase is significant since several provisions of the proposed regulation pertaining to raw milk contain language that is similar to provisions of the Act that address "milk, milk products or manufactured dairy products." IRRC recommended as follows:

> ... The final-form regulation should explain how the definition for "raw milk" is properly aligned with the Act. Specifically, the Department should clarify whether raw milk is included as part of "milk, milk products or manufactured dairy products" under the Act.

Response: The Department believes there is no confusion in the regulated community as to whether raw milk is milk. All milk begins as raw milk. There is nothing that needs to happen to raw milk (pasteurization or other processing) to make it "milk." The Department believes that the final-form regulation adequately defines "raw milk" as being "milk." For these reasons the Department declines to implement the recommended changes. As described in its response to Comment No. 39, though, the Department has revised the final-form regulation by adding references to "raw milk for human consumption" where appropriate.

Comment 39: With respect to the definition of "raw milk" in § 59a.2, PSU offered that it appears the Department is working toward the use of the term "raw milk" to mean milk that is not pasteurized and that is not heading for pasteurization before reaching the ultimate consumer. The commentator suggested the use of the term "raw milk" has the potential to confuse, and suggested the term "raw milk for human consumption" be used in those instances where the Department is referring to milk that will not be pasteurized before reaching the consumer.

Response: The Department accepts this comment and has made the recommended change in the final-form regulation, and has changed references to "raw milk for pasteurization" to "milk for pasteurization." This should add clarity to the final-form regulation.

Comment 40: USDA offered a typographical correction with respect to the definition of "USDA Recommended requirements" in § 59a.2, noting that the last word should read "Programs" rather than "Program."

Response: The recommended correction has been made in this final-form regulation.

Comment 41: With respect to § 59a.4 (relating to approved inspectors) IRRC noted that subsection (a) imposes an *application fee* of $50 and subsection (d) imposes a *renewal fee* of $20. IRRC asked what authority the Department has to establish these fees, given that the statutory definition of "approved inspector" sets these fees at $15 and $5 respectively.

Response: The referenced fees are established in Section 602-A of the Administrative Code of 1929 (71 P.S. § 240.2A).

Comment 42: With respect to § 59a.4(b), IRRC asks how the Department will determine that an applicant demonstrated that he or she is of good character. IRRC noted other vague language in that subsection, including "adequate education or experience" and "capable and efficient manner," and asked how the Department and the regulated community will know if these standards are being met.

Response: The Department agrees this subsection should be revised to provide more detail as to what education or experience is necessary in order for a person to become an approved inspector. Language has been added to the final-form regulation to address this.

As far as the referenced "good character" language is concerned, the Department notes that this originates from the Milk Sanitation Law, in the definition of an "approved inspector" (at 31 P.S. § 645). The Department has included language to disqualify an applicant who has been convicted of a felony criminal offense in the ten years preceding the date of the application. Although this is an imperfect measure of "good character," the Department believes it is reasonable and verifiable.

Comment 43: With respect to § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results), QC Laboratories noted that no reference is made to FDA 2400 Laboratory Series forms, which the commentator explains are "the official guidelines for laboratory practices." The commentator also offers that where the Standard Methods for the Examination of Dairy Products are referenced in this section, "the current edition must be mentioned and any future editions must be provided for."

Response: The requested clarifications and reference have been added to the final-form regulation.

With respect to the commentator's concern that the reference to the *Standard Methods for the Examination of Dairy Products* should address and include future editions of that document, the Department is satisfied that the definition of this document in § 59a.2 makes clear that it is the "current" edition that must be considered.

Comment 44: With respect to § 59a.5(a), IRRC asked the difference between a Pennsylvania-approved dairy laboratory, an official laboratory and other laboratories.

Response: The referenced provision is intended to cover the full spectrum of laboratories and put *all* laboratories on notice that if any undertakes to conduct dairy sampling and testing for purposes of the regulation, it must conform to designated sound, uniform scientific standards.

A *Pennsylvania-approved dairy laboratory* is a laboratory that has subjected its testing and analytical procedures and methodologies, and the basic competence of its personnel, to the Department's review and approval.

An *official laboratory* is either the Department's dairy laboratory, a private laboratory performing dairy testing and analysis under a contract with the Department or a private dairy laboratory at which Department personnel perform dairy testing and analysis. In response to Comment No. 33, the Department has revised the definition of "official laboratory" in § 59a.2 in the final-form regulation to make this clear.

The "other" laboratories referenced in § 59a.5(a) are simply those laboratories that are *not* Pennsylvania-approved dairy laboratories or official laboratories.

Comment 45: With respect to § 59a.5(a), IRRC noted that laboratories must conform to specific sampling and testing standards or "other methods approved by the Secretary." IRRC believes this phrase is vague and does not set a binding standard. It asks "What are these other methods?" and "How would a laboratory seek and obtain approval of these other methods?" IRRC recommends the final-form regulation either delete this phrase or provide the procedures that need to be followed to obtain approval by the Secretary.

Response: The problematic phrase has been deleted from the final-form regulation.

Comment 46: With respect to § 59a.5(b), IRRC asked why only Pennsylvania-approved dairy laboratories are referenced. IRRC asked why laboratory directors from the other two types of laboratories would not be required to follow the same procedures set forth in this subsection.

Response: The Department has revised the final-form regulation to require the laboratory director of an official laboratory, or a person designated by that laboratory director, or the person who performed the tests described in the report, or the Director of the Department's Bureau of Food Safety and Laboratory Services to sign reports of results.

The Department lacks authority (and any need) to impose restrictions or requirements on the third category of laboratories: those laboratories that are neither Pennsylvania-approved dairy laboratories nor official laboratories.

Comment 47: With respect to § 59a.11 (relating to adoption of Grade "A" PMO), IRRC quoted subsection (a) and asked whether the Department is required by federal law to adopt the Grade "A" PMO and, if so, the extent of the Department's statutory authority to permit state laws and regulations to supersede these federal requirements. This

comment relates to a similar comment IRRC offered with respect to § 59a.405 (relating to sanitation).

Response: There is no requirement under Federal law that the Department or the Commonwealth of Pennsylvania adopt the Grade "A" PMO. The adoption of the substance of the Grade "A" PMO is "recommended," but only to the extent it does not conflict with any current State law.

Comment 48: IRRC asked whether raw milk and PMO-defined milk products should be included in § 59a.12 (relating to permits – implementation procedures).

Response: The Department does not intend this provision of the final-form regulation as providing the regulatory permit requirements for a permit allowing the sale of raw milk for human consumption. That type of permit is addressed in Subchapter F (relating to raw milk for human consumption), and a reference to that subchapter is made in § 59a.12(a).

As for the term "PMO-defined milk products," that has been deleted from the final form regulation. The Department references its responses to Comment Nos. 31 and 34 in this regard.

Comment 49: IRRC noted that § 59a.12(b) only references milk, and not milk products or manufactured dairy products. IRRC recommended that all three types of milk be included in the text of that subsection.

Response: The Department has implemented this recommendation in the final-form regulation.

Comment 50: With respect to § 59a.12(b)(5), a commentator observed that the provision allows for a person selling milk from a single cow to be exempted from the permit requirement imposed by the Milk Sanitation Law, and suggested that – based on an assumption that a single cow can average 100 pounds of milk per day and a goat can average about 5 pounds of milk per day – this same exception should be allowed for up to 20 goats.

PASA offered a related comment, seeking clarification as to whether this provision applies in some different way to raw milk permitholders and whether it applies to other species. The commentator also characterized this provision as confusing. Another commentator quoted and joined PASA's comment.

Another commentator recommended the single-cow exemption be extended to 25 cows.

Response: The Department does not have legal authority to expand the narrowly-drawn statutory discretion afforded it under the Milk Sanitation Law. The relevant provision is at 31 P.S. § 646, and reads as follows:

> The "secretary" may, in his discretion, exempt a person selling milk from not more than one cow from such requirements of this act, as he may deem in each instance to be unnecessary for the protection of the public health.

A search of the Department's records covering the last 20 years has not revealed *a single instance* where the Secretary has exercised this discretion. In recent years several such requests have been made, and were denied on the basis that the Secretary could not ultimately conclude that the testing, sanitation and inspection standards imposed under authority of the Milk Sanitation Law are "unnecessary for the protection of the public health."

Comment 51: With respect to § 59a.12(g), IRRC noted that the provision states that the person in possession of a milk permit must immediately return or surrender the permit if the permit is suspended or revoked. IRRC asked how this provision would be administered if the permitholder requests an administrative hearing under paragraph (h)(2), and suggested the Department explain how this provision adequately protects a person's due process rights.

Response: A milk permit is not suspended or revoked until *after* the permitholder has been afforded notice and opportunity for an administrative hearing. The Milk Sanitation Law (at 31 P.S. § 647) contains a provision that requires a permitholder to receive advance notice of an opportunity for an administrative hearing, and that it be delivered "by registered letter." By the time the Department issues a final administrative adjudication suspending or revoking a milk permit, the permitholder has been afforded notice and opportunity to contest the proposed suspension or revocation and has otherwise received due process.

This particular subsection was added in response to a situation where a permitholder refused to surrender the suspended permit, left it posted at the dairy operation so that prospective customers would assume it was valid, and attempted to continue selling raw milk for human consumption.

Comment 52: With respect to § 59a.12(h)(2), IRRC questioned whether the five-day period referenced in that provision is long enough for a permitholder to decide if they want to request an administrative hearing on a proposed action involving refusal, revocation or suspension of a permit.

Response: Since the Milk Sanitation Law (at 31 P.S. § 647) specifically requires at least 5 days advance written notice of a milk permit suspension or revocation, this provision is consistent with that statute. The suspension or revocation of a milk permit is regularly a very *urgent* matter. Although almost all permitholders voluntarily cease sales of their milk when it is implicated as a possible source of food borne human illness, this is not always the case and a quick process is necessary to help protect human health.

In practice, the Department typically delivers a proposed adjudication to the permitholder, containing a detailed description of the violations(s) justifying the proposed suspension or revocation, providing copies of relevant laboratory reports, photographs or other evidence, and prescribing a step-by-step process by which the permitholder may address the violation. Most permitholders are able to identify, address and correct problems in a fairly brief period of time.

The Department also notes that § 3 of the Grade "A" PMO (relating to definitions) also prescribes a short interval within which due process is to be afforded.

Comment 53: IRRC noted the title of § 59a.13 (relating to adulterated or misbranded milk, milk products or manufactured dairy products) used the word "of" where the word "or" would make more sense, and requested the Department revise this.

Response: The Department agrees, and has made the requested revision in the final-form regulation.

Comment 54: IRRC noted the title of § 59a.14 (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products) includes milk, milk products or manufactured dairy products. IRRC observed that various other sections also include or make reference to PMO-defined milk products. IRRC recommended that the title be amended to include PMO-defined milk products, and that if this section also applies to raw milk, that the section be amended accordingly.

Response: All references to "PMO-defined milk products" have been removed from the final-form regulation. The Department references its responses to Comment Nos. 31 and 34.

The Department has added language to § 59a.14(e) to clarify that the label requirements prescribed under that section are not applicable to raw milk for human consumption.

Comment 55: A commentator from Maryland recommended that § 59a.14(f) be revised by adding specific language requiring labels to specify whether growth hormone was used in the cows that produced the milk.

Response: The Department declines to add the requested language. As related in the response to Comment No. 6, bovine growth hormone is present in all cow milk; and there is currently no way to differentiate analytically (nor are there any measurable compositional differences) between milk from cows that receive recombinant bovine growth hormone and those that do not.

Comment 56: PASA and two other commentators noted the language in § 59a.14(f) that describes the Department's role in determining whether label statements are false or misleading, and expressed serious concerns as to the Department's ability to determine what label information is "false" or "misleading." The commentator characterized the use of these terms as "tabloid-speak," expressed concern that the Department's approach to making determinations under this section might change from administration-to-administration, and asked that the provision be revised to impose a steeper burden of proof on the Department. The commentator offered specific recommended language that would prohibit label statements that are "blatantly false according to prevailing scientific opinion" or that "intended to mislead the consuming public in a grossly negligent manner."

The commentators offered this same general comment (in Comment No. 188) with respect to references to label requirement in Subchapter F (relating to raw milk for human

consumption). These references are at § 59a.411 (relating to label content review by the Department).

Response: The terms "false" and "misleading" come from the Food Act. In the provision describing what constitutes misbranding of food, the Food Act (at 31 P.S. §§ 20.9(a)(1) and 20.9(a)(12)) states that a food is misbranded if its labeling is "false or misleading in any way" or if materials in sight at the point of purchase are "false or misleading in any particular." These are common statutory terms. For example, similar language regarding false or misleading label statements can be found in the Commercial Feed Act (at 3 Pa.C.S.A. § 5107(1)) and the Fertilizer Act (at 3 Pa.C.S.A. § 6711(1)).

The Department believes the terms "false" and "misleading" are the appropriate regulatory terms, in that they are used in one of the statutes underlying the regulation. In addition, the Department does not believe the additional language offered by the commentator offers any clarification. To the extent the commentators seek to impose a steeper burden of proof on the Department to demonstrate a label statement is "false" or "misleading," the Department declines to do so. This regulatory language that is the subject of this comment is a consumer protection provision. A false or misleading label statement might result in human illness or fraud on the consumer. Against this backdrop the Department declines to narrow the terms "false" and "misleading" or impose new burdens of proof on the Department.

The referenced section also allows for the Department to issue guidance documents addressing labeling. This should be of aid to the regulated community in understanding how to avoid false or misleading label statements.

As far as the commentators' concerns regarding possible changes in enforcement or interpretation of this provision from administration-to-administration, the Department offers that the essential requirements that a food label not be "false" or "misleading" have been in effect – under the Food Act – for many years and through many administrations.

Comment 57: A commentator reviewed § 59a.17 (relating to inspection of dairy farms and milk plants) and noted that subsection (a) requires that certain inspections occur "at intervals of no greater than" 3 or 6 months (as the case may be). The commentator noted that in the preamble to the proposed rulemaking, in the portion titled *Overview of the Major Provisions of the Proposed Rulemaking*, these inspection intervals are described as occurring "at least once every" 3 or 6 months (as the case may be). The commentator expressed that the Department should select a single way of describing required inspection intervals and use that description consistently.

Response: The Department acknowledges the comment, and will endeavor to be consistent in its references to this time interval.

Comment 58: With respect to § 59a.18 (relating to sampling and examination), IRRC noted that subsection (a) states that testing required under this section shall be conducted by a "Pennsylvania-approved dairy laboratory or the Department" while subsection (c) states that samples shall be analyzed in an "approved laboratory." IRRC commented that these two provisions appear to conflict, and sought clarification as to what type of laboratory must analyze the samples required under subsection (c).

Response: The Department agrees that the referenced terminology is inconsistent. The final-form regulation has been revised to reflect that the required sampling and examination can be done by a Pennsylvania-approved dairy laboratory, or an out-of-state dairy laboratory that is listed with the NCIMS or that operates in accordance with the current FDA Laboratory Evaluation Manual and FDA 2400 Laboratory Series forms, or the Department.

Comment 59: With respect to § 59a.18(d), IRRC noted that the provision states that drug residue screening will be completed "at the direction of the Department and records of the testing shall be maintained on file by the permitholder." IRRC believes the phrase "at the direction of the Department" is vague and suggested that the drug residue screening requirements be placed in the final-form regulation. IRRC also asked how long a permitholder is required to retain the records of sampling and examination.

Response: The Department agrees that the final-form regulation should specify a minimum time for which the referenced records must be retained, and has revised the document to require a 2-year retention period.

The Department has also revised the final-form regulation by deleting the referenced provision relating to drug residue testing being "at the direction of the Department."

As a result of its review of this provision, the Department has added § 59a.18(f) to the final-form regulation. The Grade "A" PMO requires that milk be excluded from market after an accumulation of violative test results. Once the problems that caused these violations are resolved, the Grade "A" PMO would, in essence, "reset the clock" and begin calculating future accumulations of violative test results from the time the previous violations were resolved. The Department believes it more reasonable (and more consistent with its own past practice) to consider all past violations in calculating whether an accumulation of violative results should justify exclusion of milk from the market. The new subsection makes clear that the Department differs from the Grade "A" PMO in this respect.

Comment 60: With respect to § 59a.19 (relating to standards for grade "A" raw milk for pasteurization, ultrapasteurization or aseptic processing) IRRC noted that the title of this section indicates that the section pertains to raw milk, while subsection (a) indicates that the section pertains to just "milk." IRRC asked that this be resolved in the final-form regulation.

Response: The Department has revised the title of § 59a.19 in the final-form regulation to eliminate the referenced inconsistency.

Comment 61: With respect to § 59a.20 (relating to standards for grade "A" pasteurized, ultrapasteurized and aseptically processed milk and milk products), IRRC recommended that – to improve clarity and for consistency with the arrangement of the section - "applicability" be moved to subsection (a) and "reference to applicable provisions of the Grade "A" PMO" be moved to subsection (b)."

Response: This recommendation has been implemented in the final-form regulation.

Comment 62: With respect to § 59a.26 (relating to plans for construction and reconstruction), IRRC noted that although this section requires the Secretary to approve construction and reconstruction projects, the processes and procedures associated with obtaining approval are not included in the regulation. IRRC recommended that the procedures that need to be followed to obtain approval (including timeframes) should be included in the final-form regulation.

Response: The Department declines to implement formal timelines and procedures for the review process described in the comment. The requirements imposed by § 59a.26 are the same requirements imposed under the current regulation, at § 59.305 (relating to dairy building and equipment plans approval). In practice, this regulatory language has not presented any impediment to the construction of transfer stations, receiving stations or milk plants. This front-end review has proven helpful to the persons constructing these facilities, in that it helps identify and avoid structural or design problems (as opposed to problems with procedures, personnel or maintenance) that can be expensive to correct. The Department is not aware of any instance where the plan review described in this section has delayed the construction of a transfer station, receiving station or milk plant.

The Department notes that this provision of the final-form regulation is also consistent with Section 12 of the Grade "A" PMO (which does not require detailed procedures or a timeline for this plan review process).

Comment 63: With respect to § 59a.27(a) (relating to personnel health), IRRC had several concerns. IRRC noted the phrase "any disease" makes the scope of this subsection very broad, and asked whether this scope could be narrowed. IRRC also asked how an employee or employer could know if a disease is being carried if symptoms are present. IRRC also questioned the legality of requiring dairy farms or milk plant operators not to employ in any capacity a person *suspected* of having a disease in a communicable form, noting this might be a violation of federal and state civil rights and anti-discrimination laws. IRRC also questioned the legality of the reporting requirements contained in the last sentence of the subsection, particularly with respect to reporting "suspected" carriers of diseases. IRRC suggested that the entire subsection be deleted and that the Department rely on the applicable provisions of the Grade "A" PMO referenced in subsection (b).

Response: The Department has implemented IRRC's suggestion in the final-form regulation.

Comment 64: USDA offered a typographical correction with respect to § 59a.101 (relating to adoption of USDA recommended requirements), noting that "Dairy Program" should read "Dairy Programs."

Response: The recommended correction has been made in this final-form regulation.

Comment 65: With respect to § 59a.103 (relating to plant inspection), IRRC noted that this section states that plants receiving milk or dairy products for manufacturing or processing will be subject to inspection by the Secretary or an agent. IRRC further noted that § 59a.17 pertains to inspection of dairy farms and milk plants and provides more detail on inspection requirements. IRRC asked what the need is for § 59a.103, given the language of § 59a.17.

Response: The Department believes that keeping § 59a.103 in the final-form regulation will be helpful to the regulated community, in that the subchapter in which that section appears is specific to the production and processing of milk for manufacturing. The language for this section comes from the current regulation, at § 59.403 (relating to plant inspection), and provides general notice that the referenced plants are subject to inspection.

Comment 66: With respect to § 59a.104 (relating to certification of bulk milk collectors – weigher/samplers), IRRC noted that this section states that: "Weighers/samplers will be evaluated and approved by the Department." IRRC sought clarification as to the process the Department will use to evaluate and approve weighers/samplers, and recommended it be included in the final-form regulation. IRRC also suggested the word "weigher" in the title of this section should be made plural.

Response: The Department has added a reference to the applicable provisions of the Grade "A" PMO to this section. It has also added language to § 59a.12(a), to reference that separate permits or licenses might be required for bulk milk haulers and weighers/samplers under regulation promulgated by the Pennsylvania Milk Marketing Board.

Comment 67: With respect to § 59a.105 (relating to approved milk graders), IRRC asked how the Department will be able to determine if the milk grader is capable of determining the quality classifications required for raw milk, and recommended that the process for making this determination should be included in the final regulation.

Response: The Department has revised this provision in the final-form regulation by adding references to §§ 59a.107 (relating to appearance and odor), 59a.108 (relating to sediment content classification), 59a.109 (relating to bacterial estimate classification) 59a.110 (relating to somatic cell count) and 59a.111 (relating to drug residue level). These additional references encompass all the elements supporting quality classification of raw milk for manufacturing purposes. This provides the reader a complete reference to the various components of a determination of the quality classification of raw milk for manufacturing purposes.

The Department also notes that the requirements imposed by § 59a.105 are an improvement over the current regulation, at § 59.405 (relating to approved milk graders), which simply requires that milk graders be "approved by the Department."

Comment 68: With respect to § 59a.107 (relating to appearance and odor), IRRC offered that the references to "acceptable test procedure" and "other test procedures" are

vague, and recommended that the final-form regulation provide greater detail on what is considered an "acceptable test procedure" or include language that is similar to § 59a.109(b)(10).

Response: The Department has implemented this recommendation in the final-form regulation, by deleting and replacing the reference to "acceptable test procedure" with a cross-reference to the test methodology described in § 59a.108(a).

Comment 69: With respect to § 59a.109 (relating to bacterial estimate classification), five commentators offered that the proposed establishment of a maximum permissible bacterial presence of 500,000 per milliliter is too low.

Two of these commentators only produce milk in cans, for subsequent processing into cheese. These commentators offered that the bacterial estimate classification standards should be applied to the finished product (the cheese), rather than the initial ingredient (the milk in cans).

Response: The Department declines to raise the 500,000 per milliliter standard. This standard is very achievable, provided a producer pays close attention to proper milk sanitation principles - including udder hygiene, milking practices, the cleaning and sanitizing of milking equipment, and the proper cooling of milk once harvested. With proper attention in these important areas, the bacterial count of milk for manufacturing will be well below this proposed regulatory standard.

Although it is important to monitor the quality of finished products, the importance of safe, high quality raw milk prior to the commencement of the manufacturing process is important to the safety and quality of the final product.

Comment 70: With respect to § 59a.109(c)(1) and (c)(2), QC Laboratories offered that the present practice for a laboratory to follow when excessive bacterial estimates are encountered is for the laboratory to inform *the handler or dairy cooperative*, rather than the producer. The commentator apparently does not favor the proposed requirement that laboratories notify individual producers of problematic bacterial test results.

Response: The Department understands the proposed language may have placed an unreasonable burden on the laboratory. Although the USDA Recommended Requirements (at Section C4, titled *Bacterial estimate classification*) provide that a producer should be notified of excessive bacterial count, they do not specify who shall be responsible to provide this notice, and placing this burden on a laboratory might be unreasonable where the producer and the permitholder are not the same person. The final-form regulation has been revised to require the Pennsylvania-approved dairy laboratory to report excessive somatic cell counts to the permitholder, rather than the producer.

The Department references its response to Comment No. 73.

Comment 71: With respect to § 59a.110 (relating to somatic cell count), 31 commentators offered that the proposed establishment of a maximum permissible somatic cell count of 750,000 somatic cells per milliliter with respect to milk for manufacturing

would impose a hardship, and suggested this standard remain at 1,000,000 somatic cells per milliliter.

12 of these commentators related that they only produce milk in cans, for subsequent processing into cheese. These commentators offered that the somatic cell count standards should be applied to the finished product (the cheese), rather than the initial ingredient (the milk in cans).

Response: The Department declines to change this 750,000 per milliliter standard in the final-form regulation. The 750,000 per milliliter standard is reasonable, readily attainable and consistent with modern milk production practices. In fact, the USDA Recommended Requirements suggest the appropriate standard should be *500,000 bacteria per milliliter.* In addition, the vast majority of the regulated community already meets this 750,000 per milliliter standard – with most producing milk that would meet a *400,000* per milliliter standard.

The Department also believes it likely that the 750,000 per milliliter standard established in the final-form regulation will be lowered further in the future. The 500,000 per milliliter standard will immediately be out-of-step with the USDA Recommended Requirements. California is in the process of establishing a 400,000 per milliliter standard. Other jurisdictions are moving toward this, as well. The European Union also has a 400,000 per milliliter standard.

As far as whether the somatic cell count requirement should be imposed with respect to the commentators' finished product (cheese) is concerned, the Department declines to implement such a change. The Department believes that although it is important to monitor the quality of finished product, the importance of safe, high quality raw milk prior to the commencement of the cheese making process is a critical predictor of the safety and quality of the final product.

Comment 72: A commentator offered that she has no objection to the reduction of the maximum permissible somatic cell count to 750,000 somatic cells per milliliter, and would have no objection if that count was ultimately reduced to 500,000 somatic cells per milliliter.

Response: The Department accepts this comment, and references the response to Comment No. 71, which describes a likely further lowering of the 500,000 per milliliter standard in the future.

Comment 73: With respect to § 59a.110(c)(1), IRRC noted that the provision requires laboratories to provide producers with a warning of excessive somatic cell counts, and recommended that this subsection be revised to include language similar to § 59a.109(c)(1) - which states that the warning need not be in writing.

Response: The Department has revised § 59a.109 and § 59a.110 of the final-form regulation to require a laboratory to report test results to the permitholder, to require these results (showing excessive bacteria counts or somatic cell counts) to be retained as part of the producer's records, and to require a permitholder to warn producers whenever 2 of the last 4 counts exceed maximum standards.

Comment 74: With respect to § 59a.110, IRRC noted that other commentators have asked what the acceptable somatic cell count will be for goat milk. IRRC offered that if the regulation is applicable to goat milk, and the somatic cell count standard for goat milk is different from that for cow milk, that goat milk standard should be included in the final-form regulation.

Another commentator offered that the maximum somatic cell count for goat milk should be established (and remain) at no more than 1,000,000 somatic cells per milliliter.

Another commentator suggested the maximum somatic cell count for goat milk should be 1,000,000 or 1,500,000 somatic cells per milliliter.

USDA and PASA offered that the Grade "A" PMO prescribes a maximum somatic cell count of no more than 1,000,000 somatic cells per milliliter for goat milk.

USDA confirmed that NCIMS has adopted a permissible maximum somatic cell count of 1,500,000 somatic cells per milliliter with respect to goat milk. PASA expressed familiarity with this NCIMS standard, and sought confirmation as to whether this is accurate.

PASA also asked whether the standard for maximum somatic cell count standards for sheep milk would a similar to those for goat milk (and recommended that this be the case).

PASA also asked what the process would be for determining appropriate maximum somatic cell counts for milk from other species in the future.

At least one other commentator specifically quoted and endorsed PASA's comments on this subject.

Response: The final-form regulation has been revised to establish a somatic cell count of up to 1,500,000 somatic cells per milliliter with respect to goat milk. This is consistent with the referenced NCIMS standard.

As far as milk from hooved mammal species other than cows or goats are concerned, that milk is considered "milk" and is subject to the 750,000 per milliliter standard.

Comment 75: With respect to § 59a.111(a) (relating to drug residue level), IRRC noted that the subsection pertains to "industry" responsibilities, asked what is meant by this term, and recommended it be defined or further explained in the final-form regulation.

Response: IRRC's recommendation has been implemented in the final-form regulation, to reflect that "industry" refers to holders of manufactured dairy products permits.

Comment 76: With respect to § 59a.111(a)(1)(i), a commentator from Maryland offered that this provision is "redundant since organic, and other certified or non-chemical farmers are by definition pesticide and drug free."

Another commentator offered that this provision would increase costs for the "small farmstead manufacturer," and asked whether there should be an exemption for "farmstead cheeses." The commentator offered that: "If we already have 'growth inhibitor' testing done two times per month and the milk passes for raw milk consumption isn't that sufficient for manufacturing purposes as well?"

Response: The Department does not believe the existence of privately-established and enforced third-party marketing standards for a particular food presents a basis for the Department to lessen regulatory requirements with respect to that food.

With respect to the commentator's request relating to "farmstead cheeses," the Department has revised the referenced provision in the final-form regulation to allow for Department to issue a variance with respect to *beta lactam* drug residues under very limited circumstances. In summary, a variance can be issued where a person processes the milk on the farm on which it was produced, and produces that milk in accordance with a written quality control program addressing the use of animal drugs at the dairy operation. The Department would review such a quality control program and would have authority to provide the processor some relief from the referenced testing requirement.

Comment 77: PASA and another commentator noted that § 59a.111(a)(1)(i) states that "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." The commentator offered the following:

> We feel it is not proper to consider milk being "shipped for processing" and milk that is to be "processed on the farm" in exactly the same way as currently indicated by the proposed rule. We also feel that there are different styles of farming involved that should be considered separately, whether the milk is to be shipped or kept on the farm for processing. Accordingly, our recommendations are twofold, as follows:
>
> > First, we feel it should be clarified exactly what is expected of farmers who process their own milk into cheese and other products on their own farms and, given that traceability is a prime concern, major consideration and reduction of testing burden applied to those farms primarily selling directly to the public and/or with their farm name and/or location clearly indicated on product labels. These considerations should aim especially to relieve such farmers from testing each and every batch of milk before it is processed on the farm.
> >
> > Second, we feel that such testing should not be required at all when two conditions are met: a) the milk, whether shipped or kept on the farm, is not commingled with other milk and b) the milk comes from a farm that is certified organic, biodynamic or sustainable, where the potential for undesirable drug residues would in any case be eliminated by farming methods governed by best management practices, especially regarding use of therapeutic agents, and verified by independent, third-party inspection services.

Response: The Department believes the final-form regulation provides clear guidance as to the lawful production of milk, milk products and manufactured dairy products.

The Department agrees that – in the event of a human illness where food is implicated as the source – it might be easier to trace food back to its source where the food is

properly labeled and was acquired directly from the farmer, rather than through one or more intermediaries. The Department does not believe this should justify requiring less-rigorous testing requirements simply because the milk is processed on the farm where it was produced, though. The final-form regulation is primarily focused on food safety. There are basic food safety and sanitation measures that help make milk for manufacturing as safe as it can practically be made. There is no basis upon which the Department could relax food safety and sanitation standards simply because there are fewer intermediaries between the producer of the milk and the ultimate consumer of the manufactured dairy product produced from that milk, or because it might be easier to trace problematic food to its source where the farmer is also the processor. This type of distinction would afford a lower level of protection to those consumers who purchase manufactured dairy products from the producer of the milk used in making those products.

The Department declines to revise the final-form regulation to allow independent third-party inspection or certifications to supplant testing requirements.

Comment 78: With respect to § 59a.111(a)(1)(ii), a commentator suggested that the testing required in the production of raw milk for human consumption meets or exceeds any testing requirement imposed by this provision.

Response: The commentator is incorrect. The proposed testing requirements for drug residue in raw milk (at § 59a.408 (relating to regular testing of raw milk) require testing at least twice each month. The proposed drug testing requirements for milk for manufacturing require drug testing as frequently as every processing day. This is prescribed by the USDA Recommended Requirements, which reference Appendix N of the Grade "A" PMO.

In response to this comment, the Department has revised § 59a.111 of the final-form regulation to allow for the issuance of a variance from the drug testing requirements for milk processors that only process milk they have produced, and that adhere to a written quality control program addressing their use of animal drugs. This provides certain small-scale manufacturing operations the opportunity to demonstrate that their animal drug protocols justify a provisional variance from the drug testing requirements of this section.

Comment 79: With respect to § 59a.111(a)(2)(iii), a commentator suggested that the testing required in the production of raw milk for human consumption meets or exceeds any testing requirement imposed by this provision.

Response: The Department references its response to Comment No. 78.

Comment 80: With respect to § 59a.111(a)(4), QC Laboratories suggested that the appropriate record retention period should be 24 months (the "frequency between surveys"), rather than 12 months, and recommended the provision describe how these records should be retained.

Response: The Department accepts this suggestion, and has revised the final-form regulation to require that records of positive test results be retained for 24 months.

Comment 81: With respect to § 59a.111(a)(4), IRRC noted that the provision pertains to sample and record retention requirements for load samples, and asked whether there are similar requirements for individual producer sampling under paragraph (a)(2).

Response: As revised in the final-form regulation, § 59a.111(a)(4) requires the results of positive tests to be retained for two years. This includes positive tests results from the producer sampling described in § 59a.111(a)(2). The Department believes it is adequate for the *reports* of these positive samples to be retained, rather than the actual samples, themselves.

Comment 82: With respect to § 59a.111(a)(5)(i), IRRC noted this provision includes the undefined phrase, "industry personnel," asked what is meant by this term, and recommended it be defined or further explained in the final-form regulation. IRRC expressed similar concerns with subparagraphs (b)(1)(ii) and (iii).

Response: The Department agrees this phrase is vague, and has supplanted it in the final-form regulation with references to an employee or representative of the receiving plant.

Comment 83: A commentator offered that the monitoring and surveillance requirements set forth in § 59a.111(b)(1) will increase costs to the taxpayer.

Response: The Department agrees that there will be costs involved in the monitoring and surveillance requirements described in this provision. The Department will incur these costs as part of its statutory food safety responsibilities.

Comment 84: With respect to § 59a.111(b)(2)(v), IRRC noted this provision references that a producer's milk shipping privileges could be suspended "according to State policy." IRRC offered that this is vague, and asked for clarification in the final-form regulation as to what "policy" is being referred to?

Response: The Department agrees that the referenced phrase is vague, and has deleted it from the final-form regulation. The provision now references the same drug residue test requirement as is prescribed by the USDA Recommended Requirements.

Comment 85: A commentator observed the somatic cell count numbers proposed in § 59a.113 (relating to suspended milk for manufacturing) and recommended this provision be revised to establish a higher maximum somatic cell count level for goat milk.

Response: The recommended change has been made in the final-form regulation.

Comment 86: With respect to § 59a.114 (relating to inspection and quality testing of milk from producers), IRRC noted that subparagraph (d)(2)(i) requires new buyers to

obtain certain records from previous buyers, and that paragraph (d)(5) also states that if a new buyer fails to receive required records from the previous buyer, that fact must be reported to the Department. IRRC asked what the need is for this transfer of information between a previous buyer and a new buyer, what incentive there would be for the previous buyer to cooperate with the new buyer, and what can be done by the Department to require compliance once the Department is notified of this situation.

Response: Although there are many reasons a dairy producer might discontinue delivery at one milk plant and begin making deliveries at another milk plant, some of these reasons might relate to problems with the producer's milk, and some of these problems may impact human health. The Grade "A" PMO seeks to have some continuity in records with respect to a dairy producer that changes market. Section 5 of the Grade "A" PMO references this subject. Rather than attempt to paraphrase the requirements of the Grade "A" PMO on this subject, the Department has revised this provision of the final-form regulation by inserting a reference to the applicable provisions of the Grade "A" PMO.

Comment 87: With respect to § 59a.115 (relating to record of tests), IRRC observed that this provision requires records to be kept "for at least 12 months." IRRC's comment: "This language does not inform the regulated community of exactly how long the records must be kept. We recommend that the final-form regulation include a more specific timeframe for record retention."

Response: The proposed language comes from the current regulation, at § 59.508 (relating to record of tests), and has not produced any confusion of which the Department is aware during the many years this requirement has been in effect.

The final-form regulation has been revised to specify that the referenced records must be retained for 24 months, rather than the 12-month retention period described in the proposed regulation. This 24-month period is consistent with the Grade "A" PMO.

Comment 88: With respect to § 59a.117 (relating to animal health), IRRC notes the use of the terms "modified accredited area," "accredited free state," "accredited free herd as determined by the United States Department of Agriculture," "Class B status" and "Certified-Free Herds." IRRC recommends these terms be defined in the final-form regulation or that appropriate cross-references be inserted.

Response: The terms IRRC references are all defined in Federal regulations addressing tuberculosis and brucellosis. Appropriate cross-references have been inserted in the final-form regulation. The Department notes that this change makes the section more consistent with current regulatory standard at § 59.510 (relating to animal health).

Comment 89: With respect to § 59a.201(1) (relating to farm inspection), IRRC asked how a "passing score" for inspections would be established.

Response: The Department has revised the final-form regulation to add a description of what constitutes a "passing score."

In summary, a passing score is earned when there are no deficiencies of major significance to the sanitary quality of the farm's milk supply, or if any such deficiencies are corrected during the inspection.

Comment 90: With respect to § 59a.201(1), IRRC noted that inspections are required "at least once in each 6 month period," and offered: "This requirement is vague. The final-form regulation should specify exactly how often inspections will occur."

Response: The Department disagrees that "at least once in every 6 month period" is vague. It clearly means that 6 months should not elapse without an inspection. This same language is in the current regulation, at § 59.401 (relating to farm inspection), and has not been a source of confusion to the regulated community.

The final-form regulation has been revised to implement IRRC's suggestion, although the Department does not view the revision as adding clarity.

Comment 91: With respect to § 59a.201(1), IRRC asked for clarification as to how long the required records must be kept.

Response: The final-form regulation has been revised to reflect that the referenced records must be kept for at least 24 months.

Comment 92: With respect to § 59a.201(1), IRRC sought clarification as to how a permitholder would know if a form for maintaining records is "acceptable" to the Secretary.

Response: The final-form regulation has been revised by deleting the referenced phrase.

Comment 93: With respect to § 59a.201(2), IRRC asked how it will be determined that milk is "of a wholesome sanitary quality."

Response: The Department has revised the final-form regulation by replacing the referenced phrase with a more specific reference. Milk for manufacturing that meets all applicable requirements of subchapter C (relating to production and processing of milk for manufacturing purposes) and § 59a.202 (relating to milking facilities and housing) is milk that is of wholesome sanitary quality.

Comment 94: With respect to § 59a.201(2), IRRC characterized the phrase "appropriate time for correction of deficiencies" as "vague" and sought clarification as to who will decide what is an appropriate amount of time.

Response: The Department declines to try to make the referenced provision more specific in the final-form regulation. The determination as to the appropriate interval within which deficiencies should be corrected varies with the deficiency. Some deficiencies can be corrected on-the-spot, while others may require considerably more time to correct. Gross unsanitary conditions, drug residues, elevated somatic cell counts

and repeated failure to clean milking equipment are among the types of deficiencies an approved inspector might encounter. The Department's approach has been to train approved inspectors to help them make these decisions properly, and to provide them access to the Department's Milk Sanitarians for assistance in making these determinations.

The Department also notes that the referenced language is in the current regulation, at § 59.401(2) (relating to farm inspection) and has not – in the many years it has been in effect – been a source of confusion or difficulty for the regulated community.

Comment 95: With respect to § 59a.201(3), IRRC asked how a permitholder would know if a producer of milk has been instated, suspended or reinstated.

Response: In the context of the referenced section, the permitholder would be a bulk tank unit (BTU) permitholder – to which a number of separate dairy operations deliver milk. The BTU permitholder would be the entity that: (1) receives inspection information when an approved inspector conducts an inspection of the BTU; (2) receives and retains laboratory reports relating to the milk it handles; and (3) took the action to instate, suspend or reinstate a particular dairy operation.

Comment 96: With respect to § 59a.202 (relating to milking facilities and housing), IRRC noted the use of vague phrases such as "adequate size," "sufficient distance" and "ample size," and recommended that more precise language be added to the final-form regulation.

Response: The Department acknowledges that the referenced phrases are vague. Many dairy farms will be subject to the final-form regulation. The size, age, construction and complexity of these dairy operations vary dramatically. The adoption of rigid standards would immediately put a number of these dairy operations in violation, and present the violators with the choice of incurring the expense of coming into compliance or going out of business. A dairy operation facing this choice might be well-managed and consistently producing quality milk. The Department believes this is the reason (or a prominent reason) that neither the Grade "A" PMO nor the USDA Recommended Requirements seek to establish formal requirements in this area.

The Department also notes that the referenced terms are present in the current regulation, at § 59.601 (relating to milk facilities and housing), and have not been problematic to the regulated community in the many years the current regulation has been in effect.

Against this backdrop, the Department acknowledges that the referenced terms are somewhat vague, but elects to use these terms in the final-form regulation.

Comment 97: With respect to § 59a.207 (relating to water supply), IRRC offered that the first sentence of this section contains vague words or phrases such as "properly located," "easily accessible" and "ample." IRRC believes it would be difficult for the regulated community to determine if they meet the requirements of this provision. IRRC also notes that the second sentence requires the water supply to be approved by the Department; and questions the need for the first sentence. IRRC also asked what

procedures are required to obtain Department approval of a water supply, and recommended these be included in the final-form regulation.

Response: The Department notes that the proposed section comes from the USDA Recommended Requirements, at Section D7 (titled *Water Supply*).

The Department has revised this section in the final-form regulation by deleting part of the second sentence and replacing it with a reference to the Grade "A" PMO. Appendix "D" of that document (titled *Standards for Water Sources*) contains detailed standards with respect to the water supplies for dairy operations.

As far as IRRC's suggestion that the first sentence of this provision is unnecessary, the Department believes it helps the regulated community appreciate the importance of having a good water supply. In addition, terms used in this sentence come directly from Item 8r (titled *Water Supply*) of the Grade "A" PMO.

Comment 98: With respect to § 59a.302(f)(5) (relating to buildings), IRRC noted that the provision requires laboratories to be properly equipped and maintained "to meet requirements established by the Department" without the document specifying what these requirements are. IRRC recommended the final-form regulation either list the requirements or provide a cross-reference to relevant code provisions relating to these conditions.

Response: The final-form regulation has been revised to remove the reference to "requirements established by the Department" and replace it with a reference to the current *Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration* (the FDA's Laboratory Evaluation Manual) and current FDA 2400 Laboratory Series forms. These documents are well-known and state-of-the-science standards for laboratories.

Comment 99: With respect to § 59a.304(a)(2) (relating to equipment and utensils), IRRC notes that the provision contains a typographical error. IRRC's comment: "The final-form regulation should state that: 'New or rearranged equipment shall be set away from any wall or spaced **in** a manner....' (Emphasis added.)"

Response: This error has been corrected in the final-form regulation.

Comment 100: With respect to § 59a.304(i)(2), IRRC asked the circumstances under which the Department would consider a record of temperature or time of cooling to be "of significant importance." IRRC sought clarification of this vague language in the final-form regulation.

Response: The referenced language comes directly from the USDA Recommended Requirements (at Section E 1.4(h)(2)(ii)).

The Department has revised the final-form regulation to provide some examples of instances where a record of time of cooling and holding is of significant importance. These include references to §§ 59a.328 (relating to hotwells), 59a.344 (relating to operations and operating procedures: condensed surge supply) 59a.373(b) (relating to

operations and operating procedures), 59a.381(d) (relating to equipment and utensils) and 59a382.(b) (relating to operations and operating procedures) and 59a.392(b)(1) (relating to operations and operating procedures).

Comment 101: With respect to § 59a.305 (relating to personnel cleanliness) USDA suggested that "caps" be deleted as a form of clothing, and replaced with "hair nets" in order to be consistent with the current Grade "A" PMO standards. IRRC noted its agreement with this comment.

Response: This suggestion has been implemented in the final-form regulation.

Comment 102: With respect to § 59a.305, IRRC asked whether the term "hair nets" encompasses facial hair, and recommended that in the event the Grade "A" PMO does not provide this information, then it should be clarified and included in the final-form regulation.

Response: The Department has revised the final-form regulation to include a reference to "adequate hair covering." This phrase is consistent with language used in the Grade "A" PMO, and includes covering of beards, goatees, untrimmed mustaches and the like.

Comment 103: With respect to § 59a.308(c) (relating to raw product storage), IRRC noted that the provision requires the Department or "a designated representative, from each plant" to conduct raw milk sampling. IRRC sought clarification as to who determines this designated representative (the Department or the plant), and the circumstances under which the designated representative (rather than the Department) would perform the sampling.

Response: The requested clarification has been added to the final-form regulation. The referenced "designated representative" would be an approved sampler, an employee of the milk plant or an employee or representative of a Pennsylvania approved dairy laboratory.

Comment 104: With respect to § 59a.308(e)(3), IRRC sought clarification as to what the Department considers a "satisfactory" sample when a new sample is taken subsequent to a high bacteria count.

Response: The referenced provision has been revised in the final-form regulation by removing the references to "satisfactory" samples and replacing it with a specific reference to the applicable 1,000,000-per-milliliter or lower standard.

Comment 105: With respect to § 59a.310 (relating to composition and wholesomeness), IRRC commented that the "necessary precautions" to prevent contamination during manufacturing are not spelled-out. IRRC's suggestion: "To improve clarity, the final-form regulation should include a list of requisite precautions." IRRC expressed similar concerns with respect to §§ 59a.349, 59a.363(b), 59a.371(a) and 59a.373(c)(1).

Response: This provision repeats the long-standing guidance provided under the current regulation, at § 59.710 (relating to composition and wholesomeness). The Department is not aware of the regulated community having any concerns with interpretation of this language, and takes the absence of any comments from the regulated community on this subject as an indicator that that this remains true.

The provision also tracks with the USDA Recommended Requirements, at Section E 1.10 (titled *Composition and wholesomeness*).

The referenced provision is intended to offer general guidance only. The Department cannot effectively describe all of the precautions that might be necessary.

The Department notes that it offers a similar response to IRRC's comments with respect to §§ 59a.349, 59a.363(b), 59a.371(a) and 59a.373(c)(1) (Comment Nos. 113, 117, 120 and 128, respectively).

Comment 106: With respect to § 59a.311(a)(1) (relating to cleaning and sanitizing treatment), IRRC noted that the provision refers to "other similar materials" which will not adversely affect the products used to clean and sanitize. IRRC offered that this phrase is vague and should be deleted from the final-form regulation.

Response: The final-form regulation has been revised to delete the problematic reference to "other similar materials" and replace it with a general requirement that cleaning and sanitizing chemicals be used in accordance with label instructions.

Comment 107: With respect to § 59a.311(c), IRRC noted this provision discusses transport tanks, and that paragraphs (c)(1)-(3) contain a list of information that does not appear to relate to this issue. IRRC recommended the final-form regulation include additional language to explain why these provisions are included in this subsection.

Response: The Department agrees the proposed provision was confusing. The entire subsection has been revised in the final-form regulation, using language that is consistent with the Grade "A" PMO.

Comment 108: With respect to § 59a.312 (relating to insect and rodent control program), IRRC asked for clarification as to who is the "specially designated employee" referenced in that provision. IRRC also noted that § 59a.353 (relating to operations and operating procedures: insect and rodent control program) refers to a "specifically" designated employee from the commercial pest control service, and asked whether the use of "specially" in one section and "specifically" is a typographical error. IRRC requested the Department either explain this or correct this in the final-form regulation.

Response: The correct term is "specifically," and the final-form regulation has been revised accordingly. With this clarification, the Department believes the phrase "specifically designated employee" explains itself. There must be a person with primary responsibility for insect and rodent control.

Comment 109: With respect to § 59a.314(b) (relating to packaging and general identification), IRRC reviewed that subsection and noted it required packaging and repackaging of dairy products to be conducted under "rigid sanitary conditions." IRRC noted that other subsections make reference to "adequate" sanitary conditions, and commented that the terms "rigid" and "adequate" are vague and should be clarified in the final-form regulation. IRRC also asked why this section would have a higher standard than those calling for "adequate" sanitation. IRRC expressed similar concerns with respect to § 59a.373(d).

Response: The referenced subsection has been revised in the final-form regulation. The primary purpose of this provision is to emphasize the need for a high level of sanitation in packaging and repackaging activities. These are among the moments in the food production cycle where contamination is most likely to occur.

Comment 110: With respect to § 59a.316 (relating to permits), IRRC asks what constitutes the "satisfactory compliance" described in that provision. IRRC also noted a typographical error that appeared in the version of the proposed regulation as published in the *Pennsylvania Bulletin.*

Response: The term "satisfactory" has been deleted from this provision of the final-form regulation. In addition, the referenced typographical error has been corrected.

Comment 111: With respect to § 59a.343 (operations and operating procedures: Pasteurization), USDA noted that subsection (b) requires buttermilk to be pasteurized at 185 degrees Fahrenheit, while subsection (c) requires cheese whey to be pasteurized at 161 degrees Fahrenheit. IRRC joins this commentator in asking why these products are pasteurized at different temperatures.

IRRC recommended the Preamble to the final-form regulation explain the rationale for the difference.

USDA offered specific language to establish separate provisions addressing pasteurization times and temperatures for buttermilk, cheese whey and cream derived from buttermilk.

Response: The Department has revised the final-form regulation by adopting USDA's recommended language, which established a separate subsection addressing cream derived from buttermilk.

The difference in required pasteurization temperatures is related to the viscosity of the different dairy products. Products which are thicker and more viscous require a greater temperature to assure adequate heat penetration during pasteurization.

The Grade "A" PMO requires that products which contain 10% or more milkfat or are 18% or higher in total solids be pasteurized 5° F higher than regular fluid milk.

Comment 112: With respect to § 59a.348(a) (relating to operations and operating procedures: packaging, repackaging and storage), IRRC reviewed that provision and asked for clarification as to what would be considered a package or container that protects the contents "without significant impairment of quality."

Response: The phrase "without significant impairment in quality" appears in the current regulation, at § 59.748 (relating to packaging, repackaging and storage), and has not been a source of confusion in the regulated community. Packaged food is organic material that deteriorates – regardless of packaging. The objective of the referenced regulatory provision is to emphasize the need for adequate packaging.

The Department has revised the final-form regulation to include a reference to 21 CFR § 177.1520 (titled *Olefin polymers*) - a federal standard for package quality – as an example of the types of packages that are acceptable.

Comment 113: With respect to § 59a.349 (relating to operations and operating procedures: product adulteration), IRRC commented that the "necessary precautions" referenced in this section are not spelled-out. IRRC's suggestion: "To improve clarity, the final-form regulation should include a list of requisite precautions." IRRC expressed similar concerns with respect to §§ 59a.310, 59a.363(b), 59a.371(a) and 59a.373(c)(1).

Response: This provision repeats the long-standing guidance provided under the current regulation, at § 59.749 (relating to product adulteration). The Department is not aware of the regulated community having any concerns with interpretation of this language, and takes the absence of any comments from the regulated community on this subject as an indicator that that this remains true.

The provision also tracks with the USDA Recommended Requirements, at Section E 2.4.7 (titled *Product Adulteration*).

The referenced provision is intended to offer general guidance only. The Department cannot effectively describe all of the precautions that might be necessary.

The Department notes that it offers a similar response to IRRC's comments with respect to §§ 59a.310, 59a.363(b), 59a.371(a) and 59a.373(c)(1). (Comment Nos. 105, 117, 120 and 128, respectively).

Comment 114: With respect to § 59a.361(a) (relating to rooms and compartments), IRRC requested clarification as to what constitutes "good commercial practices."

Response: The Department has deleted the problematic phrase from the final-form regulation, but notes that it is used in the current regulation, at § 59.761(a) (relating to rooms and compartments), and has not been a source of confusion in the regulated community.

Comment 115: With respect to § 59a.362 (relating to equipment and utensils), IRRC reviewed subsections (d) and (e) and asked for an explanation of the difference between "easily cleanable" and "readily cleanable" IRRC commented that these terms are vague, and recommended the final-form regulation clarify this distinction.

Response: In response to this comment, the Department has revised subsection (e) to use the phrase "easily cleanable" instead of "readily cleanable." The term "easily cleanable" is a well understood term in the food industry.

The Department has also added a definition of "easily cleanable" at § 59a.2, which references the definition of that term in the current Food Code regulation, at § 46.3 (relating to definitions).

Comment 116: With respect to § 59a.363(a)(1)(i) (relating to operations and operating procedure), IRRC commented that the provision requires certain temperatures for pasteurization. IRRC requested clarification as to the circumstances under which the Department would approve "another equivalent time and temperature combination."

Response: The Department could approve "another equivalent time and temperature combination" if there was scientific information (for example, bacterial challenge studies) to support allowing such an alternative. It is most likely that such an alternative time and temperature combination would be approved *after* it had been scientifically vetted through the USDA.

Comment 117: With respect to § 59a.363(b), IRRC commented that the "necessary precautions" to prevent contamination of products are not spelled-out. IRRC's suggestion: "To improve clarity, the final-form regulation should include a list of requisite precautions." IRRC expressed similar concerns with respect to §§ 59a.310, 59a.349, 59a.371(a) and 59a.373(c)(1).

Response: This provision repeats the long-standing guidance provided under the current regulation, at § 59.763 (relating to operations and operating procedures). The Department is not aware of the regulated community having any concerns with interpretation of this language, and takes the absence of any comments from the regulated community on this subject as an indicator that that this remains true.

The provision also tracks with the USDA Recommended Requirements, at Section E 3.3.2 (titled *Composition and wholesomeness*).

The referenced provision is intended to offer general guidance only. The Department cannot effectively describe all of the precautions that might be necessary.

The Department notes that it offers a similar response to IRRC's comments with respect to §§ 59a.310, 59a.349, 59a.371(a) and 59a.373(c)(1) (Comment Nos. 105, 113, 120 and 128, respectively).

Comment 118: With respect to § 59a.363(e), IRRC noted that the provision explains how commercial bulk shipping containers should be properly identified. IRRC asked for an explanation of the circumstances under which the "other identification" referenced in that subsection would be required. IRRC recommended the final-form regulation list these circumstances.

Response: The referenced language comes from the current regulation at § 59.763(e) and the USDA Recommended Requirements, at Section E 3.3.5 (titled *General identification*). This language is meant to indicate that there may be *additional* information that is required to appear on a commercial bulk shipping container – under authority of other State or Federal statutes or regulations. For example, there may be separate requirements that the words "keep refrigerated," or a USDA Grade designation,

or information identifying the type of butter units enclosed in the commercial bulk shipping container be part of the general identification markings on a commercial bulk shipping container.

Comment 119: With respect to § 59a.363(g)(2)(i), IRRC observed that the provision explains appropriate freezer storage. It includes the sentence: "Adequate air circulation is desirable." IRRC's comment: "The terms 'adequate' and 'desirable' are vague and do not establish a binding standard that can be complied with or enforced. We recommend that the final regulation include a more measurable and definite standard."

Response: The Department has revised the final-form regulation to avoid the use of the terms "adequate" and "desirable" and, instead, require that ventilation achieve uniform storage temperatures throughout the freezer.

Comment 120: With respect to § 59a.371 (relating to rooms and compartments), IRRC commented that the "necessary precautions" to prevent contamination described in Subsection (a) are not spelled-out. IRRC's suggestion: "To improve clarity, the final-form regulation should include a list of requisite precautions." IRRC expressed similar concerns with respect to §§ 59a.310, 59a.349, 59a.363(b) and 59a.373(c)(1).

Response: This provision repeats the long-standing guidance provided under the current regulation, at § 59.771 (relating to rooms and compartments). The Department is not aware of the regulated community having any concerns with interpretation of this language, and takes the absence of any comments from the regulated community on this subject as an indicator that that this remains true.

The provision also tracks with the USDA Recommended Requirements, at Section E 4.1.1 (titled *Starter room*).

The referenced provision is intended to offer general guidance only. The Department cannot effectively describe all of the precautions that might be necessary.

The Department notes that it offers a similar response to IRRC's comments with respect to §§ 59a.310, 59a.349, 59a.363(b) and 59a.373(c)(1) (Comment Nos. 105, 113, 117 and 128, respectively).

Comment 121: A commentator noted that § 59a.371(c) requires a "drying room," and asked whether this could be an area, rather than just a room. The commentator suggested that a refrigerator could be used as a drying area.

Response: The Department declines to implement the suggested change in the final-form regulation; and notes that § 59a.371(c) of the final-form regulation mirrors the current regulatory requirement at § 59.771(c) (relating to rooms and compartments).

Comment 122: With respect to § 59a.371(g), IRRC noted that the provision refers to cutting and packaging rooms, and requires separate *rooms* for cleaning and preparation of cheese. IRRC referenced a commentator who was concerned that requiring numerous rooms would be cost prohibitive to a farmstead cheese maker, and asked for an

explanation of the need for separate rooms. IRRC also asked whether the cost of compliance with this provision has been quantified in the Regulatory Analysis Form.

A commentator asked whether the language of this provision could be changed so that an "area" rather than just a "room" could be used for cutting and packaging.

Response: The cost of compliance with this provision has not been quantified in the Regulatory Analysis Form because the provision does not impose any *new* costs. The requirements of this provision have been long-standing requirements under the current regulation, at § 59.771 (relating to rooms and compartments).

The Department also notes that § 59a.371 of the final-form regulation is consistent with Section E.4 of the USDA Recommended Requirements (titled *Supplemental requirements for plants manufacturing and packaging cheese*).

The Department believes it is important to require separate rooms (rather than separate areas) for cutting and packaging. Bulk cheese that has been in storage often contains a layer of mold that must be trimmed-away from the bulk cheese prior to further cutting and wrapping into smaller-sized packages. This trimming-away frequently causes mold colonies from the bulk cheese to become airborne. The requirement of a separate room for cleaning and preparation and a separate room for cutting and wrapping lessens the exposure of the finished cheese portions to airborne mold colonies. For this reason the Department declines to revise the final-form regulation to require a separate "area" (rather than a separate room) for cutting and packaging.

Comment 123: With respect to § 59a.372(c)(1) (relating to equipment and utensils), a commentator noted the requirement that cheese vats be made of metal and asked whether food grade plastic or some other impervious surface would also be acceptable.

Response: The Department declines to revise the final-form regulation to allow for cheese vats to have linings other than stainless steel.

The Department notes that § 59a.372(c) (1) of the final-form regulation derives from the current regulatory provision at § 59.772(c) (relating to equipment and utensils).

Comment 124: With respect to § 59a.372(e), IRRC noted that the provision includes the phrase "miscellaneous equipment" without describing what this includes. IRRC recommends that the final-form regulation define this term.

Response: The Department does not believe it is necessary or possible to draft a comprehensive list of all of the miscellaneous equipment that might now or in the future be involved in the manufacture of cheese and related products. Regardless of the length or detail of the list it would be necessary to add language allowing for additional equipment that did not appear in that listing, but that should have been included in the listing, to be included by general reference. The Department believes the general reference to "miscellaneous equipment" in § 59a.372(e) is appropriate.

The Department believes there is a good understanding among the regulated community as to what constitutes "miscellaneous equipment" for purposes of § 59a.372(e). The term is used in the current regulation, at § 59.772(e) (relating to

equipment and utensils), and is consistent with the USDA Recommended Requirements, at Section E.4.2.5 (titled *Curd mill and miscellaneous equipment*).

Comment 125: With respect to § 59a.372(f), a commentator noted the requirement that cheese hoops, forms and followers be made of stainless steel or heavy tinned steel and asked whether food grade plastic or some other impervious surface would also be acceptable. The commentator suggested "Kodova molds" as an example.

Response: The Department declines to make the recommended change. The referenced standard is consistent with the USDA Recommended Requirements, and the Department also notes that § 59a.372(f) of the final-form regulation mirrors the current regulatory requirement at a current regulatory provision § 59.772(f).

Comment 126: With respect to § 59a.372(g), a commentator noted the requirement that a cheese press be made of stainless steel, and asked whether food grade plastic or some other impervious surface would also be acceptable. The commentator also asked why a cheese press must be constructed of stainless steel if it is not a contact surface.

Response: Stainless steel is a material with good durability and is easily cleanable. The Department declines to make the recommended change. The referenced standard is consistent with the USDA Recommended Requirements, and the Department also notes that § 59a.372(g) of the final-form regulation mirrors the current regulatory requirement at a current regulatory provision § 59.772(g).

Comment 127: With respect to § 59a.372(i), a commentator offered (and IRRC repeated) a concern as to whether a food grade ceramic tank would be an acceptable tank. The commentator suggested that a "crock pot with a thermometer" should be adequate.

IRRC's comment: "The Department should explain why only 'metal tanks' are considered paraffin tanks."

Response: A food grade ceramic tank (i.e., a crock pot) would not be an acceptable paraffin tank. Metal (stainless steel being the preferred metal) is a material with good durability, is easily cleanable, and does not chip. The Department declines to expand the type of materials to be used for paraffin tanks to include crock pots. A person who seeks to manufacture cheese for commercial purposes must acquire and use the basic, essential equipment to help make the end product as safe as practicable. As stated elsewhere in this document, the Department is not inclined to reduce basic food safety requirements simply because the food producer or processor is a small-scale operation.

Comment 128: With respect to § 59a.373 (relating to operations and operating procedures), IRRC reviewed paragraph (c)(1) and commented that the "necessary precautions" described in that provision are not spelled-out. IRRC's suggestion: "To improve clarity, the final-form regulation should include a list of requisite precautions." IRRC expressed similar concerns with respect to §§ 59a.310, 59a.349, 59a.363(b) and 59a.371(a).

Response: This provision repeats the long-standing guidance provided under the current regulation, at § 59.773(c)(1) (relating to operations and operating procedures). The Department is not aware of the regulated community having any concerns with interpretation of this language, and takes the absence of any comments from the regulated community on this subject as an indicator that that this remains true.

The provision also tracks with the USDA Recommended Requirements, at Section E 4.3.3 (titled *Whey disposal*).

The referenced provision is intended to offer general guidance only. The Department cannot effectively describe all of the precautions that might be necessary.

The Department notes that it offers a similar response to IRRC's comments with respect to §§ 59a.310, 59a.349, 59a.363(b) and 59a.371(a) (Comment Nos. 105, 113, 117 and 120, respectively).

Comment 129: With respect to § 59a.373(d), IRRC noted the provision required packaging and repackaging to be conducted under "rigid sanitary conditions." IRRC noted that other subsections make reference to "adequate" sanitary conditions, and commented that the terms "rigid" and "adequate" are vague and should be clarified in the final-form regulation. IRRC also asked why this section would have a higher standard than those calling for "adequate" sanitation. IRRC expressed similar concerns with respect to § 59a.314(b).

Response: The referenced subsection has been revised in the final-form regulation. The primary purpose of this provision is to emphasize the need for a high level of sanitation in packaging and repackaging activities. These are among the moments in the food production cycle where contamination is most likely to occur.

Comment 130: With respect to § 59a.382(c) (relating to operations and operating procedures), IRRC noted that the provision states that filler crews shall handle forming containers "with extreme care." IRRC asked how the Department intends for crews to meet the standard of "extreme care?" IRRC's comment: "This term is vague and should be defined in the final-form regulation."

Response: The final-form regulation has been revised by replacing a requirement of "extreme care" with a requirement that filler crews avoid contamination of the product contact surfaces.

Comment 131: With respect to § 59a.391(a) (relating to equipment and utensils), IRRC noted that the provision states that: "...for certain other equipment, the requirements of this section shall be met." IRRC asks: "What does the Department consider the 'other equipment' that would be subject to this section?"

Response: The Department appreciates IRRC's point; and has revised the final-form regulation by deleting the final sentence of the referenced subsection.

Comment 132: Five commentators offered general comments recommending that the final-form regulation attempt to make it easier for consumers to acquire raw milk.

Two of these commentators expressed the general sentiment that the regulation should work to facilitate the production of raw milk and support the farmers who produce it.

A related comment was offered in general opposition to a "regulation to have all milk pasteurized."

Three other commentators believe the proposed regulations relating to raw milk reflect an intention to "make it illegal to be either a small dairy farmer or a small dairy farmer selling raw milk," or otherwise disproportionately impact small-scale farm operations or force raw milk operations to go out-of-business.

A commentator also wrote to express her enjoyment of raw milk.

Response: The production and sale of raw milk for human consumption is a legal activity under the Milk Sanitation Law.

Under the current regulation, the provisions that are applicable to the production and sale of raw milk for human consumption are spread through a rather lengthy regulatory chapter. The Department believes the final-form regulation – which seeks to provide prospective and current raw milk permitholders a more understandable statement of regulatory requirements – will facilitate the lawful production and sale of raw milk.

The Department disagrees with the characterization of the regulation as one that seeks to "have all milk pasteurized." As a fact, the number of raw milk permitholders has increased dramatically in recent years.

The Department does not seek for the final-form regulation to make it illegal to be a small dairy farmer or to force raw milk operations to go out of business. The final-form regulation is primarily focused on food safety. Just as a small restaurant is held to the same food safety and sanitation standards as a large restaurant, small dairy operations are held to the same food safety and sanitary standards as large dairy operations. There are basic food safety and sanitation standards that help make raw milk for human consumption as safe as it can practically be made. There is no basis upon which the Department could relax food safety and sanitation standards for small scale dairy operations. The fact that there may be fewer impacted consumers in a food borne illness outbreak involving raw milk from a *small-scale* dairy operation than from a *large-scale* dairy operation does not mean that the Department should afford lower protection to those consumers who acquire raw milk through a small-scale dairy operation.

Comment 133: A commentator referenced the definition of "milk" in § 59a.2, noted that the definition includes milk, "... skimmed milk, cream, sour cream buttermilk and all other fluid derivatives of milk," and offered that the regulation should not take away the right of the raw milk permitholder to sell these fluid derivatives of milk."

Response: The regulation does not establish any new limit or restriction with respect to raw milk. The Milk Sanitation Law does not allow the Department to issue a milk permit authorizing the sale of milk products that contain raw milk in the final product. Milk products must be made from "milk for pasteurization." Milk for pasteurization must be pasteurized or otherwise treated during the preparation of the milk products, per 31 P.S. § 660a(b).

The only raw milk products which may lawfully be sold are certain hard cheeses that have been cured for at least 60 days. There is a Federal standard of identity for this type of cheese (at 21 C.F.R. § 133.150 (titled *Hard cheeses*)).

Comment 134: Five commentators asked whether – in a situation where the Department issued a press release or otherwise publicized problems with a raw milk permitholder's dairy operation – it will follow-through with similar media outreach efforts if/when the problems have been corrected.

Response: The answer to this question is "yes." In those instances where the Department has taken action to suspend or revoke a raw milk permit and has ultimately reinstated the permit or abandoned the effort to suspend or revoke the permit, it has issued a press release to that effect. The Department's sense is that there is less media interest in publicizing this "good news" than there is in publicizing the initial news of the food borne illness outbreak or permit suspension or revocation action, though.

In addition to issuing a press release with respect to the reinstatement of a milk permit, the Department will also make an effort to disseminate that same information through Department-issued newsletters and by other means.

The Department references its response to Comment No. 195.

Comment 135: A commentator from Maryland offered general concern that proposed Subchapter F (relating to raw milk for human consumption) might impede her ability to access raw goat's milk from her Pennsylvania source.

Response: The Department is unaware of any provision of the final-form regulation that would impede the Maryland consumer from coming to Pennsylvania and acquiring goat milk from a permitted source.

The Department makes general note of the Federal regulation at 21 C.F.R. § 1240.61, which prohibits the delivery, sale or distribution in interstate commerce of raw milk for human consumption or any milk product that is made from milk that has not been pasteurized; and refers the commentator to that Federal regulation.

Comment 136: A commentator from Maryland offered that Pennsylvania should allow the sale of raw milk in retail outlets such as grocery stores.

Response: The sale of raw milk in retail outlets is not prohibited.

Comment 137: Five commentators offered general endorsement all of the comments offered by PASA with respect to raw milk, or acknowledged membership in that organization and support for PASA's comments.

Response: The Department acknowledges the detailed and thoughtful comments offered by PASA, and addresses each one in this document.

Comment 138: A commentator asked whether some provision could be made for "small farmstead operations" that process, bottle and label their own dairy products.

Response: As stated above in the response to Comment No. 132, the final-form regulation is primarily focused on food safety. Just as a small restaurant is held to the same food safety and sanitation standards as a large restaurant, small dairy operations are held to the same food safety and sanitary standards as large dairy operations. There are basic food safety and sanitation standards that help make raw milk for human consumption as safe as it can practically be made. There is no basis upon which the Department could relax food safety and sanitation standards for small scale dairy operations. The fact that there may be fewer impacted consumers in a food borne illness outbreak involving raw milk from a *small-scale* dairy operation than from a *large-scale* dairy operation does not mean that the Department should afford lower protection to those consumers who acquire raw milk through a small-scale dairy operation.

Comment 139: With respect to § 59a.402 (relating to raw milk; prohibitions), IRRC notes that subsection (a) prohibits the sale of raw milk without the seller having a valid permit issued by the Department. IRRC noted that several commentators, including Representative Samuel E. Rohrer (128th Legislative District), suggest that this type of permit is unconstitutional, as the Department does not have jurisdiction to regulate direct farmer-to-consumer transactions. IRRC notes that while the Act allows the Secretary to require permits, it also includes a section that relates to portions of the Act being ineffective due to court holdings of unconstitutionality (at 31 P.S. § 660g). IRRC requested an explanation of the Department's statutory authority for regulating these types of transactions, and also asked whether there are any court holdings related to this issue.

The commentators described by IRRC are approximately 36 in number, and include FTCLDF and at least 20 commentators from States other than Pennsylvania. In summary, these commentators offered that there should be no regulatory oversight with respect to raw milk that is sold by a dairy farmer directly to the consumer.

22 commentators (including at least 17 from States other than Pennsylvania) offered that adoption of this recommendation would improve Pennsylvania's economy.

20 commentators, including FTCLDF and at least 13 commentators from States other than Pennsylvania, characterized direct farmer-to-consumer sales as private in nature, and as transactions that do not impact the health, safety or welfare of the general public.

PICFA offered an argument in support of its position that the Milk Sanitation Law and its attendant regulations "... could never constitutionally apply to a private individual, private property, a private business and/or a private contract." The commentator offered various legal references in support of its position.

A number of the commentators identified above also offered comments to the effect that "raw milk has a healthy history in States where unlicensed raw milk sales are permitted."

FTCLDF offered that there is "...a fundamental right to the integrity of ones [sic] own body and to the custody and care of one's children" that authorizes a person to acquire food from the source of their choice, whether the source is licensed or not. The commentator also offered specific proposed language to exempt producer-to-consumer transactions from the scope of the regulation.

Response: The Department very clearly has the authority *and obligation* to regulate direct farmer-to-consumer transactions. The Milk Sanitation Law (at 31 P.S. § 646) provides that "no person shall sell" milk, milk products or manufactured dairy products within Pennsylvania without a Department-issued permit. Farmers are persons. The Milk Sanitation Law also provides an expansive definition of the words "'to sell,' 'for sale' or 'sold.'" Those terms and similar terms mean:

> ... the selling, exchanging, delivering, or having in possession , care, control, or custody with intent to sell, exchange, or deliver, or to offer or expose for sale.

The Department believes the statutory language is unambiguous. Also, had it been the intention of the Legislature to exempt direct farmer-to-consumer sales from the permitting requirements of the Milk Sanitation Law, the statute would have made that clear. This is particularly so in light of the fact that the Milk Sanitation Law was enacted *in 1935* – a time when direct farmer-to-consumer transactions were much more common than they are today (and perhaps constituted the *majority* of milk purchase transactions).

IRRC requested information as to whether any court has found a provision of the Milk Sanitation Law to be unconstitutional. The question was prompted by the provision of the Milk Sanitation Law (at 31 P.S. § 660g) addressing Constitutional construction. To the Department's knowledge there is no such court finding.

The Department is a law enforcement agency. The Department does not have the discretion to unilaterally change the basic permit requirements established in the Milk Sanitation Law. Several of the commentators on this subject referenced prospective legislation to exempt farmer-to-consumer transactions from the requirements of the Milk Sanitation Law. The Department believes it would take such a legislative change to achieve the commentators' objective.

On the issue of the Constitutionality of the permit requirements established in the Milk Sanitation Law, the Department offers that the final-form regulation and the supporting provisions of the Milk Sanitation Law are Constitutional, and that the Office of Attorney General reviewed the proposed regulation for form and legality, and will review the final-form regulation for form and legality.

Comment 140: FTCLDF offered that § 59a.402(a) describes the term "sell" in a manner that is overly-broad, and suggested deleting references to "exchanging" or "delivering" from this definition.

Response: The Department declines to make the requested change. As related in the response to Comment No. 139, the Milk Sanitation Law (at 31 P.S. § 645) defines "To sell," "for sale" or "sold" as including the "exchanging" or "delivering" of milk. The statutory definition is quite broad.

Comment 141: With respect to § 59a.402(b), IRRC noted that this provision authorizes a raw milk permitholder to obtain a permit for the sale of aged cheese manufactured from raw milk. Commentators recommend that this additional permit be expanded to include other dairy products, such as yogurt, kefir, butter and cottage cheese. IRRC asked whether the Department considered expanding the scope of the second permit.

A commentator who is a current raw milk permitholder asked whether the final regulation might be revised to allow the sale of raw milk butter. The commentator reports receiving frequent consumer requests for this product. He also reports referring his customers to raw milk operations that illegally provide the raw milk butter.

Another commentator offered that the final-form regulation allow the sale of raw milk products such as "keefer, yogurt and cheeses."

Along these lines, another commentator suggested these raw milk products be allowed if sold in a direct farmer-to-consumer transaction.

FTCLDF offered the recommendation (and proposed language) to authorize a raw milk permitholder to produce other dairy products, such as yogurt, kefir, butter, cottage cheese and the like. The commentator offered that there is great consumer demand for these products.

A commentator suggested language be added to reflect that a raw milk permitholder may also enter into a "private contract" with a customer to sell the products described above, with label warnings.

Response: The Department does not have a statutory basis upon which to allow for the production of raw milk products, other than the hard cheese referenced in § 59a.402(b) of the final-form regulation. As related in the response to Comment No. 133: The Milk Sanitation Law does not allow the Department to issue a milk permit authorizing the sale of milk products that contain raw milk in the final product. Milk products must be made from "milk for pasteurization." Milk for pasteurization must be pasteurized or otherwise treated during the preparation of the milk products, per 31 P.S. § 660a(b). The only raw milk products which may lawfully be sold are certain hard cheeses that have been cured for at least 60 days. There is a Federal standard of identity for this type of cheese (at 21 C.F.R. § 133.150 (titled *Hard cheeses*)).

The Department believes a legislative change would be necessary to allow the sale of raw milk products other than hard cheese.

Comment 142: With respect to § 59a.403 (relating to raw milk permit), IRRC notes that subsection (b) states that "Each raw milk permit will expire as of September 1 each year...." This subsection also limits a permit's validity to no more than one year. IRRC's comment:

> ... if a person receives a permit in August, for example, how can the permit be valid for a year if it automatically expires in September? In order to fulfill the entire year for the permit, has the Department considered including in this subsection a deadline for when a person can *apply* and *receive* a valid permit?

Response: The Department notes that the referenced language is substantively identical to § 59a.12(f) (relating to permits).

The provision does not state that a raw milk permit is valid for an entire year. It sets the outer limit of a permit's existence at "no more than 1 year," and then limits that still further, so the raw milk permit expires as of September 1 each year. The Department believes this is clear language, and that it keeps the requirements with respect to a raw milk permit consistent with those for any other permit under the Milk Sanitation Law.

The Department considered adding language establishing a permit application deadline. On balance, though, it believes the language in the final-form regulation is adequate. Subsection (c) encourages applications for successor permits to be submitted by July 1 each year. That deadline would likely ensure issuance of a successor permit that can take effect as of September 1 – the date the current permit expires.

Comment 143: With respect to § 59a.404 (relating to requirements for the issuance of a raw milk permit), IRRC observes that this section details the requirements for the issuance of a raw milk permit. IRRC's comment:

> ... while it does require that specific processes be followed from other sections, the majority of these requirements are included, almost verbatim, in subsequent sections of this subchapter. To improve clarity, the Department should consider only listing in this section the specific permit requirements and maintaining further details about them in other sections.

Response: The Department acknowledges that there is an amount of duplication in the referenced subchapter. One of the Department's drafting objectives is to provide raw milk permitholders a clear set of standards. Under the current regulation, the provisions that are applicable to raw milk permitholders are scattered among many pages of regulations. The Department sought to consolidate these provisions to the extent it could, and to make the document more readable by avoiding cross-references (where practical) and adding descriptive section and subsection titles. The Department agrees that this approach makes the subchapter longer than it could be, and repetitive at points. On balance, though, the Department believes this approach will provide this narrow section of the milk production community better, clearer, more-readable guidance than if the use of cross-references and the avoidance of duplication drove the drafting of this subchapter.

Comment 144: With respect to § 59a.404, QC Laboratories offered the general comment that neither this section nor § 59a.407 (relating to regular testing of water supply) make mention of cooling water used in the cooling of raw milk.

Response: In response to this comment, the Department has revised the referenced provisions of the final-form regulation to make clear that the requirement of a bacteriologically safe water supply is also applicable to recirculated cooling water in those instances where the dairy farm uses a recirculated cooling water system for milk cooling.

Although the provision at § 59a.405(18) (relating to sanitation) incorporates the Grade "A" PMO standards related to raw milk cooling, and those Grade "A" PMO standards require that bacteriologically safe water be used in cooling, this was not clear in the proposed regulation.

The Department offers a similar change in its response to Comment Nos. 147 and 161.

Comment 145: With respect to § 59a.404(a)(1), IRRC notes that the provision requires that a dairy farm be "in passing condition" to be eligible for a raw milk permit. IRRC

requested clarification as to what would constitute "passing condition," and recommended the final-form regulation clarify this.

Response: This provision of the final-form regulation has been revised by replacing the reference to "passing condition" with a requirement that the dairy farm be in compliance with the Milk Sanitation Law, the Food Act and Chapter 59a (relating to milk sanitation) to be eligible for a raw milk permit.

Comment 146: With respect to §§ 59a.404(c)(1) and 59a.404(c)(2), IRRC and another commentator noted that these provisions require applicants for both new and successor raw milk permits to provide the Department with a report from a licensed veterinarian that the herd is "...free from communicable disease." IRRC and the other commentator offered that a veterinarian might not have enough information to reach this conclusion, because the regulation is unclear as to what specific diseases this phrase encompasses. IRRC recommended that – to improve clarity - this phrase be deleted from the final-form regulation. IRRC expressed similar concerns with respect to § 59a.406(d).

The commentator also asked whether "communicable disease" includes Caprine Arthritis Encephalitis (CAE), Johnes Disease and Caseous Lymphadenitis (CL).

The commentator also suggested that the phrase "generally appears to be in good health" might be preferable to "free from communicable disease."

Response: The Department has revised the referenced provisions by making the phrase "in general good health and free from communicable disease" read "upon physical examination, the herd is in apparent good health and free from evidence of communicable disease."

The Department is aware that the issuance of animal health certificates is a routine part of veterinary medical practice. Pennsylvania requires a "health certificate" signed by a veterinarian as a condition of importing animals into Pennsylvania (at 7 Pa. Code §§ 3.3 (relating to requirements for importation) and 3.4 (relating to health certificate for imported animals)). These certificates are also referred to as "Certificates of Veterinary Inspection." These certificates are also routinely required of persons who seek to move their animals to fairs or other exhibitions within Pennsylvania. If a person seeks to move animals out of Pennsylvania, the receiving jurisdiction typically has a similar requirement of a veterinarian-issued document attesting to the general apparent good health of the subject animals. For this reason, the Department does not believe it has to provide expansive details as to every disease covered by this general document.

The Department believes the proposed language did not make clear that the referenced health certification is a general attestation to the apparent good health of the subject animals. The revised language better tracks with other regulatory language addressing veterinarian certifications of apparent animal health.

Comment 147: With respect to § 59a.404(d), IRRC and QC Laboratories expressed concern that although the referenced provision states that confirmation of a safe water supply must occur as a permit requirement, only the water supply is mentioned, and not the cooling water used in the cooling of the raw milk. IRRC's comment: "Has the

Department considered confirmation of the safety of cooling water as a permit requirement?" IRRC expressed similar concerns with respect to § 59a.407.

Response: In response to this comment, the Department has revised the referenced provisions of the final-form regulation to make clear that the requirement of a bacteriologically safe water supply is also applicable to recirculated cooling water in those instances where the dairy farm uses a recirculated cooling water system for milk cooling.

Although the provision at § 59.405(18) (relating to sanitation) incorporates the Grade "A" PMO standards related to raw milk cooling, and those Grade "A" PMO standards require that bacteriologically safe water be used in cooling, this was not clear in the proposed regulation.

The Department notes it offers essentially the same response with to Comment Nos. 144 and 161.

Comment 148: With respect to §§ 59a.404(d)(1) and 59a.404(d)(2), FTCLDF and IRRC noted that these provisions require the water supply on the farm to be "bacteriologically safe," without further explanation. Both commentators requested that the final-form regulation clarify what constitutes a "bacteriologically safe" water supply.

IRRC expressed similar concerns with respect to § 59a.407(c).

FTCLDF suggested language be added to state that water is "bacteriologically safe" if it "meets the requirements of 59a.407."

Response: The Department agrees the proposed regulation was not clear enough as to what constitutes "bacteriologically safe" water, and has revised the final-form regulation to address this. The final-form regulation implements FTCLDF's suggestion, but adds a reference to § 59a.405(8) (relating to sanitation), as well. That provision incorporates the Grade "A" PMO requirements with respect to water – which include standards for water sources and standards for bacteriological testing.

The Department references its response to Comment No. 162.

Comment 149: With respect to § 59a.404(e)(1)(v), IRRC noted that the provision requires testing for the presence of "pathogenic bacteria," as part of sampling and testing necessary for new raw milk permits. IRRC repeated concerns expressed by other commentators who argue that because all pathogenic bacteria do not cause illness in humans, it is unreasonable to test for them since they do not pose a threat to public health. IRRC asked whether it is possible for testing to occur only for pathogens that can cause illness to humans. IRRC expressed similar concerns with respect to § 59a.409(d), (d)(3) and (d)(4).

Approximately 28 commentators, including FTCLDF and at least 17 commentators from States other than Pennsylvania, offered essentially the same comment described in the preceding paragraph. These comments also included suggestions that it is an unreasonable use of State resources to test for pathogens if they do not cause illness in humans, and that it was unreasonable for the Department to suspend a raw milk permit on the basis of such tests.

FTCLDF offered specific proposed language to revise §§ 59a.404, 59a.408 (relating to regular testing of raw milk for human consumption) and 59a.409 (relating to violations of raw milk testing standards). In summary, these proposed changes would supplant references to "pathogenic bacteria" with "pathogenic bacteria that cause illness in humans," and would delete a specific requirement that raw milk be tested at least twice annually for *Salmonellae, Listeria monocytogenes, Campylobacter* and *E. coli* 0157:H7.

FTCLDF also offered that:

> ... the proposed regulatory language implies a scientifically unachievable standard of zero tolerance. Laboratories do not report that there are "no pathogens present," because that is a false finding. Laboratories use phrases like "none found" or "none within detectable limits."

Response: The Department has revised the *Raw Milk Testing Schedule and Standards* set forth in § 59a.408(c) of the final-form regulation to clarify that a raw milk permitholder is not required to routinely test (and bear the expense of testing) for *all* pathogenic bacteria – only for *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter* and *E. Coli* 0157:H7.

These four types of pathogenic bacteria do not comprise *all* of the bacteria that are pathogenic bacteria for purposes of the final-form regulation, though. The Department has discretion to act with respect to the presence of any bacteria that can cause illness in humans. Although the permitholder is not required to routinely test for all of these different types of pathogenic bacteria, the Department may conduct this testing, or might become aware of the presence of some other type of pathogenic bacteria in a permitholder's raw milk through a food borne illness investigation (where tests are conducted by Federal, State or local health departments or food safety enforcement agencies).

The types of pathogenic bacteria that can cause illness in humans are the types that are described in the scientific and epidemiological articles and studies that are found on the website maintained by the Centers for Disease Control and Prevention (commonly known as the "CDC"). The website may be accessed at: www.cdc.gov.

With respect to the commentators who expressed concern as to the expenditure of State resources in testing for pathogens that do not cause illness in humans, the Department offers that it makes no such expenditures.

With respect to the commentators who expressed concern that the Department would suspend a raw milk permit on the basis of the presence of pathogenic bacteria that do not cause illness, the Department offers that it would not take action against a raw milk permitholder on the basis of the presence of pathogenic bacteria unless the pathogenic bacteria can cause illness in humans.

With respect to FTCLDF's suggestion that the final-form regulation establishes a "scientifically unachievable standard of zero tolerance," the Department acknowledges that it *does* establish a zero-tolerance standard for pathogenic bacteria in raw milk. The Department is aware that a test might not accurately confirm the "absence" of pathogenic bacteria, but that a test may confirm the "presence" of pathogenic bacteria with extreme accuracy. The final-form regulation does not ask a current or prospective raw milk permitholder to prove a negative (that the raw milk does not have pathogenic bacteria).

Comment 150: With respect to § 59a.404(e), FTCLDF suggested that provisions referencing sampling procedures should specify that samples should be taken from the bulk tank, rather than from other locations. The same comment was offered with respect to § 59a.408.

Response: The Department has implemented this suggestion in the referenced provisions of the final-form regulation.
The Department references its response to Comment No. 167.

Comment 151: With respect to § 59a.404(f), IRRC observed that the provision deals with different types of containers for packaging raw milk. IRRC repeated another commentator's statement that in addition to there being containers owned by the consumer and the producer, there are also containers *sold* by the farmer to the consumer along with the milk. IRRC recommended the final-form regulation include this third type of container. IRRC expressed similar concerns with respect to § 59a.410 (relating to raw milk packaging).

Response: The Department has revised § 59a.410 of the final-form regulation for reasons presented in its response to Comment No. 153, and has deleted § 59a.404(f) for reasons presented in its response to Comment No. 181.

Comment 152: With respect to § 59a.404(f), PASA and two other commentators noted that the substance of this provision appears to be repeated in § 59a.410 (relating to raw milk packaging) and asked: "Is it really necessary to repeat this language, and in reverse order? We think it more suitable to address these issues under one section only, probably the latter."

Response: The Department references its response to Comment No. 181.

Comment 153: PASA offered an additional recommendation with respect to how "containers" should be addressed in § 59a.404(f) and § 59a.410. The commentator offered that although the proposed rulemaking addresses customer-owned containers and containers owned by the raw milk permitholder, it does not adequately address containers such as "the pre-sanitized, one-time-use plastic jug that is sold by the farmer to the consumer along with the milk." The commentator's recommendation:

> ... we feel that pre-sanitized, one-time-use plastic jugs should be explicitly designated as "containers owned by the customer," since they are in fact intended for ownership by the customer once the milk has been sold. Most significantly, this would mean that farmers using this method of packaging and selling raw milk would not be subject to the extra requirements as specified under the "containers owned by the raw milk permitholder" section. This single item alone would likely have a greater positive impact on public safety than any of the other proposed changes to the regulations because it would discourage direct, public access to the milk rooms and bulk storage tanks on the farms of permitholders. Fortunately, it

would also avoid requiring such farmers to have costly, separate bottling facilities and equipment in order to fill these one-time-use, customer-owned jugs themselves.

Response: The Department has revised § 59a.410 of the final-form regulation in response to this comment, and has deleted § 59a.404(f) for reasons presented in its response to Comment No. 181.

Section 59a.410 has been revised by: (1) changing the title of the section to more accurately reflect its subject matter; (2) reformatting the section and adding language to make clear that the *only circumstance* under which a raw milk permitholder is excused from the separate-room requirements and mechanical filling and capping requirements set forth in subsection (a) occurs where a consumer presents a consumer-owned container for filling and the container is not a single-service container and has not been purchased or acquired from the permitholder or the dairy farm at the time the raw milk is purchased.

The Department has also added a definition of "single-service container" to § 59a.2. This new definition derives from the definitions of "Single-service articles" and "Single-service container" in Appendix J (titled *Standards for the Fabrication of Single-Service Containers and Closures for Milk and Milk Products*) of the Grade "A" PMO.

Subsection (c) of the revised section contains language from the Milk Sanitation Law (at 31 P.S. § 657(a)), which requires that bottles or containers "be filled and closed without any part of the hand coming into contact with the inner surface of the bottles or containers, or in contact with bottle caps."

The Department notes that the current regulation (at § 59.302(b)(7) (relating to raw milk)) requires mechanical means for prepackaging raw milk.

The Department is not inclined to allow consumers to acquire single-service containers of raw milk from the raw milk permitholder without those containers having been handled and filled in accordance with the requirements of § 59a.410(a).

Single-service containers are routinely used throughout the dairy industry – but are always required to be filled, capped or sealed through the use of mechanical equipment to decrease the potential for contamination. The Department cannot justify applying a less stringent standard with respect to single-service containers used for raw milk.

In practice, the Department has encountered single-service plastic containers stored on-farm in areas to which barn cats and other animals have direct access, and which are not otherwise protected from contamination from the farm environment.

Also, the Grade "A" PMO (at Item 18p) requires the bottling, packaging and container filling of milk to be done in a sanitary manner and by use of approved mechanical equipment.

The Department notes that a similar comment was offered at Comment No. 182.

Comment 154: With respect to § 59a.404(f), IRRC noted that the provision discusses separate rooms for "bottling, single service container storage, and bottle washing." IRRC's comment continued:

> Section 59a.410(a) also requires use of a "mechanical means of filling and capping bottles." What is the need for both the separate rooms, as well as such mechanical equipment?

Response: The Department has revised § 59a.410 of the final-form regulation for reasons presented in its response to Comment No. 153, and has deleted § 59a.404(f) for reasons presented in its response to Comment No. 181.

The need for the referenced separate rooms and mechanical filling and capping equipment is driven by food safety considerations.

Milk caps and containers can be easily contaminated by contact with human hands. The regulation attempts to minimize that potential for contamination by requiring mechanical filling and capping equipment. The separate rooms requirements also help avoid contamination.

As far as the requirement of separate rooms is concerned, this is no more stringent a requirement than is imposed on permitholders who prepackage pasteurized milk.

Also, the referenced subsection is a restatement of the current regulatory requirement at § 59.302(b)(7) (relating to raw milk). Current raw milk permitholders have long been required to be in compliance with this provision. For those prospective raw milk permitholders who do not possess the necessary mechanical filling and capping equipment, a variety of small scale fillers and mechanical cappers are commercially available.

Comment 155: With respect to § 59a.404(f)(2), FTCLDF noted the provision calls for "separate rooms" for bottling, single service container storage, and bottle washing" and offered that this requirement is onerous and that there is no rational or scientific basis for this requirement. The commentator offered that:

> ... many farmers in PA use manual means of bottling and there have been no reports of health problems due to these means. Mechanical bottling equipment is an unnecessary additional expense. The requirement for "mechanical means" should be deleted or this phrase should be changed to read "mechanical or manual means of filling and capping bottles."

FTCLDF offered a similar comment with respect to § 59a.410(a).

Response: The Department has revised § 59a.410 of the final-form regulation for reasons presented in its response to Comment No. 153, and has deleted § 59a.404(f) for reasons presented in its response to Comment No. 181.

The Department declines to implement this recommendation in the final-form regulation.

With respect to that portion of the comment addressing the need for separate rooms, the Department references its response to Comment No. 154.

With respect to the portion of the comment that characterizes the expense of acquiring and operating mechanical capping and filling equipment as an "unnecessary additional expense," the Department believes this *is* a necessary expense (for the reasons set forth in the response to Comment No. 154), and that it is not an *additional* expense. The requirements relating to mechanical filling and capping equipment set forth in the final-form regulation are not new. There is a current and long-standing requirement (at §

59.302(b)(7)) that a raw milk permitholder have and use mechanical filling and capping gear for prepackaging raw milk.

Comment 156: With respect to § 59a.405 (relating to sanitation), IRRC asked whether the Department is required by federal law to adopt the Grade "A" PMO and, if so, the extent of the Department's statutory authority to permit state laws and regulations to supersede these federal requirements. This comment relates to a similar comment IRRC offered with respect to § 59a.11.

Response: As related in the Department's response to Comment No. 47, there is no requirement under Federal law that the Department or the Commonwealth of Pennsylvania adopt the Grade "A" PMO. The adoption of the substance of the Grade "A" PMO is "recommended," but only to the extent it does not conflict with any current State law.

The Department also notes that the current regulations were derived largely from the *1978* edition of the Grade "A" PMO.

Comment 157: With respect to § 59a.406 (relating to animal health), IRRC noted that subsections (b)(1), (b)(2) and (c) provide that animal health reporting requirements for the holder of a raw milk permit are relative to the "animal or herd" from which the raw milk is being produced. IRRC also noted that the Act defines raw milk as "milk from a cow or cows...." (at 31 P.S. §652 (a)). IRRC's comment:

> ... However, Section 59a.404 (c) of the proposed regulation, which discusses animal health requirements for obtaining a permit for raw milk, only refers to "the herd." A commentator also notes that Section 59a.12(b)(5) states: "A person producing and selling milk from a single cow" is an "exception" for obtaining a permit. The Preamble to the final-form regulation should clarify whether Section 59a.12 (b)(5) applies to raw milk permits. In addition, given how raw milk is defined in the statute, the Preamble should also explain the discrepancy between the use of "animal or herd" and "herd" in Sections 59a.404 (c) and 59a.406.

Response: Although the Department does not believe the proposed language would be a source of confusion among the regulated community, it has revised § 59a.404(c) of the final-form regulation by changing the reference to "herd" to "animal or herd," and has added a definition of the term "herd" at § 59a.2 to reflect that for purposes of this chapter a single animal may be considered a "herd."

With respect to the portion of the comment addressing the single-cow exception, the Department confirms that § 59a.12(b)(5) applies to raw milk permits, references its response to Comment No. 50, and again emphasizes that although the Milk Sanitation Law affords the Secretary the discretion to grant this exception, a search of the Department's records covering the last 20 years has not revealed a *single instance* where the Secretary has exercised this discretion. As a practical matter, the Secretary has not been able to make the required legal conclusion that the testing, sanitation and inspection standards imposed under authority of the Milk Sanitation Law are "unnecessary for the protection of the public health" where milk is produced from just a single cow.

Comment 158: A commentator observed the language at § 59a.406(b)(2) and noted that earlier in the regulation, at § 59a.117 (relating to animal health) – a provision addressing milk for manufacturing - the Department allows for animals to originate from brucellosis certified and accredited-free herds as an alternative to the ring test. The commentator asked that the Department address this, asking: What is this 6 months or less requirement after the annual requirement has been fulfilled?"

Response: The Department agrees that the referenced provision is duplicative and unnecessary, and has deleted § 59a.406(b)(2) from the final-form regulation.

Comment 159: With respect to the required brucellosis and tuberculosis testing described in §§ 59a.406(b) and 59a.406(c), a commentator questioned the need for this testing, given the rarity of these diseases and their infrequent transmission to humans.

Response: With respect to brucellosis testing, the Department references its response to Comment No. 158.

With respect to tuberculosis testing, the Department believes tuberculosis continues to pose a sufficient public health threat – particularly with respect to raw milk for human consumption – to warrant the prescribed testing. The prevalence and impact of tuberculosis was one of the factors that drove the widespread implementation of pasteurization of milk.

Comment 160: With respect to § 59a.406(d), IRRC noted that it requires a raw milk permitholder to regularly obtain a written report from a licensed veterinarian, confirming that the herd is "...free from communicable disease." IRRC and another commentator offered that a veterinarian might not have enough information to reach this conclusion, because the regulation is unclear as to what specific diseases this phrase encompasses. IRRC recommended that – to improve clarity - this phrase be deleted from the final-form regulation. This comment relates to a similar comment IRRC offered with respect to § 59a.404(c).

The commentator also asked that "communicable disease" include Caprine Arthritis Encephalitis (CAE), Johnes Disease and Caseous Lymphadenitis (CL) – and requested clarification on this point.

The commentator also suggested that the phrase "generally appears to be in good health" might be preferable to "free from communicable disease."

Response: The Department agrees that the proposed language did not make clear that the referenced health certification is a general attestation to the apparent good health of the subject animals.

The Department has revised the referenced provision to require the veterinarian to attest that upon physical examination, the herd is in apparent good health and free from evidence of communicable disease.

The Department references its response to Comment No. 146.

Comment 161: With respect to § 59a.407 (relating to regular testing of water supply), IRRC and QC Laboratories noted that although this section provides that confirmation of a safe water supply must occur as a permit requirement, only the water supply is mentioned, and not the cooling water used in the cooling of the raw milk. IRRC's comment: "Has the Department considered confirmation of the safety of cooling water as a permit requirement? This comment relates to a similar comment IRRC offered with respect to § 59a.404(d).

Response: The Department has revised the final-form regulation to clarify that the requirement of a bacteriologically safe water supply applies to water that is used for cooling raw milk.

The Department references its response to Comment Nos. 144 and 147.

Comment 162: With respect to § 59a.407(c), the provision requires the water supply on the farm to be "bacteriologically safe," without further explanation. IRRC suggested the final-form regulation clarify what a "bacteriologically safe" water supply is. This comment relates to a similar comment IRRC offered with respect to § 59a.404(d).
The Department references its response to Comment No. 148.

Response: The Department agrees the proposed regulation was not clear enough as to what constitutes "bacteriologically safe" water, and has revised the final-form regulation to address this. The final-form regulation implements FTCLDF's suggestion (see Comment No. 148) that water is "bacteriologically safe" if it "meets the requirements of 59a.407," but adds a reference to § 59a.405(8) (relating to sanitation), as well. That provision incorporates the Grade "A" PMO requirements with respect to water – which include standards for water sources and standards for bacteriological testing.

Comment 163: With respect to § 59a.407(d), IRRC and another commentator asked how long a raw milk permitholder must retain the water test records referenced in that provision.

Response: The final-form regulation has been revised to make clear that the referenced records must be retained for one year.

Comment 164: With respect to § 59a.408 (relating to regular testing of raw milk for human consumption), IRRC noted that subsection (c) lists the raw milk testing schedule and standards. IRRC and another commentator sought the reason for increasing testing somatic cell count to twice a month. IRRC also asked how the Department determined that 750,000/milliliter is the appropriate limit for the somatic cell count.

Response: Somatic cell count is a good general indicator of herd health and general sanitation practices; and an ongoing awareness of this count can tell the producer and the Department if there is a sanitation or production problem – perhaps before more serious problems occur or are found in the milk.

Somatic cell count is a count of the number of white blood cells in a milk sample. These counts increase in response to udder infections. The somatic cell count level in a

sample of bulk tank milk is a measurement of the level of mastitis infection within the herd and can change quickly in response to sudden flare-ups in one or more cows. By requiring that producers obtain a somatic cell count twice each month, the Department is better able to ascertain whether a raw milk permitholder is employing the hygiene and sanitation practices necessary to control and minimize udder infection.

The 750,000 cells/ml level is the current regulatory limit for Grade "A" milk for pasteurization, and is readily attainable with sound milking sanitation and production practices. It is likely that this maximum permissible somatic cell count will be lowered further in subsequent statute or regulations.

The Department also generally references its response to Comment No. 71.

Comment 165: A commentator asked that the standard for somatic cell count for goat milk be listed in § 59a.408.

Response: This Department agrees this is a good idea, and has made the suggested change in the final-form regulation. The final-form regulation has been revised to establish a somatic cell count of up to 1,500,000 somatic cells per milliliter with respect to goat milk. This is consistent with the referenced NCIMS standard. As far as milk from hooved mammal species other than cows or goats are concerned, that milk is subject to the 750,000 per milliliter standard.

The Department references its response to Comment No. 74.

Comment 166: With respect to § 59a.408, four commentators from Maryland offered that the Department should test only for pathogens that cause illness in humans.

Several of these commentators also offered comments to the effect that it is not reasonable to use state resources to test for things that don't cause illness in people and that therefore pose no public health threat.

Response: The Department has revised § 59a.408(c) to make clear that the raw milk permitholder is only required to test (and bear the expense of testing) with respect to *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter* and *E. Coli* 0157:H7. As drafted, the proposed regulation appeared to suggest the permitholder would have to test for more types of pathogenic bacteria than these four.

The Department declines to make any further changes as a result of these comments. The final-form regulation clearly indicates the type of pathogenic bacteria that are of concern, with § 59a.408 clearly identifying *Salmonellae*, *Listeria monocytogenes*, *Camphylobacter* and *E. Coli* 0157:H7 as being among the pathogenic bacteria of particular concern. The Department may take regulatory action based on the presence of pathogenic bacteria in addition to the four types described in this response.

The Department references its response to Comment No. 149.

Comment 167: With respect to § 59a.408, FTCLDF suggested that provisions referencing sampling procedures should specify that samples should be taken from the bulk tank, rather than from other locations. The same comment was offered with respect to § 59a.404(e).

Response: The Department has implemented this suggestion in the referenced provisions of the final-form regulation, by requiring that the sample used for required pathogenic bacteria testing be drawn from the bulk tank.

The Department references its response to Comment No. 150.

Comment 168: Two commentators questioned the reasonableness of testing raw milk for pathogens, offering that by the time a sample is drawn and tested, and shows the presence of pathogens, the raw milk from which that sample originated will likely have reached the consumer.

One of these commentators characterized this approach as follows: "It seems like scanning yesterdays [sic] newspaper for fatal traffic accidents, to see if it is safe to travel on the road today."

Response: The commentator makes a good point. The food safety testing process is imperfect. Test results lag behind milk production. For example, by the time the Department obtains laboratory test results that show a sample of raw milk contained *Camphylobacter*, the raw milk permitholder may have been selling that *Camphylobacter*-laden raw milk to consumers for several days, or the *Camphylobacter* may no longer be present in the raw milk. This is a reality of food safety testing, in general.

The Department believes it is reasonable to test raw milk for pathogens. The fact that consumers may ingest a pathogen in raw milk before the laboratory testing reveals the presence of the pathogen is not an adequate reason for the Department to refrain from testing, or to refrain from acting to prevent *additional* consumers from risking ingestion of that pathogen once testing identifies the presence of the pathogen in a permitholder's raw milk.

Comment 169: A commentator offered that the twice-yearly testing for pathogens required by § 59a.408 imposes an unnecessary expense on the raw milk permitholder, given that: (1) the current regulatory standards for raw milk are high; and (2) "the lactic acid in raw milk is a natural protection against pathogens."

Along this line, another commentator offered that the proposed testing would increase his per-gallon production costs by ten cents. The commentator feared that these increased testing costs would drive more raw milk producers to operate without a permit and without the Department's regulatory oversight.

Another commentator, from Maryland, expressed concern over the cost and paperwork that would attend the testing required under the proposed regulation.

A Virginia commentator expressed concern that the "irrelevant, misguided" testing requirements for raw milk would likely end her ability to acquire this product.

Another commentator offered that his costs were likely to increase by 3% to 4% as a result of the testing requirements in the regulation.

Another commentator asked how the Department expects farmers to have money to pay for pathogen testing if the Department, itself, does not have money to perform this testing. The same commentator stated that his monthly testing costs were close to $1,000.

Response: The Department believes it is reasonable for raw milk permitholders to test their raw milk for the designated pathogens twice each year. The Department has borne the expense of some pathogen testing in recent years, in part to assess the prevalence of pathogens in raw milk for human consumption. There are approximately 132 raw milk permitholders in Pennsylvania at present. In the period from January of 2008 to July 31, 2010, the Department found *Listeria monocytogenes* in raw milk from approximately 6 of these dairy operations, *Camphylobacter* in raw milk from approximately 6 of these dairy operations, *Salmonellae* in raw milk from two of these dairy operations and *Staphylococcus aureus* in raw milk from one of these dairy operations. Approximately half of this testing was performed in the context of investigations of food borne human illness outbreaks that implicated raw milk as a potential source. Although the Department believes raw milk permitholders are, in general, making improvements in raw milk sanitation and handling procedures, the referenced testing suggests pathogens remain occasionally present in raw milk produced by permitholders.

The Department does not agree that "the lactic acid in raw milk is a natural protection against pathogens." As stated above, pathogens are, as a fact, regularly found in raw milk. Raw milk is an excellent growth media for bacteria.

The Department does not believe the cost of the required pathogen testing will appreciably impact the price or availability of raw milk for human consumption. Pathogen testing should be a routine part of raw milk production and the expense of that testing should be borne by the permitholder.

As described in greater detail in its response to Comment No. 3, the approximate costs of pathogen testing is between $120 and $220. Raw milk permitholders will incur this cost twice each year – so total annual costs for pathogen testing will likely be between $240 and $440. If these costs are prohibitive to a given raw milk producer, then the producer should cease producing raw milk for human consumption. Although the Department seeks to promote the lawful production and sale of raw milk, it will not soften testing requirements at the risk of human health or safety.

Comment 170: With respect to § 59a.408, a commentator expressed general concerns to whether the required pathogen tests for raw milk are accurate.

Response: The Department believes that tests for pathogens are rather straightforward, and do not skew toward false positives. Pathogens are either present – and visible under the microscope – or they are not. Although there are circumstances where pathogens might be present in a raw milk sample and yet *not* appear under the microscope (whether through a failure of the growth medium, or an error in incubation, or after being crowded-out or consumed by other bacteria, etc...), there are no practical circumstances under which a pathogen is not present in a raw milk sample yet appears under the microscope when the sample is cultured.

Comment 171: A commentator from Maryland offered that coliform count (as referenced in § 59a.408) "is not a predictor of safe milk."

Another commentator offered a similar comment, suggesting that coliform count was devised as a means to confirm pasteurization, rather than to ensure the safety of raw milk

for human consumption. The commentator offered that a high coliform count does not mean that pathogenic bacteria are present.

Response: The Department does not agree that coliform count was devised as a means to ensure pasteurization. Phosphatase testing is the appropriate test for pasteurization.

As with somatic cell count (discussed in the Department's response to Comment No. 164) the coliform count is an excellent indicator of herd health and general sanitation; and an ongoing awareness of this count can tell the producer and the Department if there is a sanitation or production problem – perhaps before more serious problems occur or are found in the milk. Coliform count is required throughout the dairy industry with respect to all finished products.

Comment 172: With respect to § 59a.409 (relating to violations of raw milk testing standards), a commentator noted that paragraph (a)(2) requires summary criminal prosecution of raw milk permitholders who violate the provisions of that paragraph. The commentator noted that "... a farmer could be put in jail for failing a milk test." On this same subject, PASA offered that: "one begins to wonder where the facilitated partnership highlighted in the ... ("purpose" section of the proposed rulemaking) ... has gone." PASA considers this language counterproductive. Another commentator quoted and joined PASA's comment.

Another commentator offered substantially the same comment, and suggested that as an alternative to summary criminal prosecution the Department establish procedures such as are implemented when pesticides, growth inhibitors or disease-producing organisms are detected (in subsections (b), (c) and (d)). The suggestion was that the Department work with the permitholder to solve the problem.

Response: The Department erred in drafting this language. As drafted, the proposed regulation would have literally *required* the Department to revoke or suspend the raw milk permit and have the permitholder face summary criminal prosecution for repeated excessive test counts or temperature violations. The Department appreciates the commentator's input on this, and has revised the final-form regulation to make clear that administrative action and/or summary criminal prosecution remain discretionary with the Department.

The Department declines to implement the second commentator's suggestion - that the final-form regulation formalize a process by with the Department would work with the permitholder to solve problems that cause repeated test count violations. Although the Department is always willing to help, and has always offered advice and assistance to any permitholder facing problems such as this, it is the ultimate burden of the permitholder to correct these problems and prevent their recurrence. The Department does not want the final-form regulation to be perceived as in any way shifting this responsibility to the Department.

Comment 173: With respect to § 59a.409(a)(2), a commentator asked why that provision states that the Department may revoke *or* suspend a permit.

The commentator also asked for an explanation of the process by which a revoked or suspended permit is reinstated.

Response: The Milk Sanitation Law (at 31 P.S. § 647) provides the Department the discretion to refuse, suspend or revoke a permit.

In practice, the Department has sought to *suspend* permits much more frequently than it has sought to *revoke* them. The Department is required to provide a permitholder at least 5 days written notice of its proposed denial, suspension or revocation action. This is set forth in the Milk Sanitation Law, at 31 P.S. § 647. The written notice provided by the Department typically sets forth a course of action or testing regimen that – if successfully completed – would result in the Department either abandoning the effort to suspend the permit or (where the permit has already been suspended) reinstating the permit.

The Department affords a permitholder the full panoply of administrative due process rights (including notice and opportunity for a hearing) whenever it seeks to take action to deny, suspend or revoke a permit.

Comment 174: PASA reviewed § 59a.409(b) and asked for clarification as to the circumstances under which pesticide testing might be required. The commentator also asked for an explanation of the circumstances under which pesticides or other adulterating substances might be present in milk. Another commentator quoted and joined PASA's comment.

IRRC noted that the provision lists various procedures to be followed if pesticides are detected in milk samples, but does not specify a required testing regimen. IRRC recommended that the final-form regulation clarify *if* and *when* such testing is required.

Another commentator offered substantially the same question, asking for clarification of how and when pesticide testing would occur. The same commentator offered a general, favorable comment as to the steps to be taken in the event pesticide is discovered in raw milk.

Response: Although the final-form regulation does not call for the routine testing of raw milk for pesticides, there are several circumstances where pesticide testing might occur. A raw milk permitholder might conduct the testing entirely at the permitholder's discretion and expense (such as where cattle have wandered into a field and grazed on vegetation that has been treated with pesticides). The final-form regulation prescribes measures the permitholder is required to take if the results are positive for pesticides. The Department might conduct pesticide testing as part of a food borne illness investigation, or as a result of viewing pesticides stored or used at the dairy operation in a manner that might risk contamination of the animals. The Department is less concerned with identifying all of the potential circumstances under which raw milk might be tested for pesticides than it is with providing the regulated community general notice that this might occur, and establishing responsibilities and procedures for those instances when the test results show pesticides to be present in raw milk for human consumption.

Comment 175: FTCLDF offered that the presence of a pesticide should not, by itself, trigger the remedial action described in § 59a.409(b). The commentator recommended adding language triggering action only when pesticides are detected "above actionable levels established for the pesticide."

Response: The commentator is correct. Where there is a tolerance for a particular pesticide, it would be the United States Environmental Protection Agency that would establish the actionable level with respect to the presence of that pesticide. The final-form regulation has been revised accordingly.

Comment 176: A commentator referenced § 59a.409(c) and offered a general, favorable comment as to the steps to be taken in the event growth inhibitor is discovered in raw milk.

Response: The Department acknowledges and appreciates the comment.

Comment 177: FTCLDF offered that the presence of a growth inhibitor should not, by itself, trigger the remedial action described in § 59a.409(c). The commentator recommended adding language triggering action only when growth inhibitors are detected "above actionable levels established for the inhibitor."

Response: In response to another comment, the Department has changed references to "growth inhibitors" in the final-form regulation to "drugs."

The Department has revised the referenced provision in the final-form regulation by removing language that stated there would be a tolerance for drug residue in milk.

Comment 178: A commentator referenced § 59a.409(d) and offered a general, favorable comment as to the steps to be taken in the event disease producing organisms are discovered in raw milk.

Response: The Department acknowledges and appreciates the comment.

Comment 179: With respect to § 59a.409(d), IRRC noted that the provision references testing for the presence of "pathogenic bacteria" several times. IRRC repeated concerns expressed by other commentators who argue that because all pathogenic bacteria do not cause illness in humans, it is unreasonable to test for them since they do not pose a threat to public health. IRRC asked whether it is possible for testing to occur only for pathogens that can cause illness to humans. This comment relates to a similar comment IRRC offered with respect to § 59a.404.

Response: The Department references its response to Comment No. 149.

Comment 180: With respect to § 59a.410 (relating to raw milk packaging), IRRC repeated another commentator's statement that in addition to containers that are owned by the consumer and the producer, there are also containers *sold* by the farmer to the consumer along with the milk. IRRC recommended the final-form regulation include this third type of container. This comment relates to a similar comment IRRC offered with respect to § 59a.404.

Response: The Department references its response to Comment No. 153.

Comment 181: In a comment offered with respect to § 59a.410, PASA and another commentator noted that the substance of this provision appears to be repeated in § 59a.404(f) and asked: "Is it really necessary to repeat this language, and in reverse order? We think it more suitable to address these issues under one section only, probably the latter."

Response: Although the Department was initially inclined to allow the referenced language to be repeated in both sections, it has revised the final-form regulation by deleting § 59a.404(f). The Department made extensive revisions to § 59a.410 in response to comments (see the Department's response to Comment No. 153), and the revised section is more lengthy and detailed than its predecessor. On balance, the Department agrees with the commentator that it is not necessary or productive to repeat the substance of § 59a.410 in § 59a.404(f).

Comment 182: A commentator from Maryland referenced § 59a.410 and suggested that farmers should be able to use single-use plastic containers with no problems, as this practice would keep customers out of the production/bottling area and it would not be necessary to clean previously-used containers.

Response: The Department references its response to Comment No. 153.

Comment 183: A commentator referenced § 59a.410 and offered that: "Single use containers should be considered containers owned by the customer as they will never be returned to the packager."

Response: The Department references its response to Comment No. 153.

Comment 184: With respect to § 59a.410(a), FTCLDF noted the provision calls for "separate rooms" for bottling, single service container storage, and bottle washing" and offered that this requirement is onerous and that there is no rational or scientific basis for this requirement. The commentator offered that:

> ... many farmers in PA use manual means of bottling and there have been no reports of health problems due to these means. Mechanical bottling equipment is an unnecessary additional expense. The requirement for "mechanical means" should be deleted or this phrase should be changed to read "mechanical or manual means of filling and capping bottles."

FTCLDF offered a similar comment with respect to § 59a.404(f)(2).

Response: The Department has revised § 59a.410 of the final-form regulation for reasons presented in its response to Comment No. 153, and has deleted § 59a.404(f) for reasons presented in its response to Comment No. 181.

As stated in its response to Comment No. 154, the Department believes the need for the referenced separate rooms and mechanical filling and capping equipment is driven by food safety considerations.

Milk caps and containers can be easily contaminated by contact with human hands. The regulation attempts to minimize that potential for contamination by requiring mechanical filling and capping equipment. The separate rooms requirements also help avoid contamination.

As far as the requirement of separate rooms is concerned, this is no more stringent a requirement than is imposed on permitholders who prepackage pasteurized milk.

Also, the referenced subsection is a restatement of the current regulatory requirement at § 59.302(b)(7) (relating to raw milk). Current raw milk permitholders have long been required to be in compliance with this provision. For those prospective raw milk permitholders who do not possess the necessary mechanical filling and capping equipment, a variety of small scale fillers and mechanical cappers are commercially available.

Comment 185: With respect to § 59a.411 (relating to label content review by the Department), IRRC noted that paragraph (a)(1) requires labels on raw milk containers to be submitted to and approved by the Department prior to use, and recommended the final-form regulation include a timeframe for Department approval of the labels.

FTCLDF expressed apprehension over the lack of a clear label review timeline, and suggested that language be added to have the proposed label statement "deemed approved" if the Department does not act on it within 30 days of receipt.

Response: The Department agrees that it is reasonable to impose a time period within which an applicant might expect label review to be completed. It declines to have labels "deemed approved" by inaction of the Department within a stated period, though. The final-form regulation has been revised to provide the Department the same 10-business-day response window as is applicable to label review as described in § 59a.14(b)(3).

Comment 186: With respect to § 59a.411(a)(1), FTCLDF recommended that the regulation specifically address the subject of recombinant bovine growth hormone (rBGH) in milk by stating that label statement such as "from cows not treated with rBGH," or "no RBST" or "no rGBH" do not constitute misbranding or mislabeling.

Response: The Department declines to include such a statement in the final-form regulation. As stated in its response to Comment No. 6, bovine growth hormone is present in all cow milk; and there is currently no way to differentiate analytically (nor are there any measurable compositional differences) between milk from cows that receive recombinant bovine growth hormone and those that do not. On matters related to RBST, the Department will treat label review of all milk (including raw milk for human consumption), milk products and manufactured dairy products the same.

Comment 187: A commentator referenced the use of the term "net weight" in paragraph 59a.411(a)(1) and asked whether this should be "fluid volume."

Response: The commentator is right. "Fluid volume" is the better term. The Department has implemented this recommended change in the final-form regulation.

Comment 188: A commentator noted that paragraph 59a.411(a)(1) would prohibit any "false or misleading" statement on certain raw milk containers, characterized this phrase as "vague" and offered that "... it is leaving the door wide open for individual with power and influence to exert their definition of this in any particular situation."

FTCLDF offered a similar comment.

PASA and another commentator offered a general comment with respect to references to "false" or "misleading" label information. Those terms are used in § 59a.411(a)(1). The commentator describes the Department's role in determining whether label statements are false or misleading, and expressed serious concerns as to the Department's ability to determine what label information is "false" or "misleading." The commentator characterized the use of these terms as "tabloid-speak," expressed concern that the Department's approach to making determinations under this section might change from administration-to-administration, and asked that the provision be revised to impose a steeper burden of proof on the Department. The commentator offered specific recommended language that would prohibit label statements that are "blatantly false according to prevailing scientific opinion" or that "intended to mislead the consuming public in a grossly negligent manner."

As stated, the commentator offered this same general comment with respect to references to label requirement in § 59a.14(f).

Response: This Department references its response to Comment No. 56.

Comment 189: With respect to § 59a.411(a)(2)(i), PASA noted that the proposed consumer advisory is "long and cumbersome ... not an appropriate addition to any label." The commentator suggested providing notice of a website or telephone number by which interested consumers could contact the Department and obtain the information set forth in the proposed consumer advisory. Another commentator quoted and joined this comment.

Response: The Department declines to revise the final-form regulation as the commentators' request. The Department believes that a general reference to a website or telephone number would be ignored by most consumers. Milk is a "potentially hazardous food" under the Food Act (at 31 P.S. § 20.2). The Department's current Food Code regulation (7 Pa. Code Chapter 46) is modeled on the United States Public Health Service Food Code (*FDA Model Food Code*) – the state-of-the-science standards for food safety. The Food Code provision at § 46.423 (relating to consumer advisory required with respect to animal-derived foods that are raw, undercooked or not otherwise processed to eliminate pathogens) requires food facilities to:

> ... inform consumers by brochures, deli case or menu advisories, label statements, table tents, placards or other effective means of the significantly increased risk associated with certain highly susceptible populations eating these foods in raw or undercooked form.

The referenced consumer advisory language tracks with the Food Code, and is offered as an example of an acceptable notice, and not as the only notice that can be provided.

Comment 190: With respect to §§ 59a.411(a)(2)(ii) and 59a.411(b)(2), IRRC and PASA noted that both of these provisions include the following statement: "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." The commentators questioned the need for repeating this sentence.

IRRC and PASA also asked for clarification as to what is meant by the phrase "alternative written means." PASA suggested that examples be added.

Response: With respect to the portion of the comment that addresses repetition within the final-form regulation, the Department references its response to Comment No. 143.

The Department has revised the final-form regulation by deleting references to "alternative written means" of notification at §§ 59a.411(a)(2)(ii) and 59a.411(b)(2). Since Pennsylvania allows a raw milk permitholder to market its milk through third parties, the label requirement provides the most reliable vehicle by which to ensure that the consumer receives this consumer advisory.

Comment 191: With respect to § 59a.411(a)(3)(iv), FTCLDF noted that language allowing for the sampling of raw milk from a "distributor" might result in a reduction in the maximum "sell-by" date for that raw milk, and that the condition of the raw milk might be entirely the result of the carelessness or negligence of the distributor who handled the milk (rather than the permitholder). The commentator suggested either deleting this provision or revising it so that samples would have to be acquired from the permitholder only.

Response: The Department declines to delete or revise this requirement. This provision is substantively identical to § 59a.15(e) (relating to labeling: milk dating). It is also intended to protect the consumer. If a distributor (rather than a permitholder) is the source from which consumers can acquire raw milk for human consumption, it is appropriate that the Department have the discretion to sample the raw milk at any point prior to sale or delivery to the consumer. A permitholder has the discretion to refrain from doing business with a distributor that cannot hold the raw milk under conditions that do not promote excessive bacterial growth.

Comment 192: FTCLDF reviewed § 59a.412 (relating to inspection, sampling and testing by the Department) and noted that a permitholder may refuse access or entry by Department personnel absent a criminal or administrative search warrant. The commentator suggested this section be revised to state the extent of the Department's *authority* with respect to entry, rather than the extent of the raw milk permitholder's *obligation* to allow entry as a condition of the permit.

The commentator also suggested that the final sentence of this section should be deleted.

Response: This section is intended to provide a reminder to permitholders that the permit is a license to engage in an activity that would – in the absence of the permit – be illegal under the Milk Sanitation Law. If a permitholder fails to provide the Department reasonable access to ensure compliance with applicable statutory and regulatory

requirements, that denial – by itself – would justify the Department taking administrative action with respect to the permit. The Department administers a similar regulatory provision with respect to restaurants. Section 46.1101 (relating to access to food facilities) of the Department's Food Code regulations imposes a similar obligation on persons at restaurants and other food facilities.

The Department is aware of the extent of its legal authority with respect to entering private property, and declines to state it in this provision. If a search warrant is necessary, the Department will obtain one. No regulatory guidance is needed for the Department on this point.

Comment 193: With respect to § 59a.413 (relating to enforcement: suspension or revocation of a raw milk permit), IRRC asked what the process would be for reinstatement of a suspended raw milk permit; and asked whether this would be the same process described in § 59a.12.

Response: The answer to IRRC's question is "yes." The process for reinstatement of a raw milk permit is essentially the same as for any other milk permit.

In practice, the Department works with the permitholder to reinstate a suspended raw milk permit as the appropriate corrections are made. For example, if the basis for the suspension is the presence of *Listeria monocytogenes* in a raw milk sample, the Department typically requires the permitholder to address sanitation at the dairy facility and reinstates the suspended permit promptly after the permitholder completes an appropriate testing regimen and the results are test-negative for that pathogen.

Comment 194: With respect to § 59a.413(b)(2), IRRC noted that the provision discusses the detection of pathogenic bacteria as the basis for suspension or revocation of a raw milk permit. IRRC asked whether this includes detection of *all* pathogenic bacteria, or just those that would cause human illness – and requested that the final-form regulation clarify this.

Response: The Department references its response to Comment No. 149.

Comment 195: With respect to § 59a.413(b)(2), PASA noted the procedural steps prescribed by that provision and those that follow it. The commentator (and another commentator who quoted and joined the comment) noted the absence of provisions addressing the circumstances under which the press would be notified or other means would be employed to inform the general public of the status of a suspension, revocation or reinstatement action, and offered the following:

> As this has been a very problematic area of concern in the past, particularly when public notices appear upon discovery of an alleged problem, and without corresponding coverage if the problem is later resolved or found not to be credible, we propose that some clear guidelines be made explicit. In particular, we believe it is incumbent on PDA to make an extra effort, on behalf of the farmer involved, to overcome the tendency of the press to only cover the more flamboyant statement of a problem - as opposed to its resolution - and to get the

word out with any means possible whenever a perceived threat to the public has been resolved.

Response: The commentators make a fair point. In instances where pathogens or other human health risks are found in raw milk, the Department makes a prompt and serious effort to apprise consumers of the potential problem. This will not change, since the protection of human health is the Department's priority. Although the Department typically issues press releases in this type of situation, it is often not the *only* entity issuing these media releases. For example, the Pennsylvania Department of Health, local health departments and federal, state or local agencies might be involved; and each of these acts independent of the Department with respect to its media releases.

The Department issues media releases announcing the *resolution* of a raw-milk-related problem in the same manner it issues media releases announcing the *existence* of the problem. As related in its response to Comment No. 134, though, the Department's sense is that there is less media interest in publicizing this "good news" than there is in publicizing the initial news of the food borne illness outbreak or permit suspension or revocation action.

Although the Department declines to establish regulatory requirements regarding how the Department's Press Office will handle the resolution of problems relating to a particular raw milk permitholder, when the problem is resolved it will issue the same sort of media releases it issued with respect to the onset of the problem. In addition to issuing a press release with respect to the reinstatement of a milk permit, the Department will also make an effort to disseminate that same information through Department-issued newsletters and by other means.

The Department references its response to Comment No. 134.

Comment 196: With respect to § 59a.413(b)(2)(ii)(C), IRRC, FTCLDF and another commentator noted that the provision makes reference to the option of a permitholder to request an administrative hearing. These commentators asked for clarification as to the process for requesting or arranging a hearing.

IRRC's comment:

> ... this subsection does not identify the process for arranging such a hearing. The final-form regulation should set forth the hearing procedures or include a cross-reference to any provisions in the regulation pertaining to the hearing process.

Similarly, FTCLDF suggested that language be added to state that any notice sent by the Department to a raw milk permitholder under this section should set forth the method by which the permitholder may request a hearing.

Response: The Department has revised the final-form regulation to clarify that a request for an administrative hearing must be made in writing, and that a notice of proposed administrative action to deny, suspend or revoke a permit will describe the process by which an appeal can be filed (including appeal deadlines).

The Department declines to prescribe, by regulation, the process it will follow to arrange for an administrative hearing. This would entail a level of detail that does not exist in any other regulation administered by the Department.

The Department has also revised § 59a.413(b)(2)(ii) of the final-form regulation to add a requirement that it *recommend* to a raw milk permitholder who does not choose to comply with a request that it voluntarily cease raw milk sales that the permitholder advise its customers of the problem giving rise to the Department's request for voluntary cessation of raw milk sales.

Comment 197: With respect to § 59a.413(c), FTCLDF noted that the provision states that a raw milk permit remains the property of the Department and must be returned or surrendered to the Department when it is suspended or revoked. The commentator believes this violates the Due Process clause of the United States Constitution, and describes the permit as a "property interest that can only be revoked or suspended in accordance with due process." The commentator believes this provision should be deleted, or should be modified to require surrender of the permit only when administrative appeals have been exhausted.

Response: The Department agrees that it would not require the surrender of a permit until/unless due process has been afforded and exhausted, and has revised the final-form regulation to make this more clear.

As far as the commentator's due process and Constitutional arguments go, the Department is satisfied that due process and all applicable Constitutional protections will be afforded a raw milk permitholder before the Department would require the surrender of a permit.

Comment 198: A commentator referenced § 59a.414 (relating to enforcement: summary criminal prosecution) and asked: "Why prosecute? Why not just revoke or suspend the permit?"

Response: The Milk Sanitation Law (at 31 P.S. § 660d) gives the Department the authority to file summary criminal citations against violators. The decision to pursue criminal and/or administrative actions against a violator will be driven by the facts surrounding a given violation. The regulation does not seek to curtail that authority.

Comment 199: PASA offered that it is counterproductive to have § 59a.414 in Subchapter F. At a minimum, the commentator suggested moving the substance of this provision to another location in the regulation, and making it applicable to all persons who are subject to the regulations, rather than have it in Subchapter F - the subchapter addressing raw milk permitholders.

Response: The Department references its response to Comment No. 143, which provides an explanation of the Department's objectives with respect to Subchapter F. The Department understands that the inclusion of the reference to summary criminal prosecutions is conspicuous, in that similar language is not provided in chapters addressing milk other than raw milk for human consumption. On balance, though, the

Department seeks to provide raw milk permitholders a regulatory chapter that effectively covers all aspects of acquiring and keeping a raw milk permit. The Department assures the regulated community that this is not intended to be counterproductive and is not offered as a slight to raw milk permitholders. The Department will assess this subchapter on an ongoing basis, and is open to the idea of reconsidering its position if it appears the inclusion of the reference to possible summary criminal prosecutions is counterproductive.

Comment 200: With respect to § 59a.416 (relating to enforcement: seizure, condemnation, denaturing or destruction of raw milk; exclusion from sale), PASA offered that it would "be hard to get more negatively-charged words in a single heading." Two other commentators quoted and joined this comment.

Response: The Department offers that the referenced provision relates to enforcement – a necessary topic that typically addresses subject matter that may not be pleasant to the regulated community. The title accurately reflects the subject matter of that section, and is taken *verbatim* from the Department's March 20, 2008 Guidance Document titled *Permits allowing the Sale of Raw Milk for Human Consumption*. The Department mailed or delivered that Guidance Document to every raw milk permitholder in 2008. On balance, the Department is satisfied that the referenced section title is appropriate.

Comment 201: PASA noted the repeated use of the phrase "illegally-produced raw milk products" in § 59a.416, and noted the absence of a definition of this term.

Response: The Department has revised this section of the final-form regulation by deleting the phrase "illegally-produced."

The Department references its response to Comment No. 133, which relates that (with an exception for certain hard cheeses) the Milk Sanitation Law does not allow the Department to issue a milk permit authorizing the sale of milk products that contain raw milk in the final product. Milk products must be made from "milk for pasteurization." Milk for pasteurization must be pasteurized or otherwise treated during the preparation of the milk products, per 31 P.S. § 660a(b).

Comment 202: PASA also offered the following general comment with respect to § 59a.416 in support of its position that the Department, consumers and raw milk permitholders would benefit from the regulation providing a clear declaration of how "value-added, raw dairy products" can be produced without being "illegally–produced raw milk products:"

> It is our understanding that Pennsylvania statutes do not prohibit any individual from purchasing milk, or using milk from a cow he/she owns, and making with it the desired products. It is also true that other persons can be hired without limitation to make such products on behalf of an owner of milk or cow for his/her own use. We therefore now have a tremendous opportunity to clearly state in these regulations what is technically true, that *permitholders who enter into and hold private contracts on behalf of individual consumers, where said contracts*

clearly establish the prior ownership of the cow and/or milk involved. and the intentions with regard to the products desired for manufacture, may provide such products to these individuals on the basis of their private agreement. Appropriate statements can be added, as advisable, to specify the conditions under which contract files are to be confidentially maintained, and/or to hold the Commonwealth of Pennsylvania harmless in the event of unanticipated illness or other problems traced to such products.

Response: The Department declines to revise the final-form regulation to provide the regulated community guidance on how to avoid the requirements of the Milk Sanitation Law and the Food Act; and offers that the commentator may pursue legislation if it seeks formal legal standards by which to avoid the referenced requirements.

The Department serves two interests: (1) the protection of human health; and (2) the production and sale of raw milk, as allowed under the Milk Sanitation Law and the Food Act. Where these interests compete, the Department will advance the regulation that best serves the protection of human health. In the absence of legislation providing otherwise, the Department declines to provide the requested regulatory guidance that it knows might ultimately jeopardize human health.

Comment 203: With respect to § 59a.416, IRRC notes that the Milk Sanitation Law has similar language regarding seizures and injunctions, and that the language in the Milk Sanitation Law references "milk, milk products, or manufactured dairy products." IRRC referenced the provisions at 31 P.S. §§ 660e and 660f, and commented that: "... it is unclear whether raw milk is included within these categories." IRRC asked for an explanation of the Department's statutory authority for both of these types of raw milk enforcement.

Response: The Department references its response to Comment No. 38. All milk begins as raw milk. There is nothing that needs to happen to raw milk (pasteurization or other processing) to make it "milk." The Department maintains that the use of the phrase "milk, milk products or manufactured dairy products" in the referenced provisions of the Milk Sanitation Law very clearly includes raw milk.

Comment 204: A commentator reviewed § 59a.416 and asked that the final document "make it possible for the production of raw milk to be sold legally."

Response: The Milk Sanitation Law and the final-form regulation meet the commentator's objective. Raw milk may be sold legally within Pennsylvania; and the final-form regulation provides clear guidance on how that may be accomplished.

Comment 205: With respect to § 59a.416(a), IRRC noted that this provision permits the Secretary to "...seize, condemn, denature or destroy ... raw milk or illegally-produced raw milk products...considered unsafe or a menace to public health...." IRRC's comment:

... Several commentators, including Representative Rohrer, consider such conduct to be unconstitutional, in particular for raw milk involved in direct farmer-to-consumer transactions. Representative Rohrer also expressed concerns related to Section 59a.415, which permits the Attorney General to "enjoin a person from selling raw milk without the required raw milk permit." Representative Rohrer states that "the attempt of this Section to label private contracts [direct farmer-to-consumer transactions] as "illegal" is a direct violation of both the state and federal Constitutions."

Response: The referenced language authorizing the Secretary to "seize, condemn, denature, or destroy" comes directly from the Milk Sanitation Law, at 31 P.S. § 660e. The idea that a regulator should be able to take suspect food out of the stream of commerce is also embodied in the Food Act, which (at 31 P.S. § 20.6) authorizes the Department to detain food, order its relabeling or reprocessing, or order its destruction. The Department is satisfied of its legal authority in this area.

With respect to the referenced farmer-to-consumer transactions, the Department references its response to Comment No. 139.

With respect to the challenge to the Attorney General's authority to seek to enjoin illegal activity, the Department notes that § 59a.415 (relating to enforcement: injunctions) restates the authority granted by the Milk Sanitation Law, at 31 P.S. § 660f. This statutory provision is rather common in statutes administered by the Department and other Commonwealth agencies. The Attorney General has authority to seek to enjoin violations of the laws of the Commonwealth of Pennsylvania. Since it is a *court* that issues the actual injunction, there is an independent judicial determination as to whether an injunction should be issued. The Department also offers that the Office of Attorney General reviewed the proposed regulation for form and legality, and will review the final-form regulation for form and legality.

Comment 206: A commentator referenced § 59a.416(a) and offered that the seizure of a product by a government agency without just compensation is unconstitutional.

Response: The referenced language authorizing the Secretary to seize milk, milk products or manufactured dairy products that are unsafe or a menace to public health comes directly from the Milk Sanitation Law, at 31 P.S. § 660e.

The Department's initial efforts are typically focused on whether problematic food can be reprocessed, relabeled or otherwise made safe without having to order its destruction. For example, many raw milk permitholders also produce milk for pasteurization or milk for manufacturing. If there is a problem in the raw milk that can be resolved through pasteurization or processing, the Department allows the permitholder to divert the problematic raw milk to be pasteurized or otherwise rendered safe through processing.

If it becomes necessary to order the destruction of milk, milk products or manufactured dairy products that are unsafe or are a menace to public health, though, the Department believes the "just compensation" for these products is quite likely to be zero. For example, if raw milk is known to contain *Listeria monocytogenes*, and if it cannot be diverted for pasteurization or processing to be made safe, an informed prospective purchaser would likely value that raw milk at zero.

Comment 207: A commentator referenced § 59a.416(a), noted the use of the phrase "is considered" in this provision and suggested it was too vague, and that the safety of the milk should be determined by laboratory analysis or by whether it is in violation of the Milk Sanitation Law or its attendant regulations.

Response: The referenced phrase comes directly from the Milk Sanitation Law, at 31 P.S. § 660e. The Department believes it will be the Department's burden to defend the basis for any determination that raw milk is unsafe or a menace to public health and subject to exclusion from sale. As the commentator suggests, in practice this will most often entail laboratory test results and/or a determination that some provision of the Milk Sanitation Law or this Chapter has occurred.

Comment 208: With respect to § 59a.416(a), FTCLDF offered the following:

> This section is too broad and should apply only to raw milk or dairy products that are "sold" to a third party. The Department lacks any jurisdiction over an individual's own, private supply of raw milk or dairy. This section should be modified as follows: "Whenever, in the opinion of the Secretary, a given supply of raw milk or illegally-produced raw milk products that is sold to a third party is considered unsafe or a menace to public health, the Secretary may..."

Response: The Department declines to stray from the basic language of the Milk Sanitation Law (at 31 P.S. § 660e), which does not have the commentator's recommended phrase "that is sold to a third party." In context, the Department's authority only extends to milk that is: (1) sold; (2) exchanged; (3) delivered; (4) held in care, control or custody with intent to sell, exchange or deliver; or (4) offered or exposed for sale (per the Milk Sanitation Law, at 31 P.S. § 645). That is the extent of the Department's reach. The Department is satisfied that, in context, the referenced provision does not exceed the limits of the Department's statutory authority.

Comment 209: With respect to §§ 59a.416(a) and 59a.416(b)(1), IRRC noted that these provisions make reference to products that the Secretary "considers unsafe," and subsection (a) also includes those products that are a "menace" to public health. IRRC asked how the Secretary makes these determinations, and recommended the final-form regulation clarify what is considered "unsafe" as well as what would be a "menace" to public health.

Response: The Department has revised the final-form regulation to provide several general examples of the types of situations where raw milk would be considered "unsafe" or a "menace to public health." It is difficult to identify all those conditions that would render raw milk for human consumption "unsafe" or a "menace to public health," as described in the referenced section and the Milk Sanitation Law (at 31 P.S. § 660e). Not all statutory or regulatory violations would render raw milk produced under that violative condition "unsafe" or a "menace to public health." On the other hand, the presence of any pathogens in raw milk for human consumption renders it "unsafe" or a "menace to

public health," as would the presence of any disease in the herd that could be transmitted to humans through ingestion of raw milk from that herd.

The Department believes it is important to maintain some flexibility to make these determinations, and the fact that it must defend the basis for its determination will temper the Department's actions in this regard.

The Department also references its response to Comment No. 207.

Comment 210: A commentator referenced § 59a.416(b)(1), noted the use of the phrase "considers" in this provision and suggested it was too vague, and that the Secretary was overruling elected officials if he is allowed to "consider" certain raw milk to be unsafe.

Response: The Secretary would not be overruling elected officials in making such a determination. Those elected officials enacted the Milk Sanitation Law, which imparts the referenced authority to the secretary.

The term "consider" is used in the Milk Sanitation Law (at 31 P.S. § 660e). The Department believes it will be the Department's burden to defend the basis for any determination that raw milk is unsafe or a menace to public health and subject to exclusion from sale. As the commentator suggests, in practice this will most often entail laboratory test results and/or a determination that some provision of the Milk Sanitation Law or this Chapter has occurred. The Department references its response to Comment No. 207.

Affected Individuals and Organizations

The final-form regulation will benefit nearly all Pennsylvania 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 permitholders will also benefit from the regulation. In addition, approximately 132 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 final-form regulation 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 final-form regulation will 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 final-form 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 final-form regulation takes effect, or to incur costs related to testing by third party laboratories. The Department estimates these dairy operations will, in the aggregate, incur total costs of approximately $85,200 in the first year after the final-form regulation takes effect, and costs of approximately $55,200 in subsequent years.

Persons who hold milk permits that authorize the sale of raw milk for human consumption will incur approximately $740 in additional testing costs under the regulation. These permitholders will incur approximately $300 in additional somatic cell count test costs (12 additional tests, costing approximately $25 each) and $440 in pathogen testing costs (2 tests annually, costing between $120 and $220 each). There are approximately 132 such permitholders. The total annual cost increase for these permitholders will be approximately $97,680 each year.

General Public: The final-form regulation is not expected to impose any appreciable new costs or have any appreciable financial impact on the general public. The proposal will enhance public safety. It is possible that some portion of the additional testing costs imposed on the private sector will be passed-along to the consumer. The Department expects any such cost increases would be minimal.

Paperwork Requirements

The final-form regulation will not impact upon the paperwork generated by the Department or the regulated communities.

Effective Date

The final-form regulation will be effective January 1, 2011 or upon publication in the *Pennsylvania Bulletin* – whichever occurs later.

Contact Person

Individuals who need information about the final-form regulation should contact the Pennsylvania Department of Agriculture, Bureau of Food Safety, Division of Milk Sanitation, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: Paul Hoge.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on July 21, 2009, the Department submitted a copy of the notice of proposed rulemaking, published at 39 Pa.B. 4677, to the IRRC and the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department provided IRRC and the referenced Committees with copies of all comments received during the public comment period.

Under section 5.1(j.2) of the Regulatory Review Act (71 P. S. § 745.5a(j.2)), on _____, 2010, the final-form regulation was _____ approved by the House Committee and on _____, 2010, the final-form regulation was _____ approved by the Senate Committee. Under section 5.1(g) of the Regulatory Review Act, the final-form regulation was approved by IRRC on November 6, 2008.

Findings

The Department finds that:

(1) Public notice of intention to adopt this final-form regulation has been given under sections 201 and 202 of the act of July 31, 1968 (P. L. 769, No. 240) (45 P. S. §§ 1201 and 1202) and the regulations thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law; and all comments that were received were considered.

(3) The modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed regulation published at 39 *Pennsylvania Bulletin* 4677 (August 1, 2009).

(4) The adoption of the final-form regulation in the manner provided in this order is necessary and appropriate for the administration of the authorizing statute.

Order

The Department, acting under the authorizing statute, orders the following:

(1) The current regulations of the Department of Agriculture at 7 Pa. Code Chapter 59 (relating to milk sanitation) are rescinded. A new regulatory chapter – Chapter 59a (relating to milk sanitation) is hereby established, to read as set forth in Annex "A."

(2) The Secretary of Agriculture shall submit this order, 39 Pa.B. 4677 and Annex "A" to the Office of General Counsel and the Office of Attorney General for approval as required by law.

(3) The Secretary of Agriculture shall certify and deposit this order, 39 Pa.B. 4677 and Annex "A" with the Legislative Reference Bureau as required by law.

(4) This order shall take effect on January 1, 2011 or upon publication in the *Pennsylvania Bulletin* – whichever occurs later.

RUSSELL C. REDDING, Secretary

Annex A

TITLE 7. AGRICULTURE
PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
CHAPTER 59. MILK SANITATION

Sec.

CHAPTER 59a. MILK SANITATION

Subchap.

Subchapter A. PRELIMINARY PROVISIONS

Sec.

§ 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 (which includes raw 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) (31 P. S. §§ 645--660g), known as the Milk Sanitation Law.

Adulterated--As defined in section 8 of the Food Act (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.

BTU--Bulk tank unit--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 § 59a.4(h) 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] designated 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--

(i) Milk from two or more producers.

(ii) 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 or other lactating hooved mammals are kept, and a part [of] or all the milk from which is sold or delivered to any person.

Department--The Department of Agriculture of the Commonwealth.

Easily cleanable—As defined in the Food Code, at 7 Pa. Code § 46.3 (relating to definitions).

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

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

[*Food establishment--*

(i) 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.

(ii) 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--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 web site: www.agriculture.state.pa.us.

Growth inhibitor—[A] An 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. The Grade "A" PMO provisions further defining or describing HACCP include Section 1 (titled *Definitions*) and Appendix K (titled *HACCP Program*).

[*HTST*--High temperature short time.]

Herd—A group of animals, or a single animal, maintained for purposes related to this Chapter.

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 other products for human consumption, as may be designated by the Secretary. These other products include instant nonfat dry milk and other dry milk products, pasteurized process cheese and related products, sterilized milk products, butter-related products and any other products that must be produced at plants in accordance with supplemental requirements established under Subchapter E.

Milk--Milk, skimmed milk, cream, sour milk, sourcream, buttermilk and all other fluid derivatives of milk. The term includes milk from any hooved mammal species.

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*--A 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. The term includes those foods that are milk products under the Grade "A" PMO.

Misbranded--As defined in section 9 of the Food Act (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. The term includes a dairy laboratory controlled and operated by the Department, a dairy laboratory that performs dairy testing and analysis under contract with the Department, or a dairy laboratory at which Department personnel perform dairy testing and analysis.

[*PMO-defined milk products*--

(i) Milk products that fit within the following description, or as otherwise defined in the Grade "A" PMO.

(ii) The term includes the following:

(A) 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.

(B) 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).

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

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

(I) Used as an ingredient to produce any milk or milk product described in this definition.

(II) Labeled as Grade "A" as described in the Grade "A" PMO.

(E) 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 in this clause, 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 may 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, that is, sodium caseinate. This is similar to the existing FDA position that the dairy ingredient in small cans of freeze-dried starter culture need not be Grade "A."

(III) 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 2 years to do official analyses of milk and milk products.

(ii) A milk industry laboratory approved and certified by the Department within the preceding 2 years for the examination of producer samples of [raw] milk for pasteurization [or], of commingled [raw] milk for pasteurization <u>or of raw milk for human consumption</u> 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 80% on the written examinations] 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).

Permitholder--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 persons who exercise control over the production of the milk delivered to a plant, and who receive 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] provisions of Subchapter F (titled *Raw Milk for Human Consumption*).

Secretary--The Secretary of the Department, or an authorized representative.

~~*Single-service container*--A container which is constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings or similar materials, that has a milk-contact surface and that is intended by the manufacturer for one (1) usage only.~~

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.

UHT—[Ultra-heat treated] Ultra-high temperature.

UHTST--Ultra-high temperature short time.

USDA Recommended [*requirements*] *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] Programs.

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) has 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 has the meaning ascribed to it in the Grade "A" PMO, the exception of the term "regulatory agency," which means 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 web site 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 will provide application forms, or the renewal forms described in subsection (d), upon request to the address or web site identified in § 59a.3 (relating to contacting the Department). An application fee of $50 (or as otherwise prescribed by statute) must accompany the application.

(b) *Criteria for approval.* An applicant shall [be at least 18 years of age, have attended a PDA-approved seminar as described in subsection (e) within 12 months preceding the date of the application and demonstrate to the satisfaction of the Department to be of good character and to have adequate education or experience, or both, to carry-out dairy farm and milk plant inspection in a capable and efficient manner] meet the following criteria in order to be eligible for licensure as an approved inspector:

(1) The applicant must be at least 21 years of age.

(2) The applicant must not have been convicted of a felony criminal offense within the 10 years preceding the date of application.

(3) The applicant must have at least two years of academic training or experience in the area of milk production and milk sanitation. The Department may verify that an applicant has adequate experience by having Department personnel conduct one or more joint dairy farm inspections with the applicant.

(4) The applicant must complete a Department-administered Approved Inspector Examination and achieve a final score of at least 80%.

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

(d) *Duration of license; renewal.* A license will expire each year, as of January 1. Applications for renewal of a license must be accompanied by a fee of $20 (or as otherwise prescribed by statute), and confirmation that the applicant for renewal has attended a Department-approved seminar as described in subsection (e) within 12 months preceding the date of the application, and shall be returned to the Department by December 31st of each year.

(e) *Education requirement.* The Department will convene an approved inspector educational seminar on at least two separate dates each calendar year, and 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 may not represent himself 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*[,] or 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* and the Grade "A" PMO, and shall operate in accordance with current FDA 2400 Laboratory Series forms.

(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] a Pennsylvania-approved dairy laboratory director or a person designated by such a laboratory director to sign these reports. If an official laboratory issues a report of the results of laboratory examinations for purposes of this chapter, the report shall be signed by the laboratory director, a person designated by the laboratory director, the person who performed the tests described in the report or the Director of the Department's Bureau of Food Safety and Laboratory Services.

(c) *Pennsylvania-approved dairy laboratory director.*

(1) A person may apply to the Department to be certified as a Pennsylvania-approved dairy laboratory director. This approval may be sought with respect to any or all of the following categories of dairy testing procedures:

(i) Sampling.

(ii) Cultural procedures.

(iii) Coliform count (media or Petrifilm™).

(iv) Standard plate count (media or Petrifilm™ Count).

(v) Drug Residue Testing/Appendix N of the Grade "A" PMO.

(vi) Direct microscopic somatic cell count (DMSCC) and/or Electronic somatic cell count (ESCC).

(vii) Phosphatase: Electronic Fluorophos and/or Charm methodologies.

(2) The Department will consider the written application of a dairy laboratory director to be certified as a Pennsylvania-approved dairy laboratory director. The application may be by letter, or may be made on a form the Department shall provide upon request. A prospective applicant must meet two or more of the following requirements in order to be eligible to apply:

(i) The applicant has at least one year of experience, or the equivalent of that experience, conducting analysis at a dairy laboratory.

(ii) The performance of the applicant with respect to the category for which certification is sought has been evaluated on-site by Department personnel, and has been satisfactory.

(iii) The performance of the applicant in a Department-conducted milk split sample proficiency program with respect to the category for which certification is sought has been satisfactory.

(iv) The applicant has attended and completed a training session offered by the Department or the FDA, addressing the category for which certification is sought.

(3) The Department will provisionally certify a dairy laboratory director to be a Pennsylvania-approved dairy laboratory director with respect to one or more specific categories of testing procedures if the applicant meets the qualification standards described in paragraph (2), submits an application and does the following:

(i) Completes a Department-administered written examination and attains a score of at least 80% on that examination. The examination shall have a general section addressing sampling and culturing procedures, and a section addressing the specific categories of dairy testing procedures with respect to which the applicant seeks certification.

(ii) Passes an on-site performance and facilities evaluation by a Laboratory Evaluation Officer from the Department.

(4) After the provisional certification described in paragraph (3), the Department will certify a dairy laboratory director to be a Pennsylvania-approved dairy laboratory director with respect to one or more specific categories of testing procedures if the provisionally-certified person submits a split sample to the Department for analysis, retains and analyzes the other portion of the split sample, and the results of analysis are consistent between the Department and the provisionally-certified person.

Subchapter B. PERMIT REQUIREMENTS

Sec.

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 one or more of the following:

(1) The act.
(2) The Food Act.
(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 may not sell milk, milk products or manufactured dairy products within this Commonwealth 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, milk tank truck cleaning facility, and by every producer of raw milk in accordance with Subchapter F (relating to raw milk for human consumption). Additional permits or licenses may be required for milk haulers and weighers/samplers under regulations established and enforced by the Pennsylvania Milk Marketing Board at 7 Pa. Code Part VI (relating to milk marketing board).

(b) *Exceptions.* The permit requirement of subsection (a) does not apply 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.
(3) A person selling milk, milk products or manufactured dairy 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 [when milk] where milk, milk products or manufactured dairy 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 as 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 this Commonwealth) will 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 will 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 shall be met 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 will 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 will be valid for no more than 1 year. Each permit will 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 permitholder. 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 will promptly return the permit to the permitholder 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 permitholder has violated a provision of the act or this chapter.

(2) *Notice and opportunity for a hearing.* The Department will notify an applicant or permitholder of a proposed refusal, revocation or suspension of a permit by written notification, and will deliver it by personal service or certified mail. The notice will 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 will 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 permitholder 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, regarding permits, apply 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] or manufactured dairy products.

(a) *Sales of adulterated or misbranded milk prohibited.* A person may 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, regarding adulterated or misbranded milk or milk products, apply 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 permitholder 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 _____ (*Editor's Note*: The blank refers to the effective date of the adoption of this proposed rulemaking.) shall have until _____ (*Editor's Note*: The blank refers to a date 6 months after the effective date of adoption of this proposed rulemaking.) within which to come into compliance with this registration requirement.

(b) *Approval process.*

(1) A permitholder 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 must include clear, accurate copies of all labels for which approval is sought.

(2) The Department will 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 will, 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 will 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 will contain a copy of the label and assign a unique serial number to each label approved under the application. The Department will 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 reapproval of the label. If the text, type size or wording is to be changed, the label shall be submitted to the Department for approval in accordance with subsection (b).

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

(1) The name of the food.

(2) The net contents.

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

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

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

(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, ultrapasteurized, aseptically processed, condensed or dried. When the name and address of a distributor appears in lieu of that of the processor, words such as "Mfg. for," "Dist. by" or "Packed for" must 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) 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, if the milk product is made by reconstitution or recombination.

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

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

(13) The word "pasteurized," in type at least one-fourth the height of the letters in the basic product name, if the milk or milk product has been pasteurized. If desired, letters used in modifying terms and "pasteurized" may be the same size, but never larger than the product name. Printing must be readily legible.

(14) The word "homogenized," if the milk or milk product has been homogenized.

(15) 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, if the milk or milk product is a protein fortified dairy product. The label must 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) The words "artificially colored," if an artificial color is used for a flavored milk other than chocolate.

(17) The words "artificially (name of flavor imitated) flavored milk" in type at least half the size of the name of the product imitated, if an artificial flavor is used for artificially flavored milk.

(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 under this section do not apply 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), or to raw milk for human

consumption, which is addressed in § 59a.411 (relating to label content review by the Department). In addition, these requirements do not apply to cans of raw milk from individual dairy farms, which must 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 will 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, regarding labeling, apply 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] facilities 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" must precede the designation of the date, or the statement "Not to be sold after the date stamped above" must 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 nonglass 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, provided that the cap or container of all pasteurized dairy products contains, a lot number or manufacturing date code that is acceptable to the Department and can be used for product traceability in the marketplace.

(1) Ultrapasteurized 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.

(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) will be analyzed by the Department or a Pennsylvania-approved dairy laboratory, applying a methodology 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 must include on the weigh ticket or manifest the IMS Bulk Tank Unit (BTU) identification numbers or--for farm groups listed with a milk plant--the IMS Listed Milk Plant Number.

(2) Permit identification of the 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 must be accompanied by documentation, such as a weigh ticket or manifest, which includes 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, regarding labeling, apply 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 6 months, unless the dairy farm produces raw milk for human consumption 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 3 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. Producers shall be inspected at least 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 must 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 must 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 regarding drug residue testing and farm surveillance.

(c) *Notification of producer status.* A permitholder 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 permitholder.

(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, regarding inspection of dairy farms and milk plants, apply 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 permitholder or permit applicant, and shall be conducted by a Pennsylvania-approved dairy laboratory, an out-of-state dairy laboratory that is listed with the NCIMS or that operates in accordance with the current *Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration* and current FDA 2400 Laboratory Series forms, 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 Appendix N of the Grade "A" PMO, regarding 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) *Noncertified milk plants and transfer stations.* Milk plants that are not certified under the NCIMS Interstate Milk Shippers Program, and which do not receive bulk shipments of 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] a laboratory as described in subsection (a). If a milk plant is not certified under the NCIMS Interstate Milk Shippers Program, and does not receive bulk shipments of Grade "A" milk, and produces that milk in accordance with a written quality control program addressing the use of animal drugs at that dairy operation, that milk plant may request a variance from the testing requirements of this subsection. The request shall be in writing, and shall include a copy of the written quality control program. The Department may, on the basis of the request, issue a variance with respect to the requirements of this subsection. A variance issued under this subsection shall be valid for no more than one year, and may be renewed for additional periods of up to one year following the Department's review of the quality control program and any on-site inspections the Department deems necessary to determine whether a successor variance should be issued.

(d) *Drug residue testing.* Drug residue screening [shall be completed at the direction of the Department and records of the testing] test records shall be maintained on file by the permitholder for at least 2 years.

(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, regarding examination of milk and milk products, and drug residue testing and farm surveillance, respectively, apply to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

(f) *Interpretation of Grade "A" PMO.* Where milk is excluded from market under any provision of the Grade "A" PMO on the basis of an accumulation of violative test results, and the accelerated sampling testing called for under the Grade "A" PMO results in the provisional or final return of milk to market, the Department will consider tests preceding the date of return to market in determining future accumulations of violative test results.

§ 59a.19. Standards for [grade] Grade "A" [raw] milk for pasteurization, ultrapasteurization or aseptic processing.

(a) *Applicability.* The standards prescribed under this section apply to a dairy farm that produces milk for pasteurization, ultrapasteurization 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, Ultrapasteurization or Aseptic Processing* set forth in that document and section 7 of the Grade "A" PMO, regarding 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 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] Grade "A" pasteurized, ultrapasteurized and aseptically processed milk and milk products.

(a) *Applicability.* The standards prescribed under this section apply to a milk plant regardless of whether it 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" Pasteurized, Ultrapasteurized and Aseptically Processed Milk and Milk Products*, and section 7 of the Grade "A" PMO, regarding standards for Grade "A" milk and milk products, apply 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 under this section apply 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 apply to milk and [PMO-defined] milk products are as set forth in section 7 of the Grade "A" PMO, in Table 1, regarding chemical, physical, bacteriological, and temperature standards.

(b) *Standards for milk for manufacturing and manufactured dairy products.* The standards that apply 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.

(c) *Standards for ice cream and frozen dessert mixes.* Frozen desserts--vanilla, chocolate, and one other flavor when 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.

(5) *Drugs.* On test of milk ingredients, no positive results on drug residue detection methods as referenced in section 7 of the Grade "A" PMO, in Table 1, regarding chemical, physical, bacteriological, and temperature standards.

(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 regarding examination of milk and milk products and drug residue testing and farm surveillance, respectively, apply 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, regarding animal health, apply 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, regarding milk and milk products which may be sold, apply 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, regarding transferring; delivery; containers; cooling, apply 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 this Commonwealth.

(a) *General requirement.* Milk, milk products and manufactured dairy products originating from outside this Commonwealth may be sold in this Commonwealth if they are produced and pasteurized, ultrapasteurized, or aseptically processed, concentrated (condensed) or dried under regulations which are substantially equivalent to the Grade "A" PMO and one or more of the following apply:

(1) The products have been awarded acceptable Milk Sanitation Compliance and Enforcement Ratings by a Milk Sanitation Rating Officer certified by FDA.

(2) The products have been awarded a satisfactory HACCP listing, under a HACCP Program as specified in Appendix K of the Grade "A" PMO.

(3) The products 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 or milk products, or both.

(4) The products are USDA-approved manufactured dairy products.

(5) The products 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, regarding milk and milk products from points beyond the limits of routine inspection, apply 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, regarding plans for construction and reconstruction, apply to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 59a.27. Personnel health.

[(a) *Specific requirements.* A person affected with any disease in a communicable form or while a carrier of the disease may not work at any dairy farm or milk plant in any capacity which brings the person into contact with the production, handling, storage or transportation of milk, milk products, containers, equipment and utensils; and a dairy farm or milk plant operator may not employ in any capacity a person suspected of having a disease in a communicable form, or a person suspected of being a carrier of the disease. A producer or distributor of milk or milk products upon whose dairy farm or in whose milk plant a communicable disease occurs or who suspects that an employee has contracted any disease in a communicable form or has become a carrier of the 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, regarding personnel health, [apply to this section] are adopted as the regulatory standards of the Department 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 a person concerned with the handling of milk or milk products, the Department is authorized to require one or more 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, regarding procedure when infection or high risk of infection is discovered, apply 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.113. Suspended milk for manufacturing.
59a.114. Inspection and quality testing of milk from producers.
59a.115. Record of tests.
59a.116. Abnormal milk.
59a.117. Animal health.

§ 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] Programs, 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 one or more of the following:

(1) The act.
(2) The Food Act.
(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 are 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 begins September 1 of each year and ends on August 31 of the following year.

§ 59a.103. Plant inspection.

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

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

Weighers/samplers will be evaluated and approved by the Department. The provisions of the Grade "A" PMO and, in particular, the provisions of Appendix B of that document (titled *Milk Sampling, Hauling, and Transportation*) regarding the required training and periodic evaluation of weighers/samplers, apply to this section, to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 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.107 (relating to appearance and odor), 59a.108 (relating to sediment content classification), 59a.109 (relating to bacterial estimate classification) 59a.110 (relating to somatic cell count) and 59a.111 (relating to drug residue level).

§ 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 must be normal and free of excessive coarse sediment when examined visually or by [an acceptable test procedure] the methods described in § 59a.108(a) (relating to sediment content classification). The milk may not show any abnormal condition including curdles, ropy, bloody or mastitic conditions, as indicated by [sight or other test procedures] visual examination of the milk. The odor must be fresh and sweet. The milk must 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 must 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, United States Department of Agriculture, Room 2746-South, 1400 Independence Avenue, 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 set forth in this subsection. 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 may not be accepted until its quality has been determined at the farm before being picked up. 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; and the laboratory shall report the results to the permitholder.

(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) Notify the Department and provide the producer a written warning notice if two of the last four consecutive bacterial estimates exceed 500,000 per milliliter. The notice must be in effect so long as two of the last four consecutive samples exceed 500,000 per milliliter]

result shall be noted as a violation in the permitholder's records. When two of the last four consecutive bacterial estimates exceed 500,000 per milliliter, the permitholder shall send a written warning notice to the producer in violation. This notice shall be in effect as long as two of the last four consecutive samples exceed the limit of the standard.

(d) *Excluding milk with excessive bacteria from the market.* If a producer receives the written notice described in subsection (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; and the laboratory shall report the results to the permitholder.

(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) Notify the Department and provide the producer a written warning notice if two of the last four consecutive somatic cell counts exceed 750,000 per milliliter. The notice must be in effect so long as two of the last four consecutive samples exceed 750,000 per milliliter]

(1,500,000/ml for goat milk), the result shall be noted as a violation in the permitholder's records. When two of the last four consecutive bacterial estimates exceed 750,000/ml (1,500,000/ml for goat milk), the permitholder shall send a written warning notice to the producer in violation. This notice shall be in effect as long as two of the last four consecutive samples exceed the limit of the standard.

(d) *Excluding milk with an excessive somatic cell count from the market.* If a producer receives the written notice described in subsection (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.* Manufactured dairy products permitholders shall meet the requirements of this section in order to confirm their manufactured dairy products are free of violative drug residues.

(1) *Sampling and testing program.*

(i) 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, regarding drug residue testing and farm surveillance. If a person processes milk on the farm where it was produced, and produces that milk in accordance with a written quality control program addressing the use of animal drugs at that dairy operation, that person may request a variance from the testing requirements of this subparagraph. The request shall be in writing, and shall include a copy of the written quality control program. The Department may, on the basis of the request, issue a variance with respect to the requirements of this subparagraph. A variance issued under this subparagraph shall be valid for no more than one year, and may be renewed for additional periods of up to one year following the Department's review of the quality control program and any on-farm inspections the Department deems necessary to determine whether a successor variance should be issued.

(ii) When so specified by the FDA, 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 must 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 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 the FDA and accepted by the 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) Sample test results for milk that does not test positive shall be recorded. The test result records shall be retained for 6 months.

(2) *Individual producer sampling.*

(i) *Bulk milk.* A milk sample for *beta lactam* drug residue testing shall be taken at each farm and include milk from each farm bulk tank. The sample shall be tested for *beta lactam* drug residues on the same monthly schedule as the bacterial estimate testing described in § 59a.109.

(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. The

sample shall be tested for *beta lactam* drug residues on the same monthly schedule as the bacterial estimate testing described in § 59a.109.

(iii) *Producer/processor.* A milk sample for *beta lactam* drug residue testing shall be formed separately according to subparagraphs (i) and (ii) for milk produced or received by a producer/processor. The sample shall be tested for *beta lactam* drug residues on the same monthly schedule as the bacterial estimate testing described in § 59a.109.

(3) *Load sampling and testing.*

(i) *Bulk milk.* A load sample shall be taken from the bulk milk pickup tanker and tested for *beta lactam* residues 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, shall be tested for *beta lactam* residues.

(iii) *Producer/processor.* A daily load sample shall be formed at the plant using a sampling procedure that includes all milk produced and received at the plant that day, and shall be tested for *beta lactam* residues.

(4) *Sample and record retention.* A load sample that tests positive for drug residue shall be retained for at least 12 months. The records of all positive sample test results shall be retained for at least [12] 24 months.

(5) *Industry follow-up.*

(i) When a load sample tests positive for drug residue, [industry personnel] an employee or representative of the receiving plant shall notify the Department immediately of the positive test result and of the intended disposition of the shipment of milk containing the drug residue. 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 will monitor the milk industry's drug residue program by conducting unannounced onsite inspections to observe testing and sampling procedures and to collect samples for comparison drug residue testing. In addition, the Department will review industry records for compliance with drug residue program requirements. The review will seek to determine that the following conditions are met:

(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.

(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 will 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 will issue the producer initiate administrative procedures to suspend the producer's milk shipping privileges according to State policy] producer shall follow best management practices that include testing each shipment for drug residues prior to pick-up.

(vi) The actions and procedures of the Department will be in accordance with this chapter and Appendix N of the Grade "A" PMO, regarding 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 under § 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 may 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 (1,500,000/ml for goat milk), 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° F (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 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 have a passing score before the first milk is shipped.

(3) Dairy farms shall be inspected at least 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 must meet the following requirements:

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

(2) The requirements of § 59a.108 (relating to sediment content classification).

(3) The requirements of § 59a.109 (relating to bacterial estimate classification).

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

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

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

(1) The requirements of § 59a.107.

(2) The requirements of § 59a.108.

(3) The requirements of § 59a.109.

(4) The requirements of § 59a.110.

(5) The requirements of § 59a.111.

(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 have a passing score before milk is shipped.

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

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

(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.

(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 in accordance with subsection (b), and subsequently examine shipments with subsection (c).

(3) When a producer discontinues milk delivery at one plant and begins delivery at another plant for any reason, the new buyer may 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.

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

(4) The previous buyer shall furnish the new buyer with the 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 the new buyer 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, the new buyer shall report this fact to the Department]

the provisions of the Grade "A" PMO and, in particular, the provisions of Section 5 of that document (titled *Inspection of Dairy Farms and Milk Plants)* regarding certified industry inspection and change-of-market requirements, apply to the extent described in § 59a.11 (relating to adoption of Grade "A" PMO).

§ 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 [at least 12] 24 months and 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, regarding 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 handled and disposed of 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*] *recycled animal body discharges.* Poultry litter and recycled animal body discharges may not be fed to lactating dairy animals.

§ 59a.117. Animal health.

(a) *General health.* 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] state or zone, an accredited free state or zone, or an accredited free herd as determined by the United States Department of Agriculture under 9 CFR Part 77 (relating to tuberculosis). If the animals are not located in those areas or zones, they shall be tested annually [under the jurisdiction of that] in accordance with that United States Department of Agriculture program. 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 or areas meeting Class B status, or [Certified-Free] Certified Brucellosis-Free Herds, as determined by the United States Department of Agriculture under 9 CFR Part 78 (relating to brucellosis) or shall be involved in a milk ring test program or blood testing program under the current USDA Brucellosis Eradication Uniform Methods and Rules. Additions to the herd shall be from a State [or from herds], area or herd 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.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. In order to attain a passing score, there must be no deficiencies in areas of major significance to the sanitary quality of the farm's milk supply (unless these deficiencies are immediately corrected during the inspection). These areas of major significance include toilet, water supply, construction of utensils and equipment, cleaning and sanitizing of equipment, cow cleanliness, and proper storage and labeling of medications. Dairy farms producing milk for manufacturing purposes shall be inspected [at least once in each 6 month period] every 6 months by an approved inspector, and an accurate record of inspections shall be maintained by each permitholder [on forms acceptable to the Secretary] for 24 months.

(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. Milk for manufacturing is of wholesome sanitary quality if it meets all applicable requirements of Subchapter C (relating to production and processing of milk for manufacturing purposes), (including those relating to appearance and odor, drug residue, sediment content, bacterial estimate and somatic cell count) and § 59a.202 (relating to milking facilities and housing).

(3) A permitholder 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. Swine or fowl may not be permitted in the milking area. When a milking barn is used and horses are present, the horses 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 must be of ample size to prevent overcrowding, be drained to prevent forming of standing water pools, insofar as practicable, and 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 must be clean and his hands clean and dry. A person with an infected cut or open sores on the person's hands or arms may not 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 may not be conducted immediately before or during milking. Strong flavored feeds may 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 may not be squirted on the floor, on the platform or in the producer's hand. Producers shall also wash their hands after handling 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 must be conveniently located and properly constructed, lighted and ventilated. Other products may 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 must be equipped with a 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 must be partitioned, screened and sealed to prevent the entrance of dust, flies or other contamination. The floor of the building must be of concrete or other impervious material and graded to provide proper drainage. The walls and ceilings must be constructed of smooth easily cleaned material. Outside doors must 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 must 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, must be clearly labeled and used in accordance with label instructions, and 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 United States Department of Agriculture (USDA) for use in dairy animals that are properly labeled according to FDA or USDA regulations shall be administered to the 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. The drugs shall further be segregated so that drugs labeled for use in lactating dairy animals are separated from drugs labeled for use in nonlactating dairy animals.

(4) Drugs labeled for use in nondairy animals may not be stored with drugs labeled for use in dairy animals. When drugs labeled for use in nondairy 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 may 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, 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 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 must be umbrella type. New utensils and equipment must comply with applicable *3-A Sanitary Standards.*

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

(c) *Single service articles.* Single service articles shall be properly stored and may 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 must come from a source which complies with the water supply provisions of the Grade "A" PMO, including Appendix D (titled *Standards for Water Sources*), and 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

Sec.

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.331. High pressure pumps and lines.
59a.332. Dryers.
59a.333. Collectors and conveyors.
59a.334. Dry dairy product cooling equipment.
59a.335. Special treatment equipment.
59a.336. Sifters.
59a.337. Portable and stationary bulk bins.
59a.338. Automatic sampling device.
59a.339. Dump hoppers, screens and mixers.
59a.340. Filler and packaging equipment.
59a.341. Heavy duty vacuum cleaners.
59a.342. Clothing and shoe covers.
59a.343. Operations and operating procedures: Pasteurization.
59a.344. Operations and operating procedures: Condensed surge supply.
59a.345. Operations and operating procedures: Condensed storage tanks.
59a.346. Operations and operating procedures: Drying.
59a.347. Operations and operating procedures: Cooling dry products.
59a.348. Operations and operating procedures: Packaging, repackaging and storage.
59a.349. Operations and operating procedures: Product adulteration.
59a.350. Operations and operating procedures: Checking quality.
59a.351. Operations and operating procedures: Requirements for instant nonfat dry milk.
59a.352. Operations and operating procedures: Cleaning of dryers, conveyors, sifters and storage bins.
59a.353. Operations and operating procedures: Insect and rodent control program.

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

59a.361. Rooms and compartments.
59a.362. Equipment and utensils.
59a.363. Operations and operating procedures.

SUPPLEMENTAL REQUIREMENTS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

59a.371. Rooms and compartments.
59a.372. Equipment and utensils.
59a.373. Operations and operating procedures.

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

59a.381. Equipment and utensils.
59a.382. Operations and operating procedures.

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

GENERAL REQUIREMENTS

§ 59a.301. Premises.

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

(b) *Surroundings.* The adjacent surroundings of a manufacturing plant must 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. The water shall be disposed of in a manner that prevents a nuisance or health hazard.

§ 59a.302. Buildings.

(a) *General.* Manufacturing plant buildings must 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.* 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. Outside doors opening into processing rooms must be in good condition and fit properly. Hinged, outside screen doors must open outward. 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 45° 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, must 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 must be constructed of tile properly laid with impervious joint material, concrete or other equally impervious

material. The floors must be smooth, kept in good repair, graded so that there will be no pools of standing water or milk products after flushing, and the openings to the drains must be equipped with traps properly constructed and kept in good repair. On new construction, bell-type traps may not be used. The plumbing shall be installed 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 must comply with the following:

(1) Light must 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 must 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 must 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 must be protected against breakage.

(2) There must 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 must 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 must 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 must be separated from the processing rooms by a partition. Rooms for receiving can milk must 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 must comply with the following:

(1) *Coolers and freezers.* Coolers and freezers where dairy products are stored must 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 must be maintained at all times. They must be free from rodents, insects and pests. Shelves shall be kept clean and dry. Refrigeration units must 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 must 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 must 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 must 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 must be self-closing. Ventilation must be provided by mechanical means or screened openings to the outer air. Fixtures shall be kept clean and in good repair.

(ii) 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 permitholder may establish its own laboratory to perform required tests on milk received as milk for manufacturing purposes. The laboratory must be adequately equipped and maintained and be properly staffed with qualified, trained personnel, [to meet requirements established by the Department] and shall operate in accordance with the current *Evaluation of Milk Laboratories, Recommendations of the United States Public Health Service/Food and Drug Administration* and current FDA 2400 Laboratory Series forms. If the permitholder 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 the waterlines are completely separated from the waterlines carrying the sanitary water supply, and the equipment is so constructed and controlled to preclude contamination of product contact surfaces. There may be 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. The 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. The accommodations must be located in or adjacent to toilet and dressing rooms and also at other places in the plant that may be essential to the cleanliness of all personnel handling products. Vats for washing equipment or utensils may 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 must 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 must 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 must comply with the current *3-A Accepted Practices for Supplying Air Under Pressure.* The air used at the point of application must 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 must have sufficient slope and capacity to readily remove all waste from the various processing operations. When a public sewer is not available, 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 must 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 must be constructed of stainless steel, or other equally corrosion-resistant material. Nonmetallic parts other than glass having product contact surfaces must 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) Equipment and piping shall be designed and installed 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 a manner that facilitates proper cleaning and [to maintain] good housekeeping. Parts or interior surfaces of equipment, pipes (except certain piping cleaned in place) or fittings, including valves and connections, must be accessible for inspection.

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

(c) *Can washers*. Can washers must 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 must maintain a reasonably uniform pressure and if necessary be equipped with pressure regulating valves.

(d) *Product storage tanks or vats*. Storage tanks or vats must be fully enclosed or tightly covered and well insulated. The entire interior surface, agitator and all appurtenances must be accessible for thorough cleaning and inspection. Any opening at the top of the tank or vat including the entrance of the shaft must be suitably protected against the entrance of dust, moisture, insects, oil or grease. The sight glasses, if used, must be sound, clean, and in good repair. Vats which have hinged covers must be designed so 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 must 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 must be equipped with adequate refrigeration or have adequate insulation, or both. New storage tanks or vats must meet the appropriate *3-A Sanitary Standards* and be equipped with thermometers in good operating order.

(e) *Separators*. Product contact surfaces of separators must be free from rust and pits and insofar as practicable be of stainless steel or other equally noncorrosive metals. New separators must 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 must be stainless steel lined and if the coil is not stainless steel or other equally noncorrosive metal it must be properly tinned over the entire surface. Sanitary seal assemblies at the shaft ends of coil vats must 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 must be provided with removable packing glands. Dome-type pasteurizer agitators must be stainless steel except that any nonmetallic parts must meet the current *3-A Sanitary Standards for Plastic and Rubber or Rubber-like Materials*, as applicable. Each pasteurizer used for heating product at 165° F or lower for 30 minutes or less must be equipped with space heating equipment and the necessary thermometers to insure a temperature at least 5° F above that required for pasteurization of the product. There must be adequate means of controlling the temperature of the heating medium. Batch pasteurizers must have temperature

indicating and recording devices, and 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 must 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 [accrate] accurate within 0.5° 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 0.5° 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 must have thermometers which are accurate within 2.0° F, plus or minus.

(3) Air-space indicating thermometers, where applicable, which are accurate within 1.0° 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 or air above the products pasteurized, or both, also received the required minimum temperature treatment.

(i) *Recording thermometers*.

(1) HTST recording thermometers that are accurate within 1° 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 2° F, plus or minus, may be required where a record of temperature or time of cooling and holding is of significant importance. A record of temperature or time of cooling and holding is of significant importance when made in accordance with §§ 59a.328 (relating to hotwells), 59a.344 (relating to operations and operating procedures: condensed surge supply) 59a.373(b) (relating to operations and operating procedures), 59a.381(d) (relating to equipment and utensils) and 59a382.(b) (relating to operations and operating procedures) and 59a.392(b)(1) (relating to operations and operating procedures).

(j) *Surface coolers*. Surface coolers must be equipped with hinged or removable covers for the protection of the product. The edges of the fins must be designed to divert condensate on

nonproduct contact surfaces away from product contact surfaces. Gaskets or swivel connections must be leak proof.

(k) *Plate-type heat exchangers.* Plate-type heat exchangers must meet the current *3-A Sanitary Standards for Construction and Installation.* Gaskets must 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 must meet the current *3-A Sanitary Standards for Construction and Installation.*

(m) *Pumps.* Pumps used for milk and dairy products must 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 must 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, must 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, the equipment and replacements must meet the general requirements of this section.

(p) *Certain vacuum chambers.* A vacuum chamber, as used for flavor control, must be made of stainless steel or other equally noncorrosive metal. The unit must be constructed to facilitate cleaning and product contact surfaces must be accessible for inspection. The chamber must be equipped with a vacuum breaker and a check valve at the product discharge line. Only steam which meets the requirements for culinary steam may 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 must be equipped with a water level control and an automatic safety shutoff valve.

§ 59a.305. Personnel cleanliness.

Employees shall wash their hands before beginning work and upon returning to work after using toilet facilities, eating, smoking or otherwise soiling their hands. Employees 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)] <u>hair nets and adequate hair covering</u> shall be worn by all persons engaged in receiving, testing, processing milk, manufacturing, packaging or handling dairy products.

§ 59a.306. Personnel health.

A person affected with any disease in a communicable form or while a carrier of the disease may not be permitted in any room or compartment where milk and dairy products are prepared, manufactured or otherwise handled. A person who has a discharging or infected wound, sore or lesion on hands, arms or other exposed portion of the body may not 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 must be constructed 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 must meet current *3-A Sanitary Standards* for construction and 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 must be of the enclosed type, constructed and operated to protect the product from extreme temperature, dust, or other adverse conditions and 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 may not be used for any other purpose.

(2) *Transport tanks.* The exterior shell of transport tanks must be clean and free from open seams or cracks which would permit liquid to enter the jacket. The interior shell must be stainless steel and constructed so it will not buckle, sag or prevent complete drainage. Product contact surfaces must be smooth, easily cleaned and maintained in good repair. The pump and hose cabinet must be fully enclosed with tight fitting doors and the inlet and outlet must be provided with dust covers to give adequate protection from road dust. New and replacement transport tanks must 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 must 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 may 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, when applicable to particular manufacturing or processing practices.

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

(c) *Sampling.* During any consecutive 6 months, at least four samples of commingled raw milk for processing will be taken by the Department, or a designated representative, from each plant. Such a designated representative shall be an approved sampler who is either an employee of the plant or an employee or representative of a Pennsylvania-approved dairy laboratory.

(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 will 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 will notify plant management with a written warning notice. The notice will 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 will be taken by the Department after a lapse of 3 days but within 21 days of the notice required in paragraph (1). 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 market place) 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] in conformance with the 1,000,000-per-milliliter or lower bacterial classification standard for commingled raw milk for manufacturing. The plant will be assigned a full reinstatement status when three out of four consecutive commingled bacterial estimates do not exceed 1 million per milliliter. The samples will 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° F but less than 161° F for separation purposes. When enzyme deactivation is necessary for a functional reason, the cream may be further heated to less than 166° F in a continuing heating process. The resulting bulk shipment of cream shall be cooled to 45° F 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, ultrapasteurized or aseptically processed and packaged products.

Pasteurized, ultrapasteurized or aseptically processed and packaged products must 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 temperatures and holding periods that will assure proper pasteurization or sterilization of the product. The heat treatment by either process must 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 may 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 will be subject to inspection and must be wholesome and practically free from impurities. The finished product must comply with the Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301--399a) 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 must 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, equipment not designed for CIP cleaning shall be disassembled after each [day's] day of 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] Cleaning and sanitizing chemicals that are utilized for this cleaning shall be labeled, and shall be used in accordance with label directions. Steel wool or metal sponges may 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 must comply with 21 CFR 178.1010 (relating to sanitizing solutions).

(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 that cleaning is used, careful attention must be given to the proper procedures to assure satisfactory cleaning. 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. 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 must 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 information in the following paragraphs. The tag may not be removed until the tank is again washed and sanitized.

(1) The plant and specific location where cleaned.

(2) The date and time of day of washing and sanitizing.

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

The following provisions also apply:

(1) A milk transport tank shall be cleaned and sanitized at least once each day, after use.

(2) If a milk transport tank has been cleaned and sanitized in accordance with paragraph (1), and 96 hours or more hours have elapsed from that cleaning and sanitizing without the tank being used, the tank shall be cleaned and sanitized again before use.

(3) When a milk transport tank has been cleaned and sanitized, it shall bear a tag or be accompanied by a written document showing the date, time, and place of cleaning and sanitizing, and bearing the signature or initials of the person who performed the cleaning and sanitizing. This tagging or written document requirement is not applicable if the milk transport tank delivers to only one receiving facility and that receiving facility is solely responsible for cleaning and sanitizing and retains records at that receiving facility to confirm date, time and place of cleaning.

(4) A tag or written document as described in paragraph (3) shall be removed at the location where the milk tank truck is next cleaned and sanitized, and shall be retained on file at that location for fifteen (15) days.

(d) *Buildings*. 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] specifically designated employee shall be made responsible for the performance of a regularly scheduled insect and rodent control program. Poisonous substances, insecticides and rodenticides must be properly labeled, and shall be handled, stored, and used so that they do not 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 must 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 must 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] dairy products requires a high level of sanitation to prevent the contamination of exposed product. The atmosphere of the packaging rooms, the equipment and packaging material must be practically free from mold and bacterial contamination. The method for checking the level of contamination shall be as prescribed by the *Standard Methods for the Examination of Dairy Products*.

(c) *General identification.* Commercial bulk packages containing dairy products manufactured under this subchapter must 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 must 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, 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 (relating to ~~manufarturing~~ manufacturing plants).

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 must conform to § 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 must conform with § 59a.315 (relating to storage of finished product).

(b) *Storage rooms.* Storage rooms for the dry storage of product must be adequate in size, kept clean, orderly, free from rodents, insects and mold, and maintained in good repair. The rooms must 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, may 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 must 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 will 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 must meet the same requirements for construction and facilities as the bulk packaging operation.

§ 59a.326. Equipment and utensils.

Equipment and utensils must conform with § 59a.304 (relating to equipment and utensils). Additional, more specific requirements are applicable to the items of equipment listed in §§ 59a.327--59a.341.

§ 59a.327. Preheaters.

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

§ 59a.328. Hotwells.

Hotwells must 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 must also have recorders.

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

Open-type evaporators or vacuum pans, or both, must be equipped with an automatic condenser water level control, barometric leg, or constructed to prevent water from entering the product, and 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 must be constructed so that deadends, valves and the high pressure pumps can be disassembled for hand cleaning. New high pressure pumps must 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 must 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 must comply with the following:

(1) The drums of a roller dryer must 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 must have an impervious surface and be readily cleanable. The end boards 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 must be constructed of stainless steel and be readily cleanable. The lower edge of the hood must be constructed to prevent condensate from entering the product zone. The hood must be properly located and the stack of adequate capacity to remove the vapors. The stack must be closed when the dryer is not in operation. The augers must be of stainless steel or properly plated, and readily cleanable. The auger troughs and related shields must be of stainless steel and be readily cleanable. Air entering the dryer room shall be filtered to eliminate dust and dirt. The filter system must 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 must be cleaned or component parts replaced as often as necessary to maintain a clean and adequate air supply. Dryer adjustments must be made and the dryer operating normally before food grade powder can be collected from the dryer.

§ 59a.333. Collectors and conveyors.

Collectors must be made of stainless steel or equally noncorrosive material and constructed to facilitate cleaning and inspection. Filter sack collectors, if used, must comply with the current *3-A Sanitary Standards for Bag Collectors*. Conveyors must 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 may 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 must be of sanitary construction and parts must be accessible for cleaning and inspection. Instantizing systems must 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 must meet the current *3-A Sanitary Standards for Sifters for Dry Products*. Other sifters must be constructed of stainless steel or other equally noncorrosive material and must be of sanitary construction and accessible for cleaning and inspection. The mesh size of sifter screen used for various dry dairy products must be those recommended in the appendix of the referenced *3-A Sanitary Standard*.

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

Bulk bins must be constructed of stainless steel, aluminum or other equally corrosion-resistant materials, free from cracks and seams and have an interior surface that is relatively smooth and easily cleanable. Product contact surfaces must be easily accessible for cleaning. Portable bins must 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 must be constructed to prevent contamination of the product, and parts must 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, must be of stainless steel or equally corrosion resistant material and designed to prevent contamination. Parts must be accessible for cleaning. The dump hoppers must 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 must 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 must 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 must 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. The skim 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] 161° 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.

(d) *Cream derived from buttermilk*. Cream derived from buttermilk shall be pasteurized prior to condensing at a temperature of 166° 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. The 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 must be any clean, sound, commercially accepted container or packaging material which satisfactorily protects 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. Packages or containers that comply with the

requirements of 21 CFR 177.1520 (titled *Olefin polymers*) are among the packages that meet the requirements of this subsection. Containers which have previously been used for nonfood items or food which would be deleterious to the dairy product may 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 must 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. Bottles or glass materials may not be permitted in the repackaging or hopper room. The inlet openings of hoppers and bins must 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. 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.

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.

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 sublot of approximately 4,000 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 must 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 must possess a uniform white to light cream natural color and 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 may not be more than 10,000 per gram.

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

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

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

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

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

(9) *Titratable acidity.* The titratable acidity may 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 may 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, United States Department of Agriculture.

§ 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 must 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 must be adequately lighted and proper circulation of air shall be maintained at all times. The floors, walls and ceilings must be of a construction that permits thorough cleaning.

(b) *Churn rooms.* Churn rooms, in addition to proper construction and sanitation, must 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 must, 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 must meet requirements of § 59a.304 (relating to equipment and utensils).

(b) *Continuous churn.* Product contact surfaces must be of noncorrosive material. Nonmetallic product contact surfaces must 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 must be readily accessible for cleaning and inspection.

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

(d) *Bulk butter trucks, boats and packers.* Bulk butter trucks, boats and packers must be constructed of aluminum, stainless steel or equally corrosion resistant metal free from cracks, seams and 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 must be of stainless steel or equally corrosion resistant metal, sanitary construction and [readily] <u>easily</u> cleanable.

(f) *Printing equipment.* Printing equipment must 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 must be constructed of noncorrosive material and have an adequate and safe means of heating the salt solution for the treatment of the liners. The tank must also be provided with a satisfactory drainage outlet.

(h) *Starter vats.* Bulk starter vats must be of stainless steel or equally corrosion resistant metal and constructed according to applicable *3-A Sanitary Standards*. The vats must 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 at least 165° F and held continuously in a vat at that temperature at least 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 the 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 paragraph (1)(i) except that the temperature for the vat method shall be at least 170° F for at least 30 minutes, or at least 190° F for at least 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 must 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 must comply with the Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301--399a), as to composition and wholesomeness.

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

(1) Containers used for the packaging of butter and related products must 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 must comply with the following:

(i) Supplies of parchment liners, wrappers, and other packaging material must 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 at least 30 minutes. The solution must 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 must 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 must 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 must comply with the following:

(i) The room shall be maintained at a temperature of 0° F or lower. [Adequate air circulation is desirable] Air circulation shall be sufficient to preclude odors and to maintain uniform storage temperatures throughout the freezer.

(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 repiled, 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 must 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 must 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 must 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 must 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 must 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 must be well lighted, ventilated, and provided with filtered air. Air movement must 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 must meet the requirements of § 59a.304 (relating to equipment and utensils). In addition, for other equipment the following requirements in this section must be met.

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

(c) *Cheese vats.* Requirements are as follows:

(1) Open vats used for making cheese must be of metal construction with adequate jacket capacity for uniform heating. The inner liner must be minimum 16-gauge stainless steel, properly pitched from side to center and from rear to front for adequate drainage. The liner must be smooth, free from excessive dents or creases and extend over the edge of the outer jacket. The outer jacket must 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 must be constructed to prevent milk or cheese from entering the inner jacket.

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

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

(d) *Mechanical agitators.* The mechanical agitators must be of sanitary construction. The carriage and track must be constructed to prevent the dropping of dirt or grease into the vat.

Metal blades, forks or stirrers must be constructed of stainless steel, and 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 must be stainless steel or of material approved in the *3-A Sanitary Standards*. The product contact surfaces of the curd mill must be of stainless steel. Pieces of equipment must be constructed so they can be kept clean. The wires in the curd knives must be stainless steel or other suitable metal, kept tight and replaced when necessary.

(f) *Hoops and followers.* The hoops, forms and followers must 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 must be clean and sanitary.

(g) *Press.* The cheese press must be constructed of stainless steel with all joints welded and all surfaces, seams and openings readily cleanable. The pressure device must 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 must have square interior corners, reasonably smooth interior surface and have controls that provide uniform pressure and heat equally to all surfaces.

(i) *Paraffin tanks.* The metal tank must be adequate in size, have parafinned 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 must be constructed of suitable nontoxic material which is corrosion resistant. Product contact surfaces must 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 may not be located in the processing or packaging areas.

(k) *Whey probes.* Vacuum equipment used to withdraw whey from cheese must 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, must 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 must 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 at least 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 2 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] requires a high level of sanitation so as to prevent the contamination of exposed product. The atmosphere of the packaging rooms, the equipment and the packaging material must be practically free from mold and bacterial contamination.

(e) *General identification.* Each bulk cheese must 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 must 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 must 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 must be adequate in size. Product contact surfaces must 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 must be the steam jacketed or direct steam type. The cookers must be constructed of stainless steel or other equally corrosion resistant material. Product contact surfaces must be readily accessible for cleaning. Each cooker must be equipped with an indicating thermometer and a temperature recording device. Steam check valves on direct steam type cookers must be mounted flush with cooker wall, constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line must 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 must 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 at least 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] Procedures shall be in place for the handling of containers between forming and filling that will prevent contamination of the product contact surfaces. 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 must effectively measure the desired amount of product into the pouch or container in a sanitary manner and must 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, to assure against contamination. Each container in addition to other required labeling must be coded in a manner that is easily identifiable as to date of manufacture by lot or sublot 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 must meet the requirements of the

current *3-A Sanitary Standards for Milk and Milk Products Evaporators and Vacuum Pans*. New or used replacements for this type of equipment must meet the appropriate *3-A Sanitary Standards*.

(c) *Fillers*. Both gravity and vacuum type fillers must be of sanitary design and all product contact surfaces, if metal, must 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 must 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 must 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 must 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 may 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 must 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.

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 may 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 permitholder to lawfully produce and sell (within this Commonwealth) raw whole milk for human consumption. It also authorizes the permitholder 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 may not sell raw milk for human consumption 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 will be valid for no more than 1 year. Each raw milk permit will 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 permitholder wishes to obtain a raw milk permit to replace an expiring raw milk permit, the permitholder 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) *Preissuance 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 act and this chapter. The dairy farm must be in [passing condition] compliance with all applicable provisions of the act, the Food Act and this Chapter to be eligible for a raw milk permit.

(2) *Successor raw milk permits.* If a raw milk permitholder applies to the Department for a successor raw milk permit, 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 for human consumption 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 shall be provided 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 for human consumption 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 animal or herd and provide the Department a written report of this examination. The report must reflect that [the herd is in good general health and free from communicable disease], upon physical examination, the subject animals (or animal) are in apparent good health and free from evidence of communicable disease. This shall be done in accordance with § 59a.406.

(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 1 year preceding the date of the application, and 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 provide the Department with confirmation that the water is bacteriologically safe, in accordance with § 59a.407 (relating to regular testing of water supply). Water is bacteriologically safe if it meets the requirements of §§ 59a.405(8) (relating to sanitation) and 59a.407 (relating to regular testing of water supply). The requirement of a bacteriologically safe water supply is also applicable to recirculated cooling water if the dairy farm uses a recirculated cooling water system for milk cooling.

Confirmation that the water supply is bacteriologically safe shall be provided 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, done in accordance with § 59a.407 and reflect that the dairy farm water supply is bacteriologically safe. Water is bacteriologically safe if it meets the requirements of §§ 59a.405(8) (relating to sanitation) and 59a.407 (relating to regular testing of water supply).

(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 three separate samples of commingled milk from the bulk tank. The samples shall be drawn at least 7 days apart, and be taken on an unannounced basis.

(ii) Each of these three 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) will determine whether the sample meets the standards in § 59a.408 (relating to regular testing of raw milk for human consumption).

(iv) If any of the three analyzed samples described in subparagraph (iii) violates or exceeds a standard in § 59.408, the three-sample process shall repeat itself until three 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, a raw milk permit will not be issued until 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 permitholder, 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 permitholder.* 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 permitholder, 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 must protect the pouring lip to its largest diameter.]

§ 59a.405. Sanitation.

A raw milk permitholder 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 this subchapter. The provisions of the Grade "A" PMO and, in particular, the *Standards for Grade "A" Raw Milk for Pasteurization, Ultrapasteurization or Aseptic Processing* set forth in that document and section 7 of the Grade "A" PMO, regarding 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 this subchapter. This includes 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° C (40° F) within 2 hours after the completion of milking.
(19) Item 19r. Insect and Rodent Control.

§ 59a.406. Animal health.

(a) *General.* A raw milk permitholder shall monitor the health of the animals from which the raw milk <u>for human consumption</u> 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 permitholder 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 <u>for human consumption</u> is produced has been determined to be free from brucellosis by annual blood tests conducted in accordance with Chapter 7 (relating to brucellosis regulations).

[(2) *Ring tests at intervals of 6 months or less.* A raw milk permitholder 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 permitholder 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 for human consumption is produced has been determined to be free from tuberculosis by annual tests conducted in accordance with Chapter 9 (relating to control and eradication of tuberculosis of livestock).

(d) *Annual veterinary examination.* A raw milk permitholder shall, at intervals of no more than 1 year, have a licensed veterinarian examine the herd and issue a written report of this examination. The report must reflect that [the herd is in good general health and free from], upon physical examination, the herd is in apparent good health and free from evidence of communicable disease. The raw milk permitholder shall retain a copy of the written veterinarian's report for at least 3 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 for human consumption under a raw milk permit must be safe and sanitary.

(b) *Testing frequency.* The water supply for a dairy operation that produces raw milk for human consumption under a raw milk permit shall 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 permitholder's expense. If the water supply is through a public or municipal water system, this testing requirement does not apply.

(c) *Testing standards.* The water tests described in this section shall be conducted at a qualified laboratory. The testing must include bacteriological examinations to determine whether the water is bacteriologically safe. Water is bacteriologically safe if it meets the requirements of §§ 59a.405(8) (relating to sanitation) and 59a.407 (relating to regular testing of water supply). The requirement of a bacteriologically safe water supply is also applicable to recirculated cooling water if the dairy farm uses a recirculated cooling water system for milk cooling. The water supply must 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 must otherwise be safe and sanitary.

(d) *Water test records.* The raw milk permitholder shall retain all records of required water tests for one year, and shall make these available for inspection upon request of the Department.

§ 59a.408. Regular testing of raw milk for human consumption.

(a) *Responsibility.* A raw milk permitholder 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.* Raw milk samples submitted for testing shall be analyzed at an official laboratory or a Pennsylvania-approved dairy laboratory.

(c) *Testing schedule and standards*. A raw milk permitholder shall coordinate [raw milk testing] the testing of raw milk for human consumption on the following schedule, and the raw milk samples shall meet the following standards:

Raw Milk Testing Schedule and Standards

Required Action Interval	**Type of Action or Test Required**	**Standard**
At all times	Maintain raw milk temperature in accordance with raw milk temperature standards.	Raw milk shall be cooled to 40° F (4° C) or less within 2 hours after milking, provided that the blend temperature after the first and subsequent milking does not exceed 50° F (10° C).
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 subsection	Bacterial count	Bacteria may not be present in excess of 20,000 per milliliter. **NOTE:** Tested in conjunction with a drug residue/ inhibitory substance test.
At least twice each month, in conjunction with the tests for bacterial count and for the presence of drugs (including growth inhibitors), described in this subsection	Coliform count	Coliform may not exceed 10 per milliliter. **NOTE:** Tested in conjunction with a drug residue/ inhibitory substance test.
At least twice each month	Somatic cell count	The somatic cell count may not exceed 750,000/milliliter (1,500,000/ml for goat milk).
At least twice each month, in conjunction with the tests for bacterial count and for coliform count, described in this subsection	Test for presence of drugs (including growth inhibitors)	There may 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] Once every 6 months	[Test for the presence of pathogenic bacteria, including] From a sample drawn from the bulk tank, test for presence of the following pathogenic bacteria: *Salmonellae, Listeria monocytogenes, Camphylobacter, and E. Coli* 0157:H7	There may be no pathogenic bacteria present.

§ 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 for human consumption), the Department will provide the raw milk permitholder 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 permitholder [shall] may be subject to summary criminal prosecution under the act.

(b) *Pesticides.* If a raw milk sample tests positive for the presence of a pesticide at or above actionable levels established for the pesticide the United States Environmental Protection Agency, the raw milk permitholder 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 for human consumption until and unless the second test shows the sample to be free of pesticide residue, or to be below the actionable levels established for the residue by the United States Environmental Protection Agency, and the Department reviews these test results and approves the resumption of raw milk sales.

(c) [*Growth inhibitor*] *Drugs.* If a raw milk sample tests positive for the presence of a [growth inhibitor] drug, the raw milk permitholder shall do 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 for human consumption until the second test shows the sample to be free of [growth inhibitor] drug residue[, or to be below the actionable

levels established for the 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 permitholder shall do 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 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 1 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 for human consumption until and unless two consecutive tests, from samples drawn at least 1 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] Raw milk packaging.

[(a) *Containers owned by the raw milk permitholder.* If raw milk is packaged for sale in containers that are owned by the raw milk permitholder (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 must 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.]

~~(a) *General.* A raw milk permitholder that packages raw milk for human consumption shall have separate rooms for bottling, single service container storage, and bottle washing, as applicable, if raw milk is packaged for sale in any of the following types of containers:~~

~~(1) Containers that are single service containers (regardless of whether the permitholder, the consumer or some other person owns the single service containers).~~

~~(2) Containers that are owned by the permitholder (such as prepackaged containers for consumer purchase).~~

~~(3) Containers that have been provided to the consumer by the permitholder or the dairy farm at the time the raw milk is purchased.~~

~~(4) Containers that have been sold to the consumer by the permitholder or the dairy farm at the time the raw milk is purchased.~~

~~A mechanical means of filling and capping bottles shall be utilized for filling and capping the containers described in this subsection, and the closure must protect the pouring lip to its largest diameter.~~

~~(b) *Exception for certain containers.* A raw milk permitholder is not required to meet the requirements of subsection (a), and may package raw milk for human consumption in a milkroom facility, if the containers into which the raw milk is packaged are not containers as described in paragraphs (a)(1) through (a)(4). If this exception applies, the filling and capping of the containers shall be completed in a sanitary manner, using easily cleanable equipment that has been cleaned and sanitized.~~

~~(c) *Additional sanitation requirements.* Bottles or containers shall be filled and closed without any part of the hand coming in contact with the inner surface of the bottle or container, or in contact with bottle caps. Caps shall be obtained in sanitary containers and kept therein until used.~~

(A) *SALES OR DELIVERY ON PREMISES OTHER THAN THE FARM WHERE THE RAW MILK FOR HUMAN CONSUMPTION IS PRODUCED.* IF RAW MILK FOR HUMAN CONSUMPTION IS PACKAGED FOR SALE OR DELIVERY AT A LOCATION OTHER THAN THE FARM WHERE THE RAW MILK FOR HUMAN CONSUMPTION IS PRODUCED, BOTTLING AND CAPPING, OR THE FILLING AND CLOSURE OF CONTAINERS OTHER THAN BOTTLES, MUST BE CONDUCTED IN A ROOM SEPARATE FROM THE MILK ROOM BY A MECHANICAL MEANS OF FILLING AND CAPPING BOTTLES, OR BY A MECHANICAL MEANS OF FILLING AND CLOSURE OF CONTAINERS OTHER THAN BOTTLES. THE CLOSURE MUST PROTECT THE POURING LIP TO ITS LARGEST DIAMETER.

(B) *SALES OR DELIVERY ON PREMISES WHERE THE RAW MILK FOR HUMAN CONSUMPTION IS PRODUCED.* IF RAW MILK FOR HUMAN CONSUMPTION IS PACKAGED FOR SALE OR DELIVERY AT THE LOCATION WHERE THE RAW MILK FOR HUMAN CONSUMPTION IS PRODUCED, THE DEPARTMENT WILL CONSIDER A MILK ROOM FACILITY AS BEING ADEQUATE FOR BOTTLING AND CAPPING, OR THE FILLING AND CLOSURE OF CONTAINERS OTHER THAN BOTTLES. THIS ACTIVITY SHALL BE COMPLETED IN A SANITARY MANNER, USING EASILY CLEANABLE EQUIPMENT THAT HAS BEEN CLEANED AND SANITIZED.

(C) *ADDITIONAL SANITATION REQUIREMENTS.* ALL CONTAINERS SHALL BE FILLED AND CLOSED WITHOUT ANY PART OF THE HAND COMING IN CONTACT WITH THE INNER SURFACE OF THE BOTTLE OR CONTAINER OR IN CONTACT WITH BOTTLE CAPS. CONTAINERS MAY NOT BE FILLED BY THE CUSTOMER. CAPS SHALL BE OBTAINED IN SANITARY CONTAINERS AND SHALL BE KEPT IN SANITARY CONTAINERS UNTIL USED. CONTAINERS SHALL BE STORED IN A CLEAN AND DRY AREA, OFF THE FLOOR AND PROTECTED FROM ANY SOURCE OF CONTAMINATION. ANY WASHING OF RETURNABLE BOTTLES OR CONTAINERS SHALL BE CONDUCTED IN A ROOM THAT IS SEPARATE FROM ANY ROOM THAT IS DEVOTED TO BOTTLING AND CAPPING, OR THE FILLING AND CLOSURE OF CONTAINERS OTHER THAN BOTTLES.

§ 59a.411. Label content review by the Department.

(a) *Raw milk in containers owned by the raw milk permitholder.*

(1) *General label statements.* If raw milk [is packed] for human consumption is prepackaged for sale in containers that are owned by the raw milk permitholder, 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 must be labeled as raw milk, and include the [net weight] fluid volume as well as the name and address of the distributor or producer and the words "Keep Refrigerated." It may not be misbranded or contain any false or misleading statements. The Department will, within 10 business days of receiving a complete application for label approval, mail the applicant its written approval or denial of the label.

(i) If the application is denied, the written denial will 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 will contain a copy of the label and assign a unique serial number to each label approved under the application. The Department will retain copies of these approvals.

(2) *Consumer advisory for raw animal-derived foods that have not been processed to remove pathogens.*

[(i)] In addition to the information described in paragraph (1), the label must 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.

[(ii) 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, must 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" must precede the designation of the date, or the statement "Not to be sold after the date stamped above" must 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 must 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 for human consumption in the possession of the raw milk permitholder 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 permitholder 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 for human consumption) 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 permitholder cannot produce raw milk for human consumption 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 permitholder 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.

(D) A raw milk permitholder may submit samples to the Department for analysis to obtain approval to resume a [17-day] specific sell-by period for the raw milk sampled. The Department will approve resumption of a [17-day] specific 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 for human consumption is packed for sale in containers that are owned by the consumer, Departmental review of the labeling on the container or caps is not 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 for human consumption is packed for sale in containers that are owned by the consumer, the raw milk permitholder shall post a consumer advisory at the location where the customer owned containers are filled, or in close proximity to that location, 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 subsection (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 permitholder 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 other actions 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 permitholder 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 permitholder does not comply with the act or this chapter.

(b) *Procedure.*

(1) The act requires that the Department provide a raw milk permitholder with at least 5 days' advance written notice of a raw milk permit revocation or suspension. This written notice will be sent by certified mail. The Department may supplement this notice by providing the permitholder this written notice by personal service or other means. The written notice shall specify the procedure by which the permitholder may request an administrative hearing, and the 5-day window within which a written request for an administrative hearing must be submitted to the Department.

(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 will immediately notify the raw milk permitholder and request that it voluntarily cease all sales of raw milk--without regard to whether the raw milk permitholder has received the 5 days' advance written notice required under the act. The requirements of this paragraph do not alter the obligation of a raw milk permitholder to cease sales of raw milk for human consumption if required under § 59a.409 (relating to violations of raw milk testing standards).

(i) If a raw milk permitholder 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 permitholder does not choose to comply with a request that it voluntarily cease raw milk sales, the Department will do the following:

(A) Apprise the 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) Arrange for an administrative hearing before a hearing examiner, if the raw milk permitholder has been afforded written notice and

opportunity for a hearing on the proposed suspension or revocation and requests a hearing on the proposed permit suspension or revocation.

(D) Issue a final adjudication, ordering the suspension or revocation, if the raw milk permitholder does not request a hearing on the proposed permit suspension or revocation.

(E) Recommend to the raw milk permitholder that it inform its customers that it has been asked by the Department to voluntarily cease raw milk sales, and provide these customers the basis for the Department's request.

(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 permitholder. If a raw milk permit is suspended or revoked, and the permitholder has been afforded written notice and opportunity for a hearing on the proposed suspension or revocation, 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 will promptly return the raw milk permit to the permitholder at the end of the suspension period.

§ 59a.414. Enforcement: Summary criminal prosecution.

If a raw milk permitholder violates any provision of the act or this chapter, the Department may file a summary prosecution against a raw milk permitholder 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 for human consumption without the required raw milk permit or from violating the act or this chapter. Violations of an injunction can result in fines or 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. Examples of circumstances under which raw milk or raw milk products may be unsafe or a menace to public health include situations where raw milk or raw milk products have been produced in violation of the Act, the Food Act or this Chapter and these violations relate to handling and sanitation, where herd health conditions risk the transmittal of disease through the milk or milk products, or where pathogenic bacteria are present in the raw milk permitholder's raw milk supply.

(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] raw milk products to be unsafe or a menace to public health.

(2) If a raw milk permitholder 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 in Chapter 46 (relating to food code). This chapter does 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.

TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE REGULATORY REVIEW ACT

I.D. NUMBER:	2-160
SUBJECT:	Milk Sanitation
AGENCY:	DEPARTMENT OF AGRICULTURE

TYPE OF REGULATION

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

RECEIVED
IRRC
2010 NOV 22 A 11: 32

FILING OF REGULATION
REPORT FOR DISAPPROVED REGULATION SUBMITTED WITH REVISIONS

DATE	SIGNATURE	DESIGNATION
11-22-10	Mary Seiger	MAHR HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
11-22-10	Gaye M Jones	HANNA MAJORITY CHAIRMAN HANNA
11-22-10	Judy Mat Eagle	J PAKE SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
11-22-10	Kate Zeds	BRUBAKER MAJORITY CHAIRMAN BRUBAKER
11-22-10	K Cooper	IRRC INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL (for Final Omitted only)
		LEGISLATIVE REFERENCE BUREAU (for Proposed only)