

<h2 style="margin: 0;">Regulatory Analysis Form</h2> <p style="margin: 0;">(Completed by Promulgating Agency)</p> <p style="margin: 0;">(All Comments submitted on this regulation will appear on IRRC's website)</p>	<p style="margin: 0;">INDEPENDENT REGULATORY REVIEW COMMISSION</p> <p style="margin: 0; font-size: 24pt;">RECEIVED</p> <p style="margin: 0;">Independent Regulatory Review Commission May 28, 2024</p>
<p>(1) Agency</p> <p>Department of Agriculture</p>	<p>IRRC Number: 3405</p>
<p>(2) Agency Number: 02</p> <p>Identification Number: 194</p>	
<p>(3) PA Code Cite: Title 7, Chapter 59a</p>	
<p>(4) Short Title: Milk Sanitation</p>	
<p>(5) Agency Contacts (List Telephone Number and Email Address):</p> <p>Primary Contact: Sheri Morris, 717-787-5289 shmorris@pa.gov</p> <p>Secondary Contact: Stefanie Smith, 717-787-5108 stefsmith@pa.gov</p>	
<p>(6) Type of Rulemaking (check applicable box):</p> <p><input checked="" type="checkbox"/> Proposed Regulation</p> <p><input type="checkbox"/> Final Regulation</p> <p><input type="checkbox"/> Final Omitted Regulation</p>	<p><input type="checkbox"/> Emergency Certification Regulation;</p> <p><input type="checkbox"/> Certification by the Governor</p> <p><input type="checkbox"/> Certification by the Attorney General</p>
<p>(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)</p> <p>The regulation will:</p> <p>(a) Authorize the issuance of an additional raw butter permit to raw milk permitholders and establish food safety provisions for its manufacture.</p> <p>(b) Implement the statutory requirements imposed by Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), known as the Milk Sell-By Date and Best-By Date Labeling Act.</p> <p>(c) In order to align these regulations with all other food product label and labeling standards enforced by the Department, remove outdated and extraneous regulatory requirements for label and labeling pre-approval by the Department for all permitholders, except raw milk permitholders.</p> <p>(d) Establish certification standards for samplers and weigher/samplers and regulatory standards for sampler, weigher/sampler and milk tanker inspections previously conducted by the Pennsylvania Milk Marketing Board.</p> <p>(e) Clarify the current regulatory standards, make them more understandable to the regulated community and more closely align the regulatory standards with the federal Grade ‘A’ milk standards set forth in the Food and Drug Administration, US Department of Health and Human Services, Grade “A” Pasteurized Milk Ordinance (PMO).</p>	
<p>(8) State the statutory authority for the regulation. Include <u>specific</u> statutory citation.</p> <p>The act of July 2, 1935 (P.L. 589, No 210) (31 P.S. §§ 645-660g), known as the Milk Sanitation Law (Act), prescribes the powers and duties of the Pennsylvania Department of Agriculture (Department) with respect to milk sanitation, and at section 19 of the Act (31 P.S. § 660c) provides, “The Secretary of Agriculture is hereby authorized to adopt and promulgate rules and regulations for the proper enforcement of this act.” Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), known as the Milk Sell-By Date and</p>	

Best-By Date Labeling Act, at section 5747, authorizes the Department to adopt the regulations necessary to administer the provisions of that statute (3 Pa.C.S. § 5747). The Food Safety Act (3 Pa.C.S. §§ 5721-5737) includes milk within the definition of a “potentially hazardous food” (3 Pa.C.S. § 5733)(relating to definitions) and provides the Department broad authority to regulate as necessary for the proper enforcement of that statute (3 Pa.C.S. §§ 5733)(relating to rules and regulations).

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

This proposed rulemaking is authorized under the act of July 2, 1935 (P.L. 589, No. 210) (31 P.S. §§ 645-660g), known as the Milk Sanitation Law (Act). Section 19 of the Act (31 P.S. § 660c) provides, “The Secretary of Agriculture is hereby authorized to adopt and promulgate rules and regulations for the proper enforcement of this act.” In addition, Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), known as the Milk Sell-By Date and Best-By Date Labeling Act (MLA) provides, at section 5747(relating to regulations) that, “The department shall make such reasonable rules and regulations as may be deemed necessary for carrying out the provisions of this subchapter (3 Pa.C.S. §5747).” The Department has chosen to set forth label and sell-by and best-by standards and prohibitions established by the MLA in the proposed milk sanitation regulations. Finally, the United States Public Health Service and Food and Drug Administration (USPHS/FDA) produce the *Grade “A” PMO* which is the standard used in the Cooperative State-USPHS/FDA Program for the Certification of Interstate Milk Shippers. The *Grade “A” PMO* is incorporated by reference in Federal specification for procurement of milk and milk products, it is used as the sanitary regulation for milk and milk products in interstate commerce and is recognized by the Public Health Agencies and the milk industry as the national standard for milk sanitation. This regulation is required to assure Pennsylvania is compliant with those interstate standards.

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

The public has a direct health and safety interest in the Department having regulatory milk sanitation standards that are current, and that reflect the state of the science with respect to the safe production, processing and handling of milk and milk products. The dairy industry will also benefit from the added clarity on the specific implementation of new requirements and allowances. This proposed rulemaking implements the new statute regarding sell by date and best by date labeling of milk, revises Chapter 59a to remain consistent with the requirements of the federal Pasteurized Milk Ordinance, addresses ambiguities and provides clarity regarding issues that have arisen with new technologies, updates the language to reflect current food safety science, and adds new sections to accommodate the dissolution of a Memorandum of Understanding with the Milk Marketing Board regarding approved milk sampler and weigher certifications. In addition, with the number of milk operations that possess Department-issued permits allowing them to produce and sell raw (unpasteurized) milk for human consumption, and the high interest in raw milk products by both producers and consumers, it has become necessary to promulgate regulations that set clear, safe, comprehensive standards for the production and distribution of raw milk for human consumption and further-processed raw milk products. This rulemaking defines those types of activities requiring permitting and those that are exempt from permitting and provides standards for the manufacture and sale of raw milk butter within the Commonwealth. The regulation will benefit nearly all Commonwealth residents, since the majority of Pennsylvania’s 12.8 million citizens are consumers of milk and dairy products. Pennsylvania’s 8,500-plus dairy producers and 900-plus milk permitholders will also benefit from the regulation. In addition, approximately 120 raw milk producers, and the persons who acquire and consume raw milk from these producers, will benefit from the updated

raw milk permit provisions that will clarify the requirements for obtaining and maintaining a raw milk permit and attempt to protect the health of raw milk consumers. The foregoing benefits are not readily quantifiable.

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

No.

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

The changes proposed in this rulemaking are quite similar to the milk sanitation regulations of other states and will not put Pennsylvania at a competitive disadvantage with other states. If anything, this rulemaking will facilitate the flow of Pennsylvania-produced milk and milk products in interstate commerce, especially with the implementation of the sell by and best by date labeling statute. The Department researched the regulations of the surrounding states of New York, Ohio, Virginia, Maryland, Delaware and New Jersey. For purposes of this Regulatory Analysis Form we will provide an overview of four standards regarding milk sanitation regulations (incorporation of the provisions of the "Grade A Pasteurized Milk Ordinance" (PMO), certification of milk inspectors, samplers and weighers, bacteria and somatic cell standards and permitting of raw milk for human consumption) that effect all states. In order to allow review of our assessment the following citations apply: 1. New York State – Agriculture and Markets Law at 4 NYAGR §§ 46-71; 4-A NYAGR §§ 71a.-71k.; 4-B NYAGR §§ 71.1-71.o, with regulations at 1 NYCRR §§1-18; 2. State of Ohio – Dairy Products at Ohio Rev. Code §§ 917.01-917.99, with regulations at OH Admin Code §§ 901:11-1-01 - 11-1-06 (relating to Dairy), 901:11-2-01 - 11-2-44 (relating to Ohio Manufacture Milk Rules), 901:11-3-01 - 11-3-11 (relating to Ohio Frozen Dessert Rules), 901:11-4-01 - 11-4-13 (relating to Ohio Hauler, Weigher, Sampler and Tester Rules) and 901:11-5-01 (relating to Standards of Identity for Milk, Cream, Butter, Other Dairy Products); 3. State of New Jersey – Milk Control Act at N.J.S.A. §§ 24:10-57.1 *et seq.*, with regulations at N.J.A.C. §§ 8:21-10.1 - 8:21-10.23; 4. Commonwealth of Maryland – Maryland Code, Health-General at Md.Code, Health-Gen. §§ 21-401 - 21-436, with regulations at COMAR §§ 10.15.06.01 – 10.15.06.20 (relating to Grade "A" fluid milk) and COMAR §§ 10.15.09.01-10.15.09.22 (relating to Production, processing, transportation, storage and distribution of manufactured grade milk); 5. State of Delaware – Law relating to Food and Drugs at 16 Del.C. 1953 §§ 3301 and 3315, with regulations at 16 Del. Admin. Code §§ 4461-1.0 *et seq.* and 4461-2.0.; 6. Commonwealth of Virginia – Milk, Milk Products, and Dairies at Va. Code Ann. § 3.2-5200 *et seq.*, with regulations at Chapters 490, 501, 510, 520 and 531 of the Virginia Administrative Code (2 VAC § 5-490 *et seq.*; 2 VAC § 5-501 *et seq.*; 2 VAC § 5-510 *et seq.*; 2 VAC § 5-520 *et seq.*; and 2 VAC § 5-531 *et seq.*). **The first standard** to be compared is the incorporation of the Grade A PMO into surrounding state laws. The Grade A PMO is referenced in the regulations of and followed by all the surrounding states. New York references the 2017 edition of the PMO at section 2.1 (relating to applicability) of their regulations and the 1989 edition of the PMO in the definitions at section 2.2(kk). The PMO standards are also set forth at section 2.7 (relating to sampling and analysis of prepasteurized milk) and various sanitation requirements established in sections 2.9-2.28 (1 NYCRR §§ 2.1, 2.2(kk), 2.7 and 2.9-2.28). Ohio follows the provisions of the 2019 edition of the PMO, as defined at section 901:11-1-01 (relating to definitions) of the regulations. PMO provisions are referenced and incorporated into the following sections of the Ohio regulations: 901:11-1-02 (relating to materials incorporated); 901:11-2-01 (relating to definitions); 901:11-2-04 (relating to somatic cell count); 901:11-2-26 (relating to pasteurization, sterilization and

cooking); 901:11-3-01(relating to definitions) and 901:11-3-05 (relating to pasteurization)(OAC §§ 901:11-1-01, 901:11-1-02, 901:11-2-01, 901:11-2-04, 901:11-2-26, 901:11-3-01 and 901:11-3-05). Unlike Pennsylvania, Ohio specifically excludes or amends several provisions of the PMO as set forth at sections 901:11-1-03 (relating to materials deleted from PMO) and 901:11-1-05 (relating to amendments to PMO). New Jersey, at section 8:21-10.1 of its regulations, adopts the 2019 edition of the PMO "...and associated documents, as amended and supplemented..." (N.J.A.C. § 8:21-10.1) as its legal requirements for the production and processing milk and milk products in the state. The PMO applies to both in-state only and Interstate Milk Shipper listed plants and bulk tank units. Like Ohio, New Jersey does exclude certain sections of the PMO, as well as, several definitions that are superseded by definitions contained in New Jersey's Milk Control Act. (*See, e.g.*, N.J.A.C. § 8:21-10.2). Like Pennsylvania, New Jersey adopts Section 7 of the PMO as its regulatory standards for milk and fluid milk products and promulgates additional standards for pasteurized mixes for frozen desserts. (*See, e.g.*, N.J.A.C. § 8:21-10.8). New Jersey adopts Section 6 of the PMO for its sampling and testing of milk standards. The Maryland Department of Health (MD-DOH) regulates milk products. It follows the PMO for Grade A Pasteurized Milk (Md. Code, Health-Gen. §§ 21-401(k) and 21-405(a))(See also COMAR § 10.15.06.03). The regulations reference the Grade A PMO, 2017 revision. With respect to manufactured milk the MD-DOH incorporates only specific sections of the PMO (sections 5, 6, 8, 12, 14, 15, 18 and Appendices A-I, K-O and Q-S) into its regulations (*See* COMAR § 10.15.09.03). The Delaware Department of Health and Social Services (DHSS) enforces the State of Delaware Milk Code (16 Del. Admin. Code §§ 4461-1.0 *et seq.*). Chapter 33 of Title 16 (relating to food and drugs) authorizes DHSS to promulgate regulations related to food, which includes milk (16 Del. C. 1953, §§ 3301 and 3315). The Milk Code adopts the Grade "A" Pasteurized Milk Ordinance (PMO) 2015 revision (as amended) as the state's complete regulatory standards for the production, distribution, and sale of milk and milk products sold in Delaware (*See* [16 Del. Admin. Code § 4461-2.0.](#)). The regulation at § 446-2.1 further states that the production/distribution/sale of milk, inspection of facilities, and the issuing and revocation of permits "shall be regulated in accordance with the provisions of the **current edition** of the Grade 'A' PMO." The Milk Code authorizes DHSS to grant variances from those regulations from time to time (*See* [16 Del. Admin. Code §§ 4461-1.2.](#)). Virginia follows the Grade A PMO, 2017 revision. Virginia regulations state, "Any person permitted in accordance with Chapter 52 (§ 3.2-5200 *et seq.*) of Title 3.2 of the Code of Virginia regarding milk, milk products, and dairies shall comply with the provisions of the "Grade "A" Pasteurized Milk Ordinance, 2017 Revision" (2 VAC § 5-490-5)(relating to grade "A" pasteurized milk ordinance). In addition, the Grade A PMO, 2017 edition, is followed for standards of cooling, storing, sampling and transportation of milk (2 VAC § 5-501-5). Other provisions make it clear the Virginia regulations will control where any conflict exists with the Grade A PMO. **The second standard** to be compared is the certification of milk inspectors, samplers and weighers, in surrounding state laws. New York State requires each permitted transfer or receiving station, bulk tank unit and milk plant to employ and be responsible for a certified milk inspector (1 NYCRR § 2.3). The training standards and duties of certified milk inspectors and samplers are similar to those set in Pennsylvania regulations but, the educational and experience requirements are more stringent in New York (1 NYCRR § 2.6). A tester's license is required and the standards are similar to those set forth in Pennsylvania (1 NYCRR § 6.3). Ohio defines "Weigher, sampler, or tester" in much the same manner as Pennsylvania and requires licensure and examinations for weighers, samplers and testers (OAC, §§ 901:11-4-01 and 901:11-4-02). Like Pennsylvania, weighers, samplers and testers must pass an examination (Title 9, Ohio Revised Code, § 917.08 and OAC § 901:11-4-02(D)) and are subject to inspection (OAC § 901:11-4-04). The standards are similar to those established in Pennsylvania's proposed Milk Sanitation Regulation. Virginia requires weighers and samplers to be permitted by the Commonwealth and standards are consistent with and based upon The Grade "A" PMO, 2017 revision (2 VAC § 5.490-36). The State of New Jersey follows sampling and testing standards of the Grade "A" PMO but, does not establish any other separate standards in its regulations. Maryland conducts

inspection and evaluation of milk production and processing under the standards of section 5 of the Grade “A” PMO and requires sampling and examination of milk are conducted in accordance with the standards established in section 6 and Appendix B of the Grade “A” PMO (COMAR § 10.15.09.10.). Delaware’s Milk Code adopts the Grade “A” PMO, 2015 edition, as its regulatory standards for the production, distribution and sale of milk and milk products in Delaware and regulates the production, distribution, sale of milk, inspection of facilities and issuance and revocation of permits in accordance with the “current edition” of the Grade “A” PMO (16 Del. Admin. Code §§ 4461-1.2 and 4461-2.0).

The third standard to be compared is the bacteria and somatic cell standards, in surrounding state laws. New York sets forth a chart that establishes the same or very similar standards for milk temperature, coliform count, drugs, bacterial limits and pre-pasteurized raw milk as the Pennsylvania proposed regulations. Pennsylvania is more stringent as to somatic cell count standards. Pennsylvania, for both pre-pasteurized and raw milk, set somatic cell count standards at 500,000 per ml. New York is 750,000 per ml. which is in line with the PMO (1 NYCRR § 2.8). Ohio establishes the same or very similar standards for milk temperature, coliform count, drugs and bacterial limits of pre-pasteurized raw milk as the Pennsylvania regulations. Pennsylvania is more stringent as to somatic cell count standards, setting somatic cell count standards at 500,000 per ml., as opposed to Ohio’s standard of the lesser of one million or two hundred fifty thousand per ml. more than the standard adopted in the PMO (currently 750,000 per ml.)(OAC § 901:11-2-04). Goat milk shall remain at the same level as adopted in the PMO. New Jersey also has similar standards for milk temperature, coliform count, drugs and bacterial limits and establishes its somatic cell count at 750,000 per ml. for cow’s milk and 1,500,000 for goat’s milk (N.J.A.C. § 8.21-10.8). Maryland allows for higher bacterial levels than the PMO and Pennsylvania regulations but, adopts the same somatic cell count as the PMO (COMAR § 10.15.09.08(B)(6)). Virginia establishes the same or very similar standards for milk temperature, coliform count, drugs and bacterial limits of pre-pasteurized raw milk as the Pennsylvania regulations and like Pennsylvania requires a somatic cell count of not more than 500,000 per ml. for cow’s milk (2 VAC § 5-490-50).

The fourth standard to be compared involves the raw milk laws and regulations of each surrounding State and Commonwealth. Each State or Commonwealth has established its own statutes related to whether raw milk may be produced and sold directly for human consumption. It must be noted that the laws of each State or Commonwealth will not have any effect on interstate commerce as it is illegal, under federal law, to ship unpasteurized milk for consumer sale and consumption across state lines. New York, like Pennsylvania, allows the permitted sale of raw milk directly to consumers and their standards are very similar to those established or to be established in Pennsylvania’s proposed regulation. (*See* 1 NYCRR § 2.3(b)). The Ohio Revised Code at section 917.04 prohibits the sale of raw milk directly to consumers, except for those few entities that may be grandfathered. It reads, “No raw milk retailer shall sell, offer for sale, or expose for sale raw milk to the ultimate consumer except a raw milk retailer who, prior to October 31, 1965, was engaged continuously in the business of selling or offering for sale raw milk directly to ultimate consumers, holds a valid raw milk retailer license issued under section [917.09](#) of the Revised Code, and is subject to the rules regulating the sale of raw milk adopted under this chapter...”(Title 9, Ohio Revised Code, § 917.09). However, cow share agreements have been found to be legal because of the way Ohio defines “sale.” New Jersey, with the exception of 60-day aged raw cheese, prohibits the sale or distribution of raw milk or products made from raw milk, such as yogurt, soft cheese, and ice cream, for human consumption. (N.J.S.A. [§ 24:10-57.17](#)) “No person shall sell, offer for sale, or distribute to the ultimate consumer any milk or cream that is not pasteurized.” See also N.J.S.A. [§ 24:10-57.18](#) requiring pasteurization of milk products but allowing the sale of 60-day aged raw cheese. There is no explicit regulatory ban on cow-share or herd-share agreements in New Jersey. Maryland requires all milk sold for human consumption to be pasteurized. Under the current law, Maryland prohibits the sale of raw milk for human consumption unless it’s used for making farmstead cheese. *See* [MD Code, Health - General, § 21-434](#); *see also* [COMAR § 10.15.06.12](#) and [COMAR § 10.15.09.07](#). Moreover, the state has a regulatory ban on the sale and distribution of raw milk through

cow-share or herd-share agreements. *See* COMAR §§ 10.15.06.02(B)(29)(defining sale to include the "right to acquire milk and milk products... through... an agistment agreement, which is the sale of shares or interest in a cow..."). Delaware does not allow the sale of raw milk for human consumption. Federal regulation prohibits the introduction into interstate commerce of any unpasteurized milk product intended for human consumption. Likewise, Delaware does not permit the sale or offer of unpasteurized milk or milk products to consumers within the state. No variance exists for the intrastate sale of raw milk. Additionally, there is no regulation or case law either legalizing or prohibiting cow-share or herd-share agreements in Delaware. The lack of an administrative policy or a regulatory variance that allows the distribution of raw milk through herd-share agreements suggests that DHSS would reject such agreements as a circumvention of the state's (and federal) prohibition on the sale of raw milk. Virginia requires that all dairy products sold must be pasteurized. Virginia's Administrative Code provides, "No person may produce, provide, manufacture, sell, offer for sale, expose for sale, or store in the Commonwealth of Virginia or bring, send, or receive into the Commonwealth of Virginia any manufactured dairy product in final package form for direct human consumption unless (i) the product has been pasteurized in accordance with the requirements of this chapter; (ii) the product is made from dairy ingredients (milk, milk products, or dairy products) that have all been pasteurized in accordance with the requirements of this chapter; or (iii) in the case of cheese, the cheese complies with a standard of identity under 21 CFR Part [133](#) that allows for the cheese to be aged above 35° for a minimum of 60 days or the minimum number of days specified under the standard of identity for that variety of cheese." (2 VAC § 5-531-110) Finally, all 50 state, District of Columbia, and U.S. Trust Territory food safety regulatory authorities adopt at minimum the recommended regulatory standards set forth in the FDA's current Grade "A" Pasteurized Milk Ordinance as the best approach to milk sanitation, and no language in the proposed rulemaking will alter the Commonwealth's current adoption of the provisions of the current Grade "A" Pasteurized Milk Ordinance.

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

No.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

The Department regularly communicates with the dairy industry through many professional and industry associations and has done so in the preparation of the regulation as well. One of the more prominent of the professional organizations is the PA Association of Milk, Food, and Environmental Sanitarians (PAMFES). The most prominent industry organization providing input to the proposed rulemaking is the Pennsylvania Association of Sustainable Agriculture (PASA) and the Pennsylvania Farmers Union with respect to the raw milk provisions, and the Pennsylvania Association of Milk Dealers and the Center for Dairy Excellence with respect to the milk sell by and best by dating statute and provisions. Statutory and proposed regulatory amendments are also communicated with the industry through the Eastern and Western Approved Inspectors meetings (attendees are the Department approved Farm Inspectors typically employed by the various Dairy Cooperatives).

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

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

The number of people directly involved with Pennsylvania's dairy industry is difficult to quantify, but the following provides an estimate. There are approximately 8,500 dairy farms that produce milk within the Commonwealth, approximately 35 Grade "A" milk processing plants, approximately 150 Grade "A" Bulk Tank Units (permitted farm groups), approximately 120 permitted raw milk facilities, approximately 125 dairy manufacturing (non-Grade A) facilities, 35 Interstate Milk Shippers program certified laboratory facilities, 120 drug residue testing facilities, 32 manufacturers of single service containers, approximately 100 milk hauling companies with approximately 1000 milk tankers, and 1500 approved milk sampler / weighers.

This rulemaking will have little impact on the majority of the industry, as it clarifies already existing standards within the FDA's current Grade "A" Pasteurized Milk Ordinance.

The three most impactful changes:

- Raw Milk permitholders are currently limited to fluid raw milk sales. The proposed rulemaking will expand approved raw milk products to include a permit allowing production of raw milk butter. Current raw milk permitholders advocated for this expansion of allowable products.
- Existing milk tankers and approved milk sampler/weighers require inspections and certification to comply with requirements of the FDA's current Grade "A" Pasteurized Milk Ordinance. These inspections and certifications were jointly provided by the Department and the Pennsylvania Milk Marketing Board. The proposed rulemaking clarifies that the responsibility will rest with the Department alone and provides a mechanism for the Department to manage the regulatory requirements by requiring milk hauling companies to provide an annual list of milk tankers which are in service and a list of the approved sampler/weighers in their employ. The reporting requirement should not be burdensome, as milk hauling companies were already providing that data to the Pennsylvania Milk Marketing Board.
- Pasteurized milk processing facilities have the option of extending the shelf life of their milk products through scientific testing with approval by the Department. This rulemaking proposes an application process for obtaining Departmental approval, as provided for in the Sell By and Best By Dating Act, and requires the permitholder to conduct ongoing shelf life testing.

The industry advocated for the statutory changes that this rulemaking implements.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

The number of people directly involved with Pennsylvania's dairy industry is difficult to quantify, but the following provides an estimate:

- Business - approximately 8,500 dairy farms that produce milk within the Commonwealth, approximately 35 Grade "A" milk processing plants, approximately 150 Grade "A" Bulk Tank Units (permitted farm groups), approximately 120 permitted raw milk facilities, approximately 125 dairy manufacturing (non-Grade A) facilities, 35 Interstate Milk Shippers program certified laboratory facilities, 120 drug residue testing facilities, 32 manufacturers of single service containers and closures, and 100 milk hauling companies.

- Individuals – approximately 1500 certified weigher/samplers, 100 approved farm inspectors, 70 approved dairy laboratory directors and 750 certified laboratory analysts.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The regulation will benefit nearly all Commonwealth residents, since the majority of Pennsylvania's 12.8 million citizens are consumers of milk and dairy products, by protecting the public health while expanding the availability of milk and raw milk products available to the consumer.

Pennsylvania's 900-plus milk permit holders will also benefit from the regulation, as well as the 35 Interstate Milk Shippers program certified laboratory facilities. Other businesses will also benefit through the increased availability of desired dairy products. The foregoing benefits are not readily quantifiable.

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

The benefits of the regulation outweigh any adverse effects or costs. The regulation will enhance public health and safety, maintain modern state-of-the-science milk sanitation standards in Pennsylvania, and provide clarity to the dairy industry where ambiguity existed. The regulation will provide for further economic opportunities for the regulated industry by providing a path for extending shelf life dating on pasteurized milk and allowing for production of raw milk butter. Approved dairy testing laboratories will benefit from increased revenue from shelf-life testing requirements and elimination of laboratory director exam requirements. These benefits far outweigh any costs or adverse impacts associated with the regulation.

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

The regulation does not require any great change in the way the dairy industry is currently operating. Although it updates standards, technical details and program details, most of Pennsylvania's dairy industry is already in substantial compliance with the regulation and the changes are not expected to impose significant new net costs on the regulated community.

Dairy processors – (approximately 180) will incur new testing costs as a result of the Sell by and Best by Date Labeling Act and this regulation. The requirement to conduct annual or biannual shelf-life testing, at a cost of around \$100 annually will result in an estimated \$18,000 cost to that industry. If the industry wishes to extend shelf-life dating, the testing required to file an initial application with the Department will result in an additional one-time cost of \$300 per milk product. The majority of the dairy processors have a product line of 5-6 items, resulting in a net cost of \$1500-\$2000 for any processor that is seeking to voluntarily apply to extend shelf-life dating. If 20% or 35 of the processors (largest processors) apply to extend shelf life, this would result in a one-time cost of approximately \$70,000 for the entire industry. Those processors seeking to extend shelf life dating of their dairy products will realistically reap an unknown economic benefit that more than offsets the testing costs by wasting less inventory through disposal of expired products and by expanding the geographic territory in which their fresh products can be distributed, as well as by making their products more competitive with neighboring states that allow longer shelf life dating on dairy products. This estimate of increased cost is likely an overestimate, as many of the larger processors already conduct shelf life testing independent

of the regulatory requirements as part of their own quality assurance program. Any costs to dairy producers associated with the shelf-life testing will also directly benefit approved dairy laboratories subject to this same regulation, as the costs to the producer industry will be directed to the approved dairy laboratory industry.

Raw Milk processors – (approximately 131) who produce raw milk for human consumption under permit from the Department – would be required to incur additional testing costs as a result of the regulation. To maintain consistency across the Commonwealth, raw milk processors will also be required to conduct annual shelf-life testing to validate that their product will meet microbiological standards throughout the sell by or best by date they are utilizing. At a cost of \$100 annually for the test, this will result in a \$10,000 cost to this segment of the industry. Raw milk processors will receive unknown economic benefits from the regulation by providing a raw milk processor the ability to produce raw milk butter and sell this sought-after product to consumers. Therefore, the net cost to this segment of the industry is expected to be negligible.

Other segments of the associated dairy support industry will see economic benefit from the regulations. The 35 approved dairy laboratories (many of which are small businesses) will receive increased revenue from the required shelf-life testing, as well as an unknown level of economic benefit due to lost time at work for laboratory directors to partake in an examination process, that will no longer be required.

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

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

None.

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

- A cost of \$300,000 for two FTE equivalent work to assume the entirety of approved weigher sampler certifications due to the dissolution of an MOU with the Milk Marketing Board.
- A cost of \$80,000 for ½ FTE for two years and then \$40,000 for ¼ FTE subsequently, to administer and review applications submitted to extend sell-by and best by date labeling, and recordkeeping associated with hauler and milk tanker tracking.
- A savings of \$300,000 for two FTE (laboratory and field staff) as a result of the Department no longer conducting shelf-life testing and sampling.
- A savings of \$75,000 for ½ FTE as a result of eliminating Department label approval requirements for milk permitholders.
- A savings of \$40,000 for ¼ FTE as a result of eliminating the administrative burden due to the Laboratory Director's exam.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

(22a) Are forms required for implementation of the regulation? Yes.

An Application form was developed as a result of the passing of the Sell by and Best By Date Labeling Act. This regulation will not change the application requirement for firms seeking approval for Sell By or Best By dating greater than 17 days.

An application was developed for Sampler Certification requests, to replace the previous MOU process outlined with the PMMB.

The regulation will require milk hauling companies to report to the Department, yearly, their inventory of milk tankers. An annual report form will be utilized or the same annual report provided to PMMB will also be accepted by the Department.

(22b) If forms are required for implementation of the regulation, **attach copies of the forms here.** If your agency uses electronic forms, provide links to each form or a detailed description of the information required to be reported. **Failure to attach forms, provide links, or provide a detailed description of the information to be reported will constitute a faulty delivery of the regulation.**

Attached is a copy of the Sell By or Best By Dates Greater than 17 Days application.

Attached is a copy of the Sampler Certification application.

Attached is a copy of the Annual Milk Hauler report form.

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

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	\$415,000	\$415,000	\$415,000	\$415,000	\$415,000	\$415,000
Total Savings						
COSTS:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	\$380,000	\$380,000	\$340,000	\$340,000	\$340,000	\$340,000
Total Costs						

REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Milk Sanitation (est of 20% of Bureau costs)	\$2.67 M	\$2.55 M	\$2.88 M	\$2.99 M

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

No adverse impacts are expected on small businesses.

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

No such special provisions have been developed.

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

No alternative regulatory provisions were considered. The Department is satisfied that the regulation that is the subject of this document is the least-burdensome acceptable approach to achieving the Department's objectives (which are summarized in the response to Question No. 10).

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performance standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

None considered, no adverse impact on small businesses is expected.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

N/A

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

- | | |
|---|-------------------------|
| A. The length of the public comment period: | <u>30 days</u> |
| B. The date or dates on which any public meetings or hearings will be held: | <u>None scheduled</u> |
| C. The expected date of delivery of the final-form regulation: | <u>August 2024</u> |
| D. The expected effective date of the final-form regulation: | <u>November 2024</u> |
| E. The expected date by which compliance with the final-form regulation will be required: | <u>Upon publication</u> |
| F. The expected date by which required permits, licenses or other approvals must be obtained: | <u>Upon publication</u> |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

Effectiveness of the regulations will be evaluated through continued regulatory inspections and evaluation of industry compliance, as well as continued review of current food science and food safety knowledge and practices.



Application for Sell by and Best by Milk Date Labeling Greater Than 17 Days

Application process:

1. Applicant wishing to exceed 17 days for sell by date or best by date on milk must complete and submit this application to the Department.
2. Facility must submit samples of each milk type, in each container type and container size for which they are applying for a sell by or best by date greater than 17 days, to a Pennsylvania approved dairy laboratory for bacteriological shelf life testing. The testing protocol to be used is set forth in 3 Pa.C.S. § 5744 as follows:
 - a. Each milk type and type and volume of container shall be sampled from at least three different production days and submitted unopened to a Pennsylvania approved dairy laboratory;
 - b. The Pennsylvania approved dairy laboratory shall hold the samples unopened, and maintained at a temperature of between 34 and 45 degrees Fahrenheit for no less than the entire proposed sell by date or best by date period;
 - c. After the proposed sell by date or best by date period ends, each sample shall be opened and tested for bacterial count; and
 - d. The testing shall have been completed within the three (3) months preceding the date this application is submitted to the Department.
3. If test results are within the bacteriological limits for milk described in the Department's milk sanitation regulations, then the proposed sell by date or best by date will be approved. If test results from two (2) or more samples are not within the bacterial limits in the Department's milk sanitation regulations, the Department will calculate a reduced sell by date or best by date. The facility may retest but will be required to use the reduced sell by date or best by date until the facility submits a new application for approval, to include testing, demonstrating the facility can comply with the bacteriological limits at the proposed sell by or best by date.
- 4. All test results must be submitted with this application.**
5. Facilities with a sell by or best by date greater than 17 days, shall continue routine testing on the highest sales volume milk type in each container types and container size, at an interval of no longer than six (6) months.
6. Failure to comply with the Milk Sanitation Law and its attended regulations may result in enforcement action by the Department against the applicant.
7. PDA reserves the right to revoke approval status.
8. This approval shall be void if ownership is changed.

Return the completed application and any other correspondence to:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
ATTN: Milk Program Specialist
2301 North Cameron Street, Room 112
Harrisburg, PA 17110
Fax (717)-787-1873
Email: RA-AGMilkProgram@pa.gov



Application for Sell by and Best by Milk Date Labeling Greater Than 17 Days

Facility ID: _____ Facility Name: _____

Address: _____

Email: _____ Phone: _____

Point of Contact: _____

Proposed Sell by or Best by date _____ (# Of Days)

*Lab conducting testing: _____

Milk product (s): _____

Container type(s): Glass, Plastic, Paper, or other: _____

Container size(s): _____

Applicant signature _____ Date _____

Applicant Name (printed) _____



Bureau of Food Safety and Laboratory Services Use Only

Lab testing provided _____ Date of lab testing _____

Lab testing compliant _____ If not how many samples were out of compliance _____

Sell by or Best by day approved for _____ days Date of Approval _____

Products approved: _____

Sell by or Best by day approved for _____ days Date of Approval _____

Products approved: _____

Calculated date approved for the following products: _____

Department Approval Signature: _____ Date _____



Sampler Certification Application

Name: _____

Mailing Address: _____

Phone number: (_____) _____ Landline Cellphone

Email Address: _____

Employer: _____

Are you an Approved Inspector? Yes No

Are you a Weigher-Sampler? Yes No

Weigher/Sampler License Number (PMMB issued): _____

Signature: _____ Date: _____

Upon receipt of this application a PDA Food Inspector will reach out to schedule the certification exercise.

By signing this application, the applicant affirms the information in this application is true and correct to the best of the applicant's knowledge, information and belief and makes these statements subject to the penalties of 18 Pa.C.S.A. § 4904, relating to unsworn falsification to authorities.

This form can be mailed to address listed below
 Or can be emailed to: RA-AGMILKPROGRAM@pa.gov



pennsylvania

DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

**2301 North Cameron Street, Room 112
Harrisburg, PA 17110**

MILK HAULER ANNUAL REPORT

January 1, 20_____

Please complete this form and sign and date the bottom of the page and return it to the email or mailing address listed, along with a listing (example on page 2) of each bulk milk hauling unit.

Facility ID Number : _____ (if known or as completed by PA Dept. of Ag)

PMMB License Number : _____

Company Name and Physical Address:

Company Name: _____

Street Address: _____

City: _____ State: _____ Zip Code: _____

County: _____

Contact Name/Title: _____

Phone Number: _____ Emergency Phone: _____

Fax Number: _____ E-mail Address: _____

Mailing Address (If Different than Physical Address)

Street Address: _____

City: _____ State: _____ Zip Code: _____

This form can be mailed to address listed below

Or can be emailed to: RA-AGMILKPROGRAM@pa.gov

Company Name _____

MILK TANKER LIST

* This form is an example. Any format containing the same information is acceptable.

**If any Tanker has been Inspected in Another State within the last 18 months, please submit proof of that inspection.

Tanker Number	License Plate Number	Single or Dual Compartment	Tanker Type: Farm pick-up, Transfer, Tri-Axel, Other	Location of Tanker if not at the Company Address
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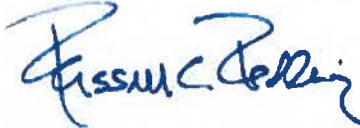

**FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU
(Pursuant to Commonwealth Documents Law)**

RECEIVED

Independent Regulatory
Review Commission

May 28, 2024

DO NOT WRITE IN THIS SPACE

<p>Copy below is hereby approved as to form and legality. Attorney General</p> <p>BY: <u>Amy M. Elliott</u> (DEPUTY ATTORNEY GENERAL)</p> <p><small>Digitally signed by Amy M. Elliott DN: cn=Amy M. Elliott, o=Pennsylvania Office of Attorney General, ou=Chief Deputy Attorney General, email=ae Elliott@attorneygeneral.gov, c=US Date: 2024.05.16 12:15:20 -0400</small></p> <p><u>5/16/2024</u> DATE OF APPROVAL</p> <p><input type="checkbox"/> Check if applicable Copy not approved. Objections attached.</p>	<p>Copy below is here by certified to be a true and correct copy of a document issued, prescribed or promulgated by:</p> <p><u>Department of Agriculture</u> (AGENCY)</p> <p>DOCUMENT/FISCAL NOTE NO. <u>2-194</u></p> <p>DATE OF ADOPTION: <u>02/16/2022</u></p> <p></p> <p>BY: <u>Russell C. Redding</u></p> <p>TITLE <u>Secretary</u> Pennsylvania Department of Agriculture</p>	<p>Copy below is hereby approved as to form and legality. Executive or Independent Agencies.</p> <p>BY: </p> <p><u>1/29/24</u> DATE OF APPROVAL</p> <p><input type="checkbox"/> Deputy General Counsel (Chief Counsel, Independent Agency) (Strike inapplicable title)</p> <p>Check if applicable. No Attorney General approval or objection within 30 days after submission.</p>
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**NOTICE OF PROPOSED RULEMAKING
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE**

Title 7 - AGRICULTURE

7 PA. CODE CH. 59a

MILK SANITATION

NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 59a]

Milk Sanitation

The Department of Agriculture (Department) proposes to amend Chapter 59a (relating to milk sanitation) to read as set forth in Annex A.

Statutory Authority

This proposed rulemaking is authorized under the act of July 2, 1935 (P.L. 589, No. 210) (31 P.S. §§ 645-660g), known as the Milk Sanitation Law (Act). Section 19 of the Act (31 P.S. § 660c) provides, “The Secretary of Agriculture is hereby authorized to adopt and promulgate rules and regulations for the proper enforcement of this act.” In addition, Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), known as the Milk Sell-By Date and Best-By Date Labeling Act, section 5747, authorizes the Department to adopt the regulations necessary to administer the provisions of that statute (3 Pa.C.S. § 5747). The Food Safety Act (3 Pa.C.S. §§ 5721-5737) includes milk within the definition of a “potentially hazardous food” and provides the Department broad authority to regulate as necessary for the proper enforcement of that statute. See 3 Pa.C.S. §§ 5722 (relating to definitions), 5733 (relating to rules and regulations).

Need for the Proposed Rulemaking

This proposed rulemaking would accomplish several regulatory objectives, including:

- (1) authorization for issuance of an additional raw milk butter permit to raw milk permitholders, in response to the industry-driven initiative to provide more raw milk products. The following sections of the proposed Chapter 59a regulations provided standards for or pertain to raw milk butter: §§ 59a.363(a)(1)(i), 59a.401, 59a.402(b)(2), 59a.402(c), 59a.405, 59a.408, 59a.409(e), 59a.411(a)(1), 59a.411(a)(2), 59a.411(c), 59a.412, 59a.413(a) and 59a.413(b).
- (2) implementation of the statutory requirements imposed by Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), known as the Milk Sell-By Date and Best-By Date Labeling Act. The following sections of the proposed Chapter 59a regulations are affected by, provide standards for or pertain to the Milk Sell By or Best By Date: §§ 59a.15(a),(b)(b.1)(c)(d)(e) and (f) and 59a.411(a)(3)(i), (ii) and (iv).
- (3) removal of an outdated and extraneous regulatory requirement for label and labeling pre-approval by the Department for all permitholders, as pre-approval of labels and labeling are not expressly required by the Act or by any other Act under which milk, milk

products, milk for manufacturing or manufactured dairy products may be regulated,¹ and to align with all other food products, which do not require pre-approval of labels. The Department has retained this requirement, however, for those raw milk permitholders subject to Subchapter F. The change was prompted by the industry stating that no other product label or labeling requires pre-approval of the label or labeling and it was delaying their ability to quickly market new products. The following section of the proposed Chapter 59a regulation is affected by and provides standards for the label and labeling requirements for milk, milk products, manufactured dairy products or milk for manufacturing purposes: § 59a.14(a),(b) and (c) which, currently establish the parameters for preapproval of labels, are proposed to be "Reserved." Subsection (d) has been expanded to establish minimum label and labeling requirements for bottles, containers, and packages enclosing milk, milk products or manufactured dairy products. While labels must comply with those standards, no preapproval of the labels will be required. The raw milk label content review provisions of § 411 (relating to label content review by the Department) are not changed and not affected. Raw milk labels must still be submitted to the Department for preapproval.

(4) regulating sampler, weigher/sampler, and milk tanker inspections previously conducted by the Pennsylvania Milk Marketing Board (MMB) pursuant to a Memorandum of Understanding (MOU) with the Department. The MOU was terminated in 2019, and since then, the Department has been tasked with conducting the field certifications and inspection programs required by the Interstate Milk Shippers Grade A Program (a United States Food and Drug Administration (FDA) Federal cooperative program that each state and Commonwealth must adopt and conform to in order for their dairy industry to ship in interstate commerce) and the PMO. The PMO, at Appendix B, requires samplers and weigher/samplers to be approved and milk tanker inspections to be done. The Department had established an MOU with the MMB under which the MMB did a large percentage of the sampler and weigher/sampler certification and milk tanker inspections. As set forth previously, the MOU terminated in 2019 and was not renewed. The Department has no certification standards or requirements set forth in regulation. Therefore, it is necessary to establish uniform standards through regulation and to properly inform the regulated community of the requirements to be met. The following sections of the proposed Chapter 59a regulations are affected by or provide standards for regulation of a sampler or weigher/sampler and milk tanker inspections: §§ 59a.6(a),(b),(c) and (f), 59a.16(g),(h) and (i), 59a.107(a), 59a.382(g), and 59a.409(d).

(5) making the regulation more understandable and user-friendly for the regulated community, and more closely aligned with the federal Grade 'A' milk standards outlined in the Food and Drug Administration, US Department of Health and Human Services, Grade "A" Pasteurized Milk Ordinance (PMO). The most current revision of the Grade "A" Pasteurized Milk Ordinance and its appendices, as published by the United States Food and Drug Administration (FDA), may be found on the Department's website at

¹ act of July 2, 1935 (P.L. 589, No. 210)(31 P.S. §§ 645-660g), known as the Milk Sanitation Law; The act of August 8, 1961 (P.L. 975, No. 436)(31 P.S. §520-1.1 *et seq.*) known as the Milk Adulteration and Labeling Act, at section 520-6 (31 P.S. §520-6); The Food Safety Act (3 Pa.C.S. §§ 5721-5737); and Act 62 of 2021 (3 Pa.C.S. §§ 5741-5747), commonly referred to as the Milk Sell-By Date and Best-By Date Labeling Act

www.agriculture.pa.gov/consumer_protection/foodsafety. The website contains a link to an electronic copy of the document. Many provisions of the current regulations contained references to the PMO. The following sections of the proposed Chapter 59a regulations are new or revised and are affected by, contain slight changes to, or provide standards related to the PMO: §§ 59a.2 (relating to the definition) – see “Approved sampler,” “Certified industry inspector,” “Grade A PMO or PMO” and “(c) Additional terms used in the Grade “A” PMO”, 59a.4(i), 59a.5(b)(3) and (c)(3), 59a.6(c)(4) and (f), 59a.7, 59a.12(j), 59a.16(g),(i) and (j), 59a.21(a) and (d) and 59a.28(a)(1) and (b).

Summary of the Proposed Rulemaking

Proposed revisions to § 59a.2 (relating to definitions). This section is proposed to be revised by adding or refining various defined terms and including citations for various statutes referenced elsewhere in the regulation. These revisions include the following:

The definition of “Approved inspector” would be deleted. The current definition is different from the statutory definition. In addition, the proposed amendments to section 59a.4.(b)(3) clarify the licensure standards for approved inspectors.

The definition of “Approved sampler” would be revised to make it clear that an approved sampler includes a certified person that obtains milk sampled as a “Dairy Plant Sampler” or “Industry Plant Sampler,” as those terms are defined under the federal Grade “A” Pasteurized Milk Ordinance (PMO). The rationale for this revision is to achieve consistency with federal milk regulations standards as outlined in the Grade “A” PMO.

The definition of the term “BTU – Bulk tank unit” is defined in the current regulation. The Department proposes to modify the definition slightly to clarify that it includes both individual and groups of dairy farms from which milk is collected. The current definition references only a “group” of dairy farms. However, many bulk tank units are located on individual farms. Therefore, the definition now includes a specified farm in addition to a group of dairy farms. This was done to assure both accuracy and clarity of the definition. The term bulk tank unit, while not defined in the PMO, is utilized in the PMO, which is adopted under the current and this proposed regulation, and at § 59a.16(e)(relating to additional documentation) of both the current and this proposed regulation.

The definition of a “certified industry inspector” has been added to the proposed regulation because the term is utilized in § 59a.4(h)(relating to certified industry inspector) of the current regulation and (i)(relating to certification process) of the proposed regulation.

The Department proposes to amend the current definition of “Grade “A” PMO” to set forth information disclosing the federal agencies that publish it, provides factual information disclosing it provides the minimum standards for Grade A milk production and processing as established by the United States Food and Drug Administration, and to provide the proper link to the Department’s website.

The definition of “HTST” is proposed to be amended to correct the definition. The current definition is incorrect because it states that HTST stands for “high temperature short term.” In actuality, HTST stands for “high temperature short time,” as provided in the definition of “pasteurization” in the PMO, at section 1. RR (definition of pasteurization)..

The Department proposes the addition of the definition of “ISO/IEC 17025.” This term appears in the amended regulations at § 59a.5(a)(3)(relating to pathogen testing laboratories) and § 59a.5(b)(2)(relating to other laboratories).

The Department proposes to amend the definition of “Manufactured dairy products” to assure it is the same as the statutory definition under the act of July 2, 1935 (P.L. 589, No. 210, § 1) (31 P.S. § 645), known as the Milk Sanitation Law (Act).

The Department proposes to amend the definition of “Milk products” by removing the last sentence, “The term includes those foods that are milk products under the Grade “A” PMO.” This sentence is inconsistent with the definition of “Milk products” set forth in the Milk Sanitation Law (act of July 2, 1935, P.L. 589, No. 210, § 1) (31 P.S. § 645).

The Department proposes the addition of the definition of “Pasteurization” for clarity purposes. It is utilized in the definitions of “Pasteurized” and “Pennsylvania-approved dairy laboratory,” and in sections 59a.7, 59a.12, 59a.14, 59a.15, 59a.17, 59a.19, 59a.20, 59a.21, 59a.309, 59a.363, 59a.373, 59a.382, 59a.402, and 59a.405. The definition of “pasteurization” comes from section 1. RR of the PMO. The Department has added the phrase, “the milk used for” when referring to manufactured dairy product to clarify only milk, and not to other ingredients in the manufacture dairy product, must be pasteurized.

The Department proposes to add the definition of “Pasteurized” for clarity. The definition of pasteurized is combined with the definition of pasteurization at section 1. RR of the PMO. Webster’s Dictionary defines “pasteurize” as to subject to pasteurization. Therefore, the Department has defined “pasteurized” in a manner that denotes the milk, milk product or milk utilized in manufactured dairy product has undergone pasteurization. The word pasteurized is uses in the definition of “Grade “A” PMO or PMO,” and in §§ 59a.7, 59a.14, 59a.15, 59a.16, 59a.20, 59a.309, 59a.363, 59a.373, and 59a.382.

The Department proposes to add the definition of “raw milk butter” since it is different from “butter” which is made from pasteurized milk and the term is utilized in the proposed regulation in §§ 59a.363(a), 59a.401, 59a.402(b)(2) and (c), 59a.408, 59a.409(e), 59a.411(a) and (c), 59a.412 and 59a.413, all of which set forth standards for raw milk butter.

The Department proposes to add the definition of a “retail food facility” because that term is utilized throughout the regulation at § 59a.12(b)(3)(relating to permits), § 59a.15(relating to labeling: milk dating) and § 59a.501(relating to interrelatedness with the Retail Food Facility Safety Act and the Food Safety Act).

The Department proposes to amend the definition of “Weigher/sampler” by (1) adding the terms “certified industry inspector,” “approved inspector,” and “other authorized designee,” and (2) removing the term “milk plant person,” because there is no such person specifically defined or set forth in the Act or the PMO related to weigher and sampler and (3) removing the “Pennsylvania Milk Marketing Board” and replacing it with “or other Department-approved certifying body.” The Department had established a Memorandum of Understanding (MOU) with the Pennsylvania Milk Marketing Board (MMB) to do a large percentage of the certification, but the MOU expired in 2019 and the MMB did not approve a renewal. Therefore, the specific reference to the MMB has been replaced with the broader term “Department-approved certifying body.” The amendment clarifies that certified inspectors, approved inspectors, as defined in the regulation, and other persons certified by the Department may be a weigher/sampler. In addition, the PMO, at Appendix B, Milk Sampling, Hauling and Transportation, requires weigher/samplers to be approved by the regulatory agency.

The Department proposes to amend subsection (c) “Additional terms used in the Grade “A” PMO” by adding subparagraphs (1) and (2). Subparagraph (1) is simply created from current language for clarity and in order to add subsection (2) to clarify that additional terms used in the Grade “A” PMO include “milk products” which include both “milk” and “manufactured dairy products.”

Proposed revisions to § 59a.3 (relating to contacting the department). The Department proposes to revise this section by updating the contact and address information.

Proposed revisions to § 59a.4 (relating to approved inspectors and certified industry inspectors). The Department proposes to:

1. Add “and certified industry inspectors” to the title.
2. Reduce the applicant age from 21 to 18 in subsection (b)(1). There is no legal reason to require a person to be 21 years of age to become a licensed approved inspector when the legal age of adulthood in Pennsylvania is 18 years of age – see 23 Pa.C.S.A. § 5101 - and there are no special circumstances to require a person to be 21 years of age prior to licensure.
3. Amend subsection (b)(3) to establish that the Department will evaluate each applicant and to increase the number of joint dairy farm evaluation inspections to five. The increase in joint dairy farm evaluation inspections is more consistent with the standards established in section 5 of the Grade A PMO.
4. Amend subsection (e) by removing the reference to “subsections (b) and” in the second sentence resulting in only subsection (d) being referenced. The reason for the change is that subsection (b) does not apply to continuing education requirements for license renewals. The amendment will correct an error in the current regulation.

5. Change the heading in subsection (g) to read “license” instead of “certificate” as the Department issues licenses.
6. Add subsection (i)(relating to certification process) to make it consistent with the federal PMO, and current industry practice. The Department established language that clarifies a person must be licensed as an approved inspector prior to seeking certification as a certified industry inspector. In addition, the Department set forth general standards for initial certification and renewal of certification that are established in the Grade A PMO.

Proposed changes to § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results).

1. The Department proposes to amend the title of subsection (a), by adding “laboratory,” to clarify these are general standards for all laboratories covered under this section. In addition, the Department proposes to add subsections to break down standards for all laboratories, pathogen testing laboratories, and to provide for alternate laboratory methods.
2. The Department proposes to add subsection (a)(1)(Pennsylvania-approved, official and other laboratories). The general laboratory standards for sampling and testing conducted by Pennsylvania-approved laboratories, official laboratories and other laboratories were not substantively changed from those that appear in the current regulations under subsection (a). The Department did add a website reference, “found at AOAC.org,” to allow the regulated community to view any updates or familiarize itself with the standards of the “Official Methods of Analysis of the Association of Official Analytical Chemists.”
3. The Department proposes to add subsection (a)(2) which requires all laboratories that conduct sampling or examinations to be listed with the National Conference on Interstate Milk Shippers (NCIMS). That listing identifies the interstate milk shippers who have been certified by Milk Sanitation Rating Officers (SROs) as having attained the necessary milk sanitation compliance and enforcement ratings. The ratings are based on compliance with the requirements of the latest revision of the USPHS/FDA Grade "A" Pasteurized Milk Ordinance (PMO) and are made in accordance with the procedures set forth in the latest revision of the Methods of Making Sanitation Rating of Milk Shippers.
4. The Department proposes to add subsection (a)(3)(Pathogen testing laboratories). Subsection (a)(3) provides specific standards that must be attained by laboratories that conduct pathogen specific testing required by the regulations. It requires laboratories conducting pathogen testing to have received accreditation to the ISO/IEC 17025 standard, from a national third-party laboratory accrediting body that is a full member of the International Laboratory Accreditation Cooperation (ILAC) and a signatory to the ILAC mutual recognition arrangement. This

proposed amendment helps to establish uniform standards across the industry and assure proper, legally defensible, and valid testing.

5. The Department proposes to add subsection (a)(4)(Alternate laboratory methods) which provides that the Department may evaluate and approve alternative laboratory sampling and testing standards and procedures concerning bacteriological analysis of milk, milk products and manufactured dairy products. Approved methods would be published in the Pennsylvania Bulletin. This amendment would provide some flexibility for “Alternate Laboratory Methods” as new testing standards and techniques, proven to be just as effective as those currently followed, may come available in the future. Section 16 of the act of July 2, 1935 (P.L. 589, No. 210, §16) (31 P.S. §660), known as the Milk Sanitation Law (Act) provides the Secretary authority to, “...make requirements concerning the number and character of bacteria in milk, milk products and manufactured dairy products after hearing. Bacteriological analysis of milk, milk products and manufactured dairy products shall be made under the supervision of a laboratory, the equipment and director of which have been approved by the Secretary of Agriculture. The bacterial analysis of milk, milk products and manufactured dairy products shall be in accordance with..., unless special permission is given by the secretary for a modification of the above standard methods.”
6. The Department proposes to amend the title of subsection (b), to read “Laboratory reports.” The intent is to provide clarity that the standards under this section address laboratory reports. In addition, the Department proposes to split subsection (b) into three parts, (b)(1) addressing Pennsylvania-approved laboratory signatories, (b)(2) addressing other laboratories’ signatories and (b)(3) addressing reporting timetables for all laboratories.
7. The Department proposes to add subsection (b)(1)(Pennsylvania-approved laboratories) to this section. The standards for reports issued by Pennsylvania-approved laboratories and official laboratories were not changed from those that appear in the current regulations under subsection (b).
8. The Department proposes to add subsection (b)(2)(Other laboratories) to address signature standards for laboratories, other than Pennsylvania-approved dairy laboratories or an official laboratory, issuing reports of the results of laboratory examinations. The proposed change is intended to provide clarity and to assure uniform standards across the industry. The language of subsection (b)(2) establishes substantially the same signatory standards as those established in subsection (b)(1), allowing the laboratory director or person designated by the laboratory director to sign the laboratory reports. The only difference is that if the laboratory report is signed by someone other than the laboratory director or a designee, the signatory must be a person designated by the laboratory’s ISO/IEC standard accreditation documents. Pennsylvania may not specify a higher standard than that accepted by the industry.

9. The Department proposes to add subsection (b)(3)(Report timetable) to clarify and establish reporting time periods for all laboratories. The timetables are those required in the NCIMS Grade “A” program, or within 30 days of the test completion. This proposed amendment also addresses the timetable, 48 hours, for reporting results that are non-compliant with the standards of the PMO or the regulations. This is intended to provide clarity and a uniform standard for the industry to follow.
10. The Department proposes to amend subsection (c)(Pennsylvania-approved dairy laboratory director) by removing subparagraphs (c)(3)(i) and (ii) and adding subparagraphs (5),(6),(7) and (8).
11. The Department proposes to amend subsection (c) by removing subparagraph (i) standards that required the completion of a written examination as part of the criteria for becoming a provisionally certified dairy laboratory director as that is not required by the statute or the PMO. Subparagraph (ii) would no longer be necessary without a subparagraph (i) so the language will be incorporated into (c)(3). The language of what was subparagraph (ii) would be amended by adding language to require an onsite performance and facility evaluation that is “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.” The Department’s rationale for this revision is that it is already industry practice and the Bureau desires to codify current practice consistent with federal milk regulations standards including the PMO provisions.
12. The Department proposes to amend subsection (c) by adding subparagraphs (5), (6) and (7) which provide additional standards that a certified Pennsylvania-approved dairy laboratory director must follow. The language of subparagraph (c)(5) requires the director to continue to participate in the Department-conducted milk split sample proficiency program. Subparagraph (c)(6) requires the director to operate the Pennsylvania-approved laboratory in conformance with the standards of the Act (act of July 2, 1935, P.L. 589, No. 210) and the regulation, and subparagraph (c)(7) requires the director to assure all records of laboratory test results are accurate and in compliance with the standards of the Act and the regulations. These additions are intended to help assure compliance and accountability.
13. The Department proposes to amend subsection (c) by adding subparagraph (8) to clarify that any falsification of required records is a violation of the regulation. This will help to assure compliance and accountability.
14. The Department proposes to amend this section by adding subsection (d)(Refusal, revocation or suspension of approval of certification) which provides that upon written notice and opportunity for a hearing the Department may refuse, revoke or suspend a Pennsylvania-approved laboratory approval or a Pennsylvania-

approved laboratory director certification for any violation of the Act (act of July 2, 1935, P.L. 589, No. 210) or regulation.

Proposed addition of a new § 59a.6 (relating to approved sampler and weigher/sampler). The Department proposes a new section be added to the regulation which establishes certification criteria for an individual to be approved as a sampler or weigher/sampler consistent with the requirements established in the PMO. This new section is more specific in detailing current practices of the Department in fulfilling the standards established in § 59a.104(relating to certification of bulk milk collectors-weighers/samplers). This amendment would assure samplers and weigher/samplers are properly and uniformly trained thereby providing better service to the industry and assuring accountability now that the Department has assumed full responsibility for these certifications. By way of background, the Department had previously established a Memorandum of Understanding (MOU) with the Milk Marketing Board (MMB) to do a large percentage of the certification but, the MOU expired in 2019 and the MMB did not approve a renewal. The overall purpose of this new section is to align the regulation with the standards set forth in the PMO, provide for uniform certification standards and provide applicants with a general overview of the requirements for certification as a sampler or weigher/sampler. The proposed amendments require forms that will be provided by the Department. Those forms are attached to this proposed regulation. More specifically the Department proposes to:

1. Add subsection (a)(Application for approved sampler) which sets forth the manner by which a person may apply to the Department to be certified as an approved sampler. The Department will provide the certification application forms and the certification renewal forms.
2. Add subsection (b)(Application for weigher/sampler) which sets forth the manner by which a person may apply to the Department to be certified as a weigher/sampler. The Department will provide the certification application forms and the certification renewal forms.
3. Add subsection (c)(Criteria for approval) which includes three subparagraphs. Subparagraph (1) establishes the general criteria for certification as a sampler or weigher/sampler. The criteria include training and experience in the area of sampling milk, milk products and manufactured dairy products and passing a Department administered or approved field test to verify the applicant is utilizing proper sampling techniques. The Department added examples of the basic training or experience a person should have prior to applying for the position. Once the application is accepted the applicant must pass a field test, involving sampling technique, that is administered by the Department, or a Department approved certifying body. Subparagraph (2) sets forth additional criteria for a weigher/sampler certification, including training and experience in weighing milk for approval of the initial application, and once the applicant is accepted, the completion of a Department or Milk Marketing Board administered written examination with a final score of at least 70%. Subparagraph (3) provides

language that will allow the Department to modify the training and approval criteria to remain consistent with the provisions of the Grade “A” PMO, particularly Appendix B (related to milk sampling, hauling and transportation). This will help to assure samplers and weigher/samplers are consistently trained and certified thereby providing uniformity in sampling and weighing and sampling across the industry.

4. Add subsection (d)(Certificate) establishing that the Department will issue a certificate in the appropriate field (sampler or weigher/sampler) to any applicant meeting the standards established in subsection (c)(relating to criteria for approval).
5. Add subsection (e)(Duration of certificate; renewal) which establishes that certificates expire January 1 of each calendar. Subparagraph (1) of this subsection requires that applicants apply or reapply for a certificate by December 31 of the proceeding calendar year and Subparagraph (2) requires the applicant to provide verification of compliance with the continuing education requirements of the regulation.
6. Add subsection (f)(Continuing education and recertification requirements) which requires continuing education for certified samplers and weigher/samplers. Subparagraph (1) of subsection (f) establishes that a prerequisite to renewal of certification as a sampler or weigher/sampler is that the applicant attend a Department or Department-approved continuing education training course that meets the requirements established in Appendix B of the Grade “A” PMO. Subparagraph (2) of subsection (f) requires applicants to demonstrate proper sampling techniques to the Department every 24 months. This subsection is intended to help assure all samplers and weigher/samplers have up-to-date training and remain competent in the necessary skills to carry out their jobs.
7. Add subsection (g)(Refusal, revocation or suspension of certificate) which provides that the Department may, upon written notice and opportunity for a hearing, refuse, revoke, or suspend a certificate for any violation of the Act or the regulation.

Proposed addition of a new § 59a.7 (relating to pasteurization standards). This section provides specific standards for milk, milk products or manufactured dairy products that are sent for pasteurization. This section does not change the regulatory requirements enforced under the PMO and will provide clarity and ease of finding the requirements to the regulated community by referencing and providing a citation to the PMO pasteurization standard details within the regulation.

Proposed amendments to § 59a.12 (relating to permits). The Department proposes the following changes to § 59a.12:

Amend subsection (b)(relating to exceptions) by making the following changes to subparagraphs (3)(4) and (5):

1. In subparagraph (3) delete the broad reference to “store” and add clarity by adding “Retail Food Facility” or any other facility where such products are to be consumed on-premises...” In addition, delete the redundant, and now incorrect phrase “milk or milk products” and allows it to read “...when products have been purchased...” with “products” referring to the beginning of the sentences which clarifies it refers to “milk, milk products or manufactured dairy products.” Finally, the “manufactured dairy products” are added to the end of the sentence. This creates uniform language throughout the subparagraph clarifying it pertains to milk, milk products and manufactured dairy products.
2. Delete the current subparagraph (4) and “Reserve” that subparagraph. The same language appears in the Milk Sanitation Law at section 2 (31 P.S. § 646). This is redundant in the regulation because the facilities set forth are all retail food facilities that are addressed in subparagraph (3).
3. In subparagraph (5), deleted the phrase “..., and exempted from permit requirements in accordance with the act...” That phrase is unnecessary as the Act has a specific exemption for a person production and selling from a single cow. 31 P.S. § 646.
4. Amend subsection (j) by adding two sentences: one citing the standards and provisions of the Grade “A” PMO that require a permit for the interstate movement of milk products including the movement, manufacture, sale, storage, or receipt of milk products, and the second identifying when the Department will issue a permit. The Department added the information to provide additional clarity for the regulated community.

Proposed amendments to § 59a.13 (relating to adulterated or misbranded milk, milk products or manufactured dairy products). The Department proposes to make a small formatting change to the title of section 2 of the Grade “A” PMO to assure it matches the title set forth in the Grade “A” PMO.

Proposed amendments to § 59a.14 (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products). The Department proposes the following changes to § 59a.14:

1. Delete and “Reserve” subsections (a)(relating to department approval required), (b)(relating to approval process) and (c)(relating to changes of approved labels). The requirement for all Dairy labels to be approved by the Bureau is not a requirement under the statute and it is extremely time consuming and burdensome on the Bureau. Furthermore, no other food has to have the labeling approved by a regulatory entity at a federal or state level. The industry has the ultimate responsibility to make sure their labels are compliant with labeling standards

established by the Department and at the federal level. As with every other food under the Food Safety Act, if a label is non-compliant the Department would document that on an inspection and the firm would need to correct it. With regard to raw milk, the requirement for the Raw Milk permittees to seek label approval before using their labels was maintained. These small processors need guidance and it will be much easier to work with them prior to them printing large amounts of labels, than to force corrections if they are non-compliant. The Bureau will also continue to do ‘courtesy reviews’ of labels upon request, as it currently does with any other food processors.

2. Amendments to the language related to label requirements – in subsection (d) – were necessary to establish and ensure compliance with Pennsylvania and federal labeling standards, including the Milk Sanitation Law (act of July 2, 1935, P.L. 589, No. 210) (31 P.S. §§ 645-660g.), Food Safety Act (3 Pa.C.S.A. §§ 5721-5737) and Subchapter C. (relating to milk sell-by date and best-by date labeling) (3 Pa.C.S.A. §§ 5741-5747) and the Fair Packaging and Labeling Act (15 U.S.C. §§ 1451-1461). In addition, the Bureau of Food Safety and Laboratory Services clarified that “manufactured dairy products” must also meet the label requirements. Amendments were also made to replace any reference to “product” with the more specific references to “milk,” “milk product” or “manufactured dairy product.”
3. Amendments to subsection (e) setting forth the proper title of section 59a.16 of the regulation and removing the label requirement exclusion for raw milk for human consumption, addressed in section 59a.411 of the regulation.
4. The addition of subparagraphs (1) and (2) to subsection (f) (regarding false and misleading material), for clarity and the purpose of consumer protection. Subparagraph (1) clarifies that labels containing additional claims, such as A2A2, organic, kosher, grass fed or other such marks or endorsements must be accompanied by documentation supporting such claims and the documentation must be provided to the Department upon request. Subparagraph (2) provides that certification issued by a national or third-party accreditation or certification process must be maintained by the permittee and must support the marks, words or endorsements used on the label. Proof of certification must be provided to the Department upon request.
5. Amend subsection (g) by changing the word “regarding” to “relating to” in the PMO section reference.

Proposed amendments to § 59a.15 (relating to labeling: milk dating). The Department proposes the following changes to § 59a.15:

1. Clarification of which entities are included under this section by adding the more encompassing “retail food facility” and providing additional examples of farmers markets and roadside stands which commonly provide milk to consumers.

2. Addition of a new subsection (b.1) that specifies “sell by” and “best by” date limitations of 17 days which is in accordance with recently passed legislation found at 3 Pa.C.S.A §§ 5741-5747.
3. Provisions for both a “sell by” and “best by” date. These provisions are proposed to be added to subsections (a),(b),(b.1) and (c) and are in accordance with recently passed legislation relating to milk sell-by date and best-by date labeling, found at 3 Pa.C.S.A §§ 5741-5747, allowing for a “best by” date designation.
4. An additional process, in subsection (f), to petition the Department for approval to utilize a “sell by” or “best by” date that is greater than the 17-day period, as allowed by Chapter 57, Subchapter C (relating to milk sell-by date and best-by date labeling) (3 Pa.C.S.A §§ 5741-5747), established by the regulation. The process contains strict provisions for sampling, testing methodology, bacterial limits and storage, as well as authorizing the Department to take regulatory samples and view results of all testing. These provisions provide for a safe product while at the same time reducing food waste.
5. An amendment to subsection (e)(relating to monitoring by the permitholder and the department), including adding “the permitholder and” to the title to denote the permitholder now has monitoring duties, to require, under subsection (e)(1), the permit holder to sample and submit milk for routine monitoring testing dependent on whether the permitholder uses sell by or best by dates of 17 days or less or sell by and best by dates of greater than 17 days. Subsection (e)(1.1) provides the Department discretion to monitor permitholders through the pulling and testing of samples. Subsection (e)(2) further clarifies the testing methodology to be utilized and subsection (e)(3) establishes the process for sampling and retesting milk that exceeds bacterial limits for pasteurized milk. Subsection (e)(4) was amended by adding a header to distinguish it as providing the process for resumption of a 17-day or less sell by or best by date, the language was clarified to require the submission of 3 samples in accordance with the requirements of section 5746(d)(2) and 5744(b)(3)(i) of the subchapter relating to milk sell-by date and best-by date labeling (3 Pa.C.S.A. §§ 5746 (b)(3)(i) and (d)(2)) and the language was amended to be consistent with the provisions of section 5746(b)(relating to methodology) that requires samples to be submitted to a Pennsylvania-approved dairy laboratory. Finally, subsection (e)(5) establishes sample submission standards for reapplying to reinstate an extended sell by or best by date, and subsection (e)(6) provides that test results must be submitted to the permitholder and the department.

Proposed amendments to § 59a.16 (relating to markings, sealing, documentation and inspection requirements for vehicles containing milk, milk products or manufactured dairy products). The Department proposes the following changes to § 59a.16:

1. The section name is changed to better reflect the standards set forth in the section and to add manufactured dairy products since, the substantive provisions of the section add and thereby clarify that manufactured dairy products are also regulated under these provisions.
2. Subparagraph (c)(12) clarifies the product Grade references “Grade A” products to clarify the provisions apply to Grade “A” and not non-grade “A” milk.
3. Added subsection (g)(relating to vehicle or milk tank truck inspection). The subsection provides clarity for the industry by adding language in accordance with the PMO, Appendix B, Section VIII (relating to milk tank truck permitting and inspection), which requires the Department inspect all vehicles transporting raw, heat-treated or pasteurized milk, milk products or manufactured dairy products at least every 24 months, or sooner if violations are found.
4. Added subsection (h)(relating to reporting and inspection). This provision relates to subsection (g) by requiring haulers and milk plants to provide, on forms supplied by or approved by the Department, an annual report of vehicles and milk trucks in their fleet and making milk trucks and vehicles available for inspection by the Department.
5. Added subsection (i)(relating to proof of inspection). Again, in accordance with subsection (g) which, requires inspections, this subsection provides that upon a compliant inspection the Department will issue and apply a sticker to each vehicle or milk truck passing inspection, indicating such compliance and setting for the expiration date of the valid inspection.
6. Subsection (f)(relating to reference to applicable provisions of the Grand “A” PMO) was (Reserved.) and recodified as (j) because of the other amendments. This allowed the regulations to have a proper order and clarity. In addition, the provisions of what had been subsection (f) were amended to update the applicable provisions of the Grade “A” PMO, by adding a reference to Appendix B of the Grade “A” PMO.

Proposed amendments to § 59a.17 (relating to inspection of dairy farms and milk plants). The Department proposes the following changes to § 59a.17:

1. Deletion of a sentence related to inspection of raw milk producers in subsection (a). Raw milk is addressed later in the regulations.
2. Addition of a standard requiring the bulk milk tank of the producer to be empty for any initial or change of market inspection.
3. Other changes are minor and reflect clarity changes, such as setting forth a “relating to...” phrase when an Appendix or section of the PMO is mentioned.

Proposed amendments to § 59a.18 (relating to sampling and examination). The Department proposes the following changes to § 59a.18: The majority of amendments to this section are minor clarity changes, such as setting forth a “relating to...” phrase when an Appendix or section of the PMO is mentioned. The Department proposes to add language to subsection (a) requiring laboratories to be compliant with the requirements of section 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results). Therefore, the Department proposes to delete what would be redundant language in subsection (a), requiring a laboratory to be listed with the NCIMS or to 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, or the Department.”

Proposed amendments to § 59a.19 (relating to standards for grade “A” milk for pasteurization, ultrapasteurization or aseptic processing). The Department proposes the following changes to § 59a.19: The one amendment to this section is a minor clarity change setting forth a “relating to...” phrase when a section of the PMO is mentioned.

Proposed amendments to § 59a.20 (relating to standards for grade “A” pasteurized, ultrapasteurized and aseptically processed milk and manufactured dairy products). The Department proposes the following changes to § 59a.20:

1. The title of the section was changed to reflect it covers manufactured dairy products, as well as milk and that it covers all milk whether Grade “A” or non-grade “A” milk. The words “Grade A” have been removed as the standard applies to all the milk and manufactured dairy products produced in the Commonwealth, whether from Grade “A” milk or non-grade “A” milk. Non-grade “A” milk may be pasteurized, ultrapasteurized or aseptically processed. It may also be utilized for manufactured dairy products. The Department also changed the title in the Section header.
2. Subsection (a) reflects that same change.
3. Subsection (b) reflects a change to “(relating to...)” which is a proper formatting amendment.
4. Changes to subparagraphs (b)(14), (16) and (20) reflect amendments to the terms of the Grade “A” PMO they fall under.

Proposed amendments to § 59a.21 (relating to standards). The Department proposes the following changes to § 59a.21:

1. The title of subsection (a) was changed to reflect it covers manufactured dairy products, as well as milk. The term “milk products” in the Milk Sanitation Law and in the Milk Sanitation regulations includes ice cream. The definition of “milk products” differ between the Milk Sanitation Law and the Grade “A” PMO. The

definition under the Milk Sanitation Law and its regulations states, “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.” The PMO defines “milk products” in a manner that excludes ice cream or frozen desserts. Therefore, to include milk products under this subsection would be inconsistent with the PMO. The standards for “milk products” are established under subsection (b) and (c) of Section 59a.21.

2. The rest of the amendments, with the exception of the Somatic Cell Count exception in subsection (a), reflect formatting (“relating to...”) changes, including manufactured dairy products and changes to reflect amendments to the Grade “A” PMO section numbers and titles.
3. The exception, in subsection (a), to the Somatic Cell Count reflects and is consistent with negotiated changes with the industry. These occur throughout the proposed regulation.

Proposed amendments to § 59a.22 (relating to animal health). The Department proposes a minor formatting change.

Proposed amendments to §59a.23 (relating to milk, milk products and manufactured dairy products which may be sold). The Department proposes the following changes:

1. The title of the section was changed to reflect that it covers manufactured dairy products, as well as milk and milk products.
2. The rest of the proposed amendments reflect minor formatting changes and changes to reflect amendments to the title of section 9 of the Grade “A” PMO.

Proposed amendments to § 59a.24 (relating to transferring; delivery containers; cooling). The Department proposes a minor formatting change and changes to reflect amendments to the title of section 10 of the Grade “A” PMO.

Proposed amendments to § 59a.25 (relating to milk, milk products and manufactured dairy products from points outside this commonwealth). The Department proposes a minor formatting change to subsection (b) and changes to reflect amendments to the title of section 11 of the Grade “A” PMO.

Proposed amendments to § 59a.26 (relating to plans for construction and reconstruction). The Department proposes a minor formatting change to subsection (b).

Proposed amendments to § 59a.27 (relating to plans for personal health). The Department proposes a minor formatting change.

Proposed amendments to § 59a.28 (relating to procedure when infection or high risk of infection is discovered). The Department proposes the following changes to §59a.28:

1. Clarity to assure inclusion of “manufactured dairy products” in the regulated products throughout the section.
2. Subsection (a)(1), an amendment to reflect the actual sections of the Grade “A” PMO, sections 13 (relating to personnel health) and 14 (relating to procedure when infection or high risk of infection is discovered), that apply to immediate exclusion of a person from handling milk, milk products or manufactured dairy products, and not section 15, which relates enforcement. .
3. Subsection (b), an amendment to reflect the actual section of the Grade “A” PMO, section 14 (relating to procedure when infection or high risk of infection is discovered), and not section 16 (relating to penalty), applies.

Proposed amendments to § 59a.102 (relating to milk permits). The Department proposes minor changes for clarity to assure milk products and manufactured dairy products are included in this section.

Proposed amendments to § 59a.103 (relating to plant inspection). The Department proposes minor changes for clarity to assure milk products and manufactured dairy products are included.

Proposed amendments to § 59a.104 (relating to certification of bulk milk collectors-weighers/samplers). The Department proposes to delete and “Reserve” this section. The Department proposes to delete the broad and somewhat vague standard contained in subsections (a) and (b) and instead rely on the new and very specific certification and training provisions for samplers and weigher/samplers which is established in section 59a.6 (relating to approved sampler and weigher/sampler) of the proposed regulation.

Proposed amendments to § 59a.105 (relating to approved milk graders). The Department proposes to remove and “Reserve” this section. No current approved milk graders exist and the current PMO or USDA recommended requirements have no provisions for such graders.

Proposed amendments to § 59a.106 (relating to basis). The Department proposes a minor change, removing “sediment content” from the raw milk quality classification, consistent with deletion of §59a.108(relating to sediment content classification), and has set forth the sections of the regulation (59a.107, 59a.109, 59a.110 and 59a.111) that establish the appearance and odor, bacterial estimate classification, somatic cell count and drug residue level standards.

Proposed amendments to § 59a.107 (relating to appearance and odor). The Department proposes to break the section into subsection (a) and subsection (b). Subsection (a) provides that approved samplers shall be responsible for ensuring that raw milk for manufacturing purposes meets the requirements of the section for appearance and odor. Subsection (b) contains the current language of the section but, the Department

proposes to delete the reference to section 59a.108 (relating to sediment content classification) since section 59a.108 is proposed to be deleted and reserved. Section 59a.108 is proposed to be deleted because it establishes sediment content classifications which the Department will no longer require. The Department has also removed the word “excessive” from the language of subsection (b) as that term is too broad. In practice if the inspector can visually see any sediment in the milk, then the milk should be rejected.

Proposed amendments to § 59a.108 (relating to sediment content classification). The Department proposes to delete this provision and “Reserve” the section. The Department proposes, consistent with section 59a.106 and section 59a.107 amendments, to remove all standards regarding sediment content, other than visual examination under section 59a.107, as sediment content is no longer used to determine quality of milk for manufacturing under the current PMO, and is only a recommended requirement under the current United State Department of Agriculture, Agricultural Marketing Service, Dairy Programs, titled *Milk for Manufacturing Purposes and its production and Processing-Recommended Requirements*..

Proposed amendments to § 59a.109 (relating to bacterial estimate classification). The Department proposes two minor changes. First, the addition of language allowing other laboratories that are compliant with section 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) to analyze milk samples. The proposed compliant laboratory standard has been added throughout the regulation and expands the scope, while still requiring the same high standards, of laboratories sanctioned to test milk samples. Second, inserting the word “producer” to clarify that any bacterial count in excess of 500,000 bacteria per milliliter will be considered a producer violation.

Proposed amendments to § 59a.110 (relating to somatic cell count). The Department proposes the following changes to § 59a.110:

1. The Department proposes to add language allowing other laboratories that are compliant with section 59a.5 of the regulations (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) to analyze milk samples. The compliant laboratory standard has been added throughout the regulation and expands the scope, while still requiring the same high standards, of laboratories sanctioned to test milk samples. This clarifies what is happening in the industry and provides a service to producers that border other states.
2. In accordance with changes requested by the regulated community, the Department proposes to reduce the somatic cells per millimeter from 750,000 to 500,000. The industry is already requiring these lower counts from their producers, the lower somatic cell counts make the milk easier to pasteurize and process and helps to insure a safer raw milk product.

3. For clarity, the Department proposes to add “sheep” to the somatic cell count standards that previously only included “goat” milk.
4. For clarity, the Department proposes to insert the word “producer” to clarify that any excess somatic count violations will be considered a producer violation.

Proposed amendments to § 59a.111 (relating to drug residue level). The Department proposes a minor formatting change and to insert “Milk products...” in subsection (a) to clarify milk products are regulated under this section. The Department proposes a change to subparagraph (a)(1)(v) to clarify that all sample results, positive and negative, are to be reported.

Proposed amendments to § 59a.112 (relating to rejected milk). The Department proposes to delete language referencing sediment content. The Department proposes, consistent with proposed amendments to sections 59a.106, 59a.107 and 59a.108, to remove all standards regarding sediment content.

Proposed amendments to § 59a.113 (relating to suspended milk for manufacturing). The Department proposes the following changes to § 59a.113:

1. The Department proposes to delete and “Reserve” the language in subsections (1) and (2) referencing now deleted section 59a.108 and sediment content.
2. The Department proposes, consistent with proposed amendments to sections 59a.106, 59a.107, 59a.108 and 59a.112, to remove all standards regarding sediment content.
3. The Department proposes to make changes consistent with the proposed reductions to somatic cell counts and the addition of sheep in other sections of the proposed regulation.

Proposed amendments to § 59a.114 (relating to inspections and quality testing of milk from producers). The Department proposes the following changes to § 59a.114:

1. Consistent with proposed amendments to section § 59a.17 (relating to inspection of dairy farms and milk plants, in subsection (a)(1) the Department proposes to add the requirement that initial and change market inspections be done with an empty bulk milk tank.
2. The Department proposes to delete and “Reserve” subparagraphs (b)(2) and (c)(2) referencing section 59a.108.
3. The Department proposes, consistent with proposed amendments to sections 59a.106, 59a.107, 59a.108, 59a.112 and 59a.113, to remove all standards regarding sediment content.

4. The Department proposes a minor formatting change to subsections (c) and (d).

Proposed amendments to § 59a.116 (relating to abnormal milk). The Department proposes the following changes to § 59a.116:

1. The Department proposes that all references to “cows” or “dairy cattle” be changed to “dairy animals” for clarity and consistency.
2. The Department proposes a minor formatting change to subsection (c).

Proposed amendments to § 59a.201 (relating to farm inspection). The Department proposes the following changes to § 59a.201:

1. The Department proposes, consistent with proposed amendments to section §59a.17 (relating to inspection of dairy farms and milk plants), to amend subsection (1) by adding the requirement that initial and change market inspections be done with an empty bulk milk tank.
2. The Department proposes to delete the language in subsection (2) referencing sediment content. The Department proposes, consistent with sections 59a.106, 59a.107, 59a.108, 59a.112, 59a.113 and 59a.114 amendments, to remove all standards regarding sediment content.
3. The Department proposes to amend subsection (3) by adding “email” as an accepted means of notification.

Proposed amendment to § 59a.202 (relating to milking facilities and housing). The Department proposes to remove the word “pools” from subsection (e), as it is redundant and is covered by the “standing water” standard.

Proposed amendments to § 59a.205 (relating to milkhouse and milkroom). The Department proposes to amend subsection (b) to add insects to the list of contaminants that must be controlled.

Proposed amendments to § 59a.207 (relating to water supply). The Department proposes a minor formatting change to this section.

Proposed amendments to § 59a.302 (relating to buildings). The Department proposes the following changes to § 59a.302:

1. The Department proposes to amend subsection (b) by adding self-closing to the requirements for outside doors opening into processing rooms and adding insects to the list of contaminants that must be controlled.
2. The Department proposes to amend subsection (f)(5) by removing the language, “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,” as the required standard and replacing it with the updated standards established in § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results). This is consistent with the changes made to other sections related to laboratory standards.

Proposed amendments to § 59a.303 (relating to facilities). The Department proposes to amend subsection (a) by removing the language “twice a year” and replacing it with “every six months.” This adds clarity to the standard and assures the bacteriological examinations are spread out over the year.

Proposed amendments to § 59a.307 (relating to protection and transport of raw milk and cream). The Department proposes to remove the word “milkstone” from subsection (a) and replaced it with “milk residue” for clarity.

Proposed amendment to § 59a.308 (relating to raw product storage). The Department proposes to amend subsection (e)(4) by replacing the word “license” with the word “permit” since a plant holds a “permit” under the Act and that is what would be affected.

Proposed amendments to § 59a.309 (relating to pasteurized, ultrapasteurized or aseptically processed and packaged products). The Department proposes to amend § 59a.309 to cite to the pasteurization standards that are now set forth in the substantive provisions of the regulation at § 59a.7 (relating to pasteurization standards), instead of citing a definition in § 59a.2 (relating to definitions) and to change the word “insure” to “ensure” for proper grammar purposes.

Proposed amendments to § 59a.310 (relating to composition and wholesomeness). The Department proposes to amend § 59a.310, to assure consistency and clarity, by adding “milk,” “milk products” and “manufactured” dairy products throughout, adding a citation to applicable federal regulations at 21 CFR, Chapter I, Subchapter B and adding the requirement of adherence to Commonwealth regulations and statutes.

Proposed amendments to § 59a.313 (relating to plant records). The Department proposes to amend § 59a.313 by deleting language in subsection (1) referring to “Sediment.” The proposed change is consistent with proposed amendments to sections 59a.106, 59a.107, 59a.108, 59a.112, 59a.113, 59a.114 and 59a.201 removing all standards regarding sediment content.

Proposed amendments to § 59a.314 (relating to packaging and general identification). The Department proposes to amend § 59a.314, to assure consistency and clarity, by adding “milk,” “milk products” and “manufactured” dairy products throughout.

Proposed amendments to § 59a.315 (relating to storage of finished product). The Department proposes to amend § 59a.315, to assure consistency and clarity, by adding

“milk,” “milk products” and “manufactured” dairy products throughout and amending the structure of the sentence for ease of reading and clarity.

Proposed amendments to § 59a.317 (relating to Federal Food Safety Regulations).

The Department proposes to amend the current regulations by adding § 59a.317. The purpose of the proposed amendment is to add clarity for the regulated community related to applicable statutory and regulatory standards. The Food Safety Act requires the Department to adopt all federal regulations related to food. This proposed section sets forth those regulatory requirements.

Proposed amendments to § 59a.348 (relating to operations and operating procedures: packaging, repackaging and storage). The Department proposes the following changes to § 59a.348:

1. The Department proposes to amend this section by adding “manufactured” dairy products to subsection (a).
2. The Department proposes to correct the wording of subsection (b) to reference “palletizing” not “palleting.”
3. The Department proposes to correct subsection (d)(1) by removing the reference to “milk” products. It now refers to all packaged dry products.

Proposed amendments to § 59a.350 (relating to operation and operating procedures: checking quality). The Department proposes to amend this section by adding the term “milk products” to assure dried milk products, such as dried ice cream mix, are included in the products regulated under this section. In addition, the Department replaced “and” with “to include” related to dry milk products because those products are part of milk or manufactured dairy products and the “and” made it sound like it was a separate product to be regulated.

Proposed amendments to § 59a.351 (relating to operations and operating procedures: requirements for instant nonfat dry milk). The Department proposes to amend subsection (a) through the addition of language allowing other laboratories that are compliant with section 59a.5 of the regulations (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) to sample and test nonfat dry milk samples. The proposed compliant laboratory standard has been added throughout the regulation and expands the scope, while still requiring the same high standards of laboratories sanctioned to test milk samples.

Proposed amendments to § 59a.363 (relating to operations and operating procedures). The Department proposes to amend § 59a.363 by adding language exempting cream used for the production of raw milk butter from the pasteurization standards, established in subsection (a)(1)(i), for the production of butter since, pasteurization standards do not apply to raw milk.

Proposed amendments to § 59a.371 (relating to rooms and compartments). The Department proposes to amend § 59a.371 by removing the random text at the end of subsection (c).

Proposed amendments to § 59a.372 (relating to equipment and utensils). The Department proposes to amend § 59a.372 by adding subsections (m),(n),(o) and (p), which establish construction and cleaning standards for conveyors, grinders and shredders, cookers and fillers used in the manufacturing of cheese and related products. These standards are already included in the current regulation at section 59a.381(b)-(e). The standards are being moved to this section because the purpose and regulatory requirements of the subchapter are being changed from addressing pasteurized processed cheese, to addressing milk products, to include ice cream, frozen desserts and related products. In addition, section 59a.372 of the current regulation at subsection (a) states, “*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 shall met.” Therefore, the additions are intended to provide standards for other equipment and utensils that are utilized in the manufacture of cheese that are not covered or set forth in the current regulation at section 59a.372. This is to help to assure public safety by establishing standards for all equipment utilized and assuring they can be properly cleaned and sanitized, just as the equipment and utensils were covered, previously, under section 59a.381.

Proposed amendments to § 59a.373 (relating to operations and operating procedures). The Department proposes the following changes to § 59a.373:

1. The Department proposes to amend subsection (a)(1) by deleting the reference to specific temperature and time standards and replacing it with language referencing the pasteurization standards established in § 59a.7 (relating to pasteurization standards).
2. The Department proposes to amend subsection (a)(2) by deleting the reference to HTST pasteurization units and instead broadly referring to any type of pasteurization unit since there are multiple types of pasteurization units and all must be properly equipped to assure pasteurization.
3. The Department proposes to amend subsection (b) by breaking it into separate subsections for clarity and regulatory purposes and adding subsection (b)(3) creating standards for the labeling of “raw aged” cheese.
4. The Department proposes to add new subsections (c.1), (c.2) and (d.1), creating standards for forming containers, filling containers, and trimming and cleaning cheese. The addition of subsection (c.1) (relating to forming containers) was added for clarity and to address sanitation in the handling and storage such containers. The addition of subsection (c.2) (relating to filling containers) was added for clarity and to address sanitation and proper weight controls during the

filling of the containers and the addition of subsection (d.1) (relating to trimming and cleaning) was added for clarity and to address sanitation and cleaning of natural cheese.

5. The Department proposes to amend subsection (e) (relating to general identification) by adding language requiring each consumer sized container of cheese to include the wording “raw milk,” “made with raw milk” or similar identifying language and the number of days the cheese was aged to the labeling requirements.

Proposed amendments to § 59a.381 (relating to equipment and utensils). The Department proposes the following changes to § 59a.381:

1. The standards for “Supplemental Requirements For Plants Manufacturing and Packaging Cheese” are addressed in sections 59a.371-59a.373. The Department has chosen to amend the title of this subchapter to include milk products and no longer addresses pasteurized processed cheese. The title was changed to “Supplemental Requirements For Plants Manufacturing, Processing and Packaging Milk Products, To Include Ice Cream, Frozen Desserts And Related Products.” The Department proposes to delete the reference to “cheese” in subsection (a) and add a reference to “milk.” This section already references the proper section, 59a.304, of the regulations concerning standards for equipment and utensils used for milk and manufacture of dairy products.
2. The Department proposes to delete and “Reserve” subsections (b) through (e) and remove the “(a)” for subsection (a) since there will only be one paragraph for this section.
3. The Department proposes to delete and “Reserve” subsections (b),(c),(d) and (e) related to specific construction and cleaning requirements for conveyors, grinders or shredders, cooker and fillers utilized for handling and processing “milk” products, as those standards are already addressed in subsection 59a.304 which relates to equipment and utensils utilized for milk and manufacture of dairy products.

Proposed amendments to § 59a.382 (relating to operations and operating procedures). The Department proposes the following changes to § 59a.382:

1. The Department proposes to delete and “Reserve” subsections (a),(b),(c) and (d), as they reference standards for cheese, which are covered earlier in the regulations, so these provisions are redundant. In addition, they no longer apply since this section now covers milk products.
2. The Department proposes to add new provisions, subsections (d.1),(d.2),(d.3),(f),(g) and (h) establishing standards for milk products related to

pasteurization of milk products, purchase of pasteurized mixes for production of milk products, filling containers, freezer storage, sampling and inspections.

3. The Department proposes to keep old subsection (e)(related to closing and sealing containers), as its provisions may be applied to milk products.

Proposed amendments to § 59a.401 (relating to raw milk; general). The Department proposes to amend § 59a.401 by adding “raw milk butter” to the permitting, testing and inspection requirements as new provisions related to raw milk butter are proposed to be established later in this Subchapter.

Proposed amendments to § 59a.402 (relating to raw milk; prohibitions). The Department proposes the following changes to § 59a.402:

1. The Department proposes to add language to subsection (a) clarifying that the term “sell” applies to selling, exchanging, or delivering to consumers that are members of a “buyer’s club,” cow share herd agreement or other type of membership purchasing group. These type of groups and entities have arisen since the passage of the current regulation and need to be addressed to add clarity.
2. The Department proposes to amend subsection (b) by breaking a long paragraph down into separate subparagraphs of regulatory areas covered, and add clarifying language related to the actions authorized by a raw milk permit. The Department also proposes to remove the provisions related to obtaining an additional raw milk permit for cheese and related cheese products. Raw milk aged cheeses are addressed under § 59a.373 and are allowed under the CFR provisions, at 21 CFR, Part 133, to be manufactured and sold in interstate commerce if the cheese has been aged at least 60 days. Therefore, the sale of raw milk aged cheeses is not unique to Pennsylvania producers. However, cheese manufacturers are still required to hold a milk permit under 21 CFR, Part 133, Subpart B, because they are producing a manufactured dairy product but, would not be required to hold a special raw milk permit.
3. The Department proposes to establish a new provision – 59a.402(b)(2) – allowing a raw milk permitholder to obtain an additional permit authorizing the production and sale of raw milk butter manufactured from raw milk and setting standards for the manufacturing, processing, packaging, storage and equipment and utensils utilized and operating procedures applicable to raw milk butter.
4. The Department proposes to add the term “raw milk butter” to subsection (c) (relating to compliance with testing and documentation requirements) to assure compliance with those standards.

Proposed amendments to § 59a.404 (relating to requirements for issuance of a raw milk permit). The Department proposes to amend § 59a.404 (e)(1)(ii) by clarifying the submission, testing and analyzing process for new raw milk permit applicants and

deleting “or the Department for analysis” since the new language provides the type of laboratories that may be utilized.

Proposed amendments to § 59a.405 (relating to sanitation). The Department proposes a minor formatting change to § 59a.405.

Proposed amendments to § 59a.408 (relating to regular testing of raw milk and raw milk butter for human consumption). The Department proposes the following amendments to § 59a.408:

1. The Department proposes to amend the title of the section to clarify it includes standards for raw milk butter.
2. The Department proposes to amend subsection (a) by adding the term “raw milk butter.”
3. The Department proposes to amend subsection (b) by adding the term “raw milk butter” and adding the standards for analysis set forth in §59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results).
4. The Department proposes to make minor changes to the chart – “Raw Milk Testing Schedule and Standards” – including, adding “cfu” prior to per milliliter as the unit of measure throughout, reducing the somatic cell count to 500,000 per milliliter consistent with changes made throughout the regulation and adding “sheep” to the somatic cell count requirement for goats to be consistent with changes made throughout the rest of the regulation. Reducing the somatic cell count is in the interest of the general public because it lowers the bacteria count and enhances the quality of the milk.
5. The Department proposes to add subsection (d) (relating to raw milk butter testing schedule and standards) to set forth the Commonwealth regulatory requirements for testing intervals and bacterial coliform and yeast and mold standards per gram. The proposed standards are consistent with federal CFR standards for butter from pasteurized milk.

Proposed amendments to § 59a.409 (relating to violations of raw milk testing standards). The Department proposes the following changes to § 59a.409:

1. The Department proposes to amend subsections (d)(3) and (4) to provide a reference to §59.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories; reports of results).
2. The Department proposes to amend subsections (d)(4) and (5), to provide language consistent with other provisions of the regulation requiring there be an empty tank between samples being taken.

3. The Department proposes to add subsection (e) (relating to raw milk butter not meeting testing standards) for purposes of clarity and to provide a standard and procedure to be followed by the producer that has not met microbiological limits for the raw milk butter. This also helps to assure consumer health.

Proposed amendments to § 59a.411 (relating to label content review by the Department). The Department proposes the following changes to § 59a.411:

1. The Department proposes to add raw milk butter labeling standards and requirements to this section.
2. The Department proposes to add a reference to what laboratories meet the testing standards of the regulations at §59.5(relating to standards for Pennsylvania-approved dairy laboratories, official laboratories; reports of results).
3. The Department proposes to add “best by” language to this section.
4. The Department proposes to amend subsection (a)(3)(i) by adding subparagraphs (A) and (B) for ease of reading and clarity and adding clarifying language and standards to subsections (a)(3)(i)(A) and (B) related to both a “sell by” and “best by” date.
5. Consistent with previous proposed amendments to section 59a.15 (relating to labeling: milk dating) the Department proposes to amend subsection (a)(3)(iv) to require the permitholder to submit samples and have them tested in accordance with the standards established at section 59a.15 of the regulations and at a laboratory meeting the requirements of section 59a.5 of the regulations (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results). In addition, the Department removed the provision that requires it to take at least one raw milk sample from each permitholder each year. The language requiring periodic testing remains. The language that provides discretion to periodically take samples and have them tested, addresses both raw milk and raw milk butter and establishes a standard and procedure a permitholder must follow for re-sampling and re-testing when product fails to meet bacterial and coliform standards.
6. The Department proposes to add subsection (c) establishing specific label standards for raw milk butter.

Proposed amendments to § 59a.412 (relating to inspection, sampling and testing by the Department). The Department proposes to amend § 59a.412 by adding raw milk butter to the inspection, sampling and testing standards of this section.

Proposed amendments to § 59a.413 (relating to enforcement: suspension or revocation of a raw milk or raw milk butter permit).

1. The Department proposes to amend § 59a.413 by adding raw milk butter standards to all provisions of this section and changing the titled of the section to reflect that change.
2. The Department proposes to amend subsection (b)(2)(i) in order to address initial enforcement procedures when a raw milk permitholder or raw milk butter permitholder, or both, voluntarily complies with a request from the Department to cease sales. It establishes that the Department will consider such action as mitigating factor in determining any penalty or sanction issues.
3. The Department proposes to amend subsection (b)(2)(ii) to establish the enforcement measures the Department will follow when a raw milk permit holder or a raw milk butter permit holder, or both, does not choose to comply with a request from the Department to voluntarily cease the sale of raw milk, raw milk butter, or both. It provides the regulated community with clarity related to potential Department enforcement actions.
4. The Department proposes to amend subsection (c) to make it clear to the regulated entity that the Department owns the raw milk permit or raw milk butter permit that was issued, and that such permit must be returned to the Department, after the permitholder has been afforded written notice and opportunity for a hearing, upon a proposed suspension or revocation of the raw milk permit or raw butter permit issued to the regulated entity. Where a suspension has been imposed the Department will promptly return the raw milk permit, or raw milk butter permit, or both, to the permitholder at the end of the suspension period.

Proposed amendments to § 59a.501 (relating to interrelatedness with the Retail Food Facility Safety Act and the Food Safety Act). The Department proposes to amend § 59a.501 by adding provisions and citations referencing the Retail Food Facility Safety Act (3 Pa.C.S.A. §§ 5701-5714) and the Food Safety Act (3 Pa.C.S.A. §§ 5721-5737 and their applicable regulations.

Persons Likely to be Affected

The number of people directly involved with Pennsylvania’s dairy industry is difficult to quantify, but the following provides an estimate: Business - approximately 8,500 dairy farms that produce milk within the Commonwealth, approximately 35 Grade “A” milk processing plants, approximately 150 Grade “A” Bulk Tank Units (permitted farm groups), approximately 120 permitted raw milk facilities, approximately 125 dairy manufacturing (non-Grade A) facilities, 35 Interstate Milk Shippers program certified laboratory facilities, 120 drug residue testing facilities, 32 manufacturers of single service containers and closures, and 100 milk hauling companies. Individuals – approximately 1500 approved milk samplers/weighers, 100 approved farm inspectors, 70 approved dairy laboratory directors and 750 certified laboratory analysts.

Fiscal Impact

Commonwealth

This proposed rulemaking would have some minor positive fiscal impact upon the Commonwealth. However, for the most part the proposed changes to the regulations are to provide consistency with the federal standards and clarity. The regulation will enhance public health and safety, maintain modern state-of-the-science milk sanitation standards in Pennsylvania, and provide clarity to the dairy industry where ambiguity existed. The proposed regulatory amendments will not substantially affect the ongoing business practices or regulatory standards of the industry.

Political Subdivisions

This proposed rulemaking would have no appreciable fiscal impact on political subdivisions.

Private Sector

This proposed rulemaking would have some appreciable fiscal impact on the private sector. Pennsylvania's 800-plus milk permit holders will benefit from the regulation, as well as the 35 approved dairy laboratories. Other businesses will also benefit through the increased availability of desired dairy products. The regulation will provide for further economic opportunities for the regulated industry by providing a path for extending shelf life dating on pasteurized milk and allowing for production of raw milk butter. Approved dairy testing laboratories will benefit from increased revenue from shelf-life testing requirements and elimination of laboratory director exam requirements.

General Public

This proposed rulemaking will benefit nearly all Commonwealth residents, since the majority of Pennsylvania's 12.8 million citizens are consumers of milk and dairy products, by protecting the public health, while expanding the availability of milk and raw milk products available to the consumer. It will enhance public health and safety by maintaining modern state-of-the-science milk sanitation standards in Pennsylvania.

Paperwork Requirements

This proposed rulemaking will not add to paperwork requirements for the regulated community. The various documents that comprise licensing and label applications and review will remain constant, with perhaps slight changes such as allowing for raw milk butter production. The proposed rulemaking does not add to those documents.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on May 28, 2024 the Department submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria in section 5.2 of the Regulatory Review Act (71 P. S. § 745.5b) which have not been met. The Regulatory Review Act specifies detailed procedures for review of such comments, recommendations or objections by the Department, the General Assembly and the Governor prior to final publication of the rulemaking.

Effective Date

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

Public Comments

Interested persons are invited to submit written comments, suggestions or objections regarding this proposed rulemaking to Stefanie Smith, Chief, Division of Policy & Programs, Bureau of Food Safety and Laboratory Services, Pennsylvania Department of Agriculture, 2301 North Cameron Street, Harrisburg, PA 17110-9408, (717) 787-5108 within 30 days of the publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

Contact Person

The contact person for technical questions regarding this proposed rulemaking is Sheri Morris, Assistant Director, Bureau of Food Safety and Laboratory Services, Pennsylvania Department of Agriculture, 2301 North Cameron Street, Harrisburg, PA 17110-9408, (717) 787-5289.

RUSSELL C. REDDING, *Secretary*

ANNEX A

Title 7. AGRICULTURE

PART III. BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

SUBPART B. LIQUID FOODS

CHAPTER 59a. MILK SANITATION

* * * * *

§ 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.

* * * * *

[*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. This includes Dairy Plant Samplers and Industry Plant Samplers as defined in the PMO.

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

* * * * *

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

* * * * *

Grade “A” PMO or PMO —The most current revision of the Grade “A” Pasteurized Milk Ordinance and its appendices, as published by the [FDA] United States Department of Health and Human Services, Public Health Service and United States Food and Drug Administration. The Grade “A” Pasteurized Milk Ordinance is a set of minimum standards and requirements for Grade A milk production and processing, established by the United States Food and Drug Administration. The Department maintains a link to an electronic copy of this document on its web site at [www.agriculture.\[state.pa.us\]pa.gov](http://www.agriculture.[state.pa.us]pa.gov).

* * * * *

HTST—High temperature short [term]time.

* * * * *

ISO/IEC 17025 – The 2017 edition of the standard owned by the International Standards Organization entitled General Requirements for the Competence of Testing and Calibration Laboratories. Copies of the standard can be found at www.iso.org.

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, [including:

- (i) Instant nonfat dry milk and other dry milk products.
- (ii) Pasteurized process cheese and related products.
- (iii) Sterilized milk products.
- (iv) Butter-related products.
- (v) Other products that must be produced at plants in accordance with supplemental requirements established under Subchapter E (relating to manufacturing plants).]

* * * * *

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.]

* * * * *

Pasteurization- The process of heating every particle of milk, milk product or the milk used for manufactured dairy product, in properly designed and operated equipment, to one of the temperatures set forth in section 59a.7 of this chapter and held continuously at or above that temperature for at least the corresponding specified time.

Pasteurized – Milk, milk products or the milk used for manufactured dairy products that has undergone pasteurization.

* * * * *

Raw milk butter- Butter made from raw milk, provided it conforms to Subchapter F (relating to raw milk for human consumption).

Retail food facility- As defined in the Retail Food Facility Safety Act (3 Pa.C.S. § 5702)

(relating to definitions).

* * * * *

Weigher/sampler—A bulk milk pick-up driver, [or a milk plant person] certified industry inspector, approved inspector, or other authorized designee certified by the Department [or the Pennsylvania Milk Marketing Board] or other Department-approved certifying body, 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, with the exception of:

(1) The term “regulatory agency,” which means the Department[.]; and

(2) The term “milk products,” which means both “milk” and “manufactured dairy products” as defined in this chapter.

§ 59a.3. Contacting the Department.

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

(1) By mail, at the following address:

Pennsylvania Department of Agriculture
Bureau of Food Safety and Laboratory Services
ATTN: [Division of] Milk [Sanitation] Program

2301 North Cameron Street
Harrisburg, PA 17110-9408

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

(3) Through the following web site: www.agriculture.state.pa.us/pa.gov/consumer_protection/foodsafety.

§ 59a.4. Approved inspectors and certified industry inspectors.

* * * * *

(b) *Criteria for approval.* An applicant shall meet the following criteria to be eligible for licensure as an approved inspector:

(1) The applicant shall be [21] 18 years of age or older.

* * * * *

(3) The applicant shall have at least 2 years of academic training or experience in the area of milk production and milk sanitation. The Department [may] will verify that an applicant has adequate experience by having a Department [personnel] evaluator conduct [one or more] 5 joint dairy farm inspections with the applicant.

* * * * *

(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] subsection (d), attendance at an educational seminar is a requisite to the Department issuing or renewing a license.

* * * * *

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

* * * * *

(i) *Certification Process.* A person seeking to become a certified industry inspector must be a licensed approved inspector. To become and remain a certified industry inspector a person shall meet the standards established in Section 5 of the Grade “A” PMO. These standards include the following for initial certification and recertification:

(1) Initial Certification. For initial certification, a person shall conduct twenty-five joint dairy farm inspections with a Department evaluator and achieve a passing score of 80% agreement with the same inspection completed by the Department’s evaluator.

(2) Renewal Certification. For recertification, a certified industry inspector shall conduct ten joint dairy farm inspections, over a period of 3 years, with a Department evaluator and achieve a passing score of 80% agreement with the same inspection completed by the Department’s evaluator.

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

(a) *General laboratory standards.*

(1) Pennsylvania- approved, official and other laboratories. 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* found at AOAC.org. 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 operate in accordance with current FDA 2400 Laboratory Series forms.

(2) All Laboratories. All laboratories that conduct sampling or laboratory examinations for purposes of this chapter shall be listed with NCIMS.

(3) Pathogen Testing Laboratories. For pathogen specific testing required by this Chapter, laboratories shall have received accreditation to the ISO/IEC 17025 standard, found at ISO.org, from a national third-party laboratory accrediting body to analyze food products. The accreditation body of the laboratory must be a full member of the International Laboratory Accreditation Cooperation (“ILAC”) and a signatory to the ILAC mutual recognition arrangement (“MRA”).

(4) Alternate Laboratory Methods. The Department may evaluate and approve alternative laboratory sampling or testing standards and procedures concerning bacteriological analysis of milk, milk products and manufactured dairy products as necessary and shall publish such approved methods in the *Pennsylvania Bulletin*.

(b) [Reports of results] Laboratory reports.

(1) Pennsylvania-approved laboratories. 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 a Pennsylvania-approved dairy laboratory director or a person designated by 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.

(2) Other laboratories. If any other laboratory issues a report of the results of laboratory examinations for the purposes of this Chapter, the report shall be signed by the laboratory director, person designated by the laboratory director or as otherwise specified under the laboratory's ISO/IEC 17025 standard accreditation documents.

(3) Report timetable. All reports shall be provided to the Department within the time periods established in the NCIMS Grade "A" program, or within 30 days of test completion.

Laboratories shall report results that are non-compliant under the standards established in the PMO or this chapter within 48 hours. The Department, through publication in the *Pennsylvania Bulletin*, may specify the format in which laboratories must submit test results.

(c) *Pennsylvania-approved dairy laboratory director.*

* * * * *

(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 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%. The examination must have the following parts:

(A) A general section addressing sampling and culturing procedures.

(B) A section addressing the specific categories of dairy testing procedures with respect to which the applicant seeks certification.

(ii) Passes] passes an onsite performance and facilities evaluation by a laboratory evaluation officer from the Department 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.

* * * * *

(5) A certified Pennsylvania approved dairy laboratory director shall continue to participate in the Department-conducted milk split sample proficiency program and performance shall be satisfactory.

(6) A certified Pennsylvania-approved dairy laboratory director shall perform their functions and shall operate an Pennsylvania-approved laboratory in compliance with the standards of the Act and this Chapter.

(7) A certified Pennsylvania-approved dairy laboratory director shall assure recorded laboratory test results are accurate and in compliance with the Act and this Chapter.

(8) Falsification of required records shall be a violation of this Chapter.

(d) *Refusal, revocation or suspension of approval or certification.* The Department may, upon written notice and opportunity for a hearing, refuse, revoke or suspend a Pennsylvania-approved dairy laboratory approval or a Pennsylvania-approved laboratory director certification for any violation of the Act or this Chapter.

§ 59a.6. Approved sampler and weigher/sampler.

(a) *Application for approved sampler.* A person may apply to the Department to be certified as an approved sampler for purposes of the Act and this Chapter. The Department will provide

certification application forms and the certification renewal forms described in section (e), upon receiving a request sent to the address or website identified in section 59a.3 (relating to contacting the Department).

(b) Application for weigher/sampler. A person may apply to the Department to be certified as a weigher/sampler for purposes of the Act and this Chapter. The Department will provide certification application forms and the certification renewal forms described in subsection (e), upon receiving a request sent to the address or web site identified in section 59a.3 (relating to contacting the Department).

(c) Criteria for approval.

(1) An applicant for either certification must have training and experience in the area of sampling milk, milk products and manufactured dairy products, such as experience on a dairy farm, taking the Pennsylvania Milk Marketing Board's Power Point training, working with a milk co-operative or dairy processor or other dairy or weighing and sampling experience, and shall pass a field test, administered by the Department, or other Department approved certifying body, verifying appropriate sampling technique. At least one passing inspection score must be obtained.

(2) An applicant for a weigher/sampler certification must also have training and experience in weighing milk and shall complete a Department or Milk Marketing Board administered written examination and achieve a final score of at least 70%.

(3) The Department may modify criteria for approval to be consistent with provisions of the Grade "A" PMO, in particular Appendix B (related to milk sampling, hauling and transportation), which specifies the required training and periodic evaluation of samplers and weighers/samplers.

(d) Certificate. The Department will issue a certificate, verifying certification in the appropriate field, to any applicant meeting the standards established in subsection (c).

(e) Duration of certificate; renewal. A certificate shall expire as of January 1 of each calendar year. Applicants shall:

(1) Apply or reapply by December 31 of the calendar year preceding the year for which certification is requested.

(2) Provide documentation verifying compliance with the continuing education training requirements established in subsection (f)(1).

(f) Continuing Education and Recertification Requirements.

(1) As a prerequisite to renewal of certification under subsection (e), the applicant shall attend a Department or Department-approved continuing education training for Approved Samplers and Weigher/Samplers that meets the training requirements established in the Grade “A” PMO, Appendix B (relating to milk sampling, hauling and transportation), during the period of certification.

(2) Applicants are required to demonstrate proper sampling techniques every 24 months to the Department as referenced in Appendix B of the Grade “A” PMO.

(g) Refusal, revocation or suspension of certificate. The Department may, upon written notice and opportunity for a hearing, refuse, revoke or suspend a certificate for any violation of the Act or this Chapter.

§ 59a.7. Pasteurization standards.

To be considered pasteurized, every particle of milk, milk product or manufactured dairy product must be heated in properly designed and operated equipment to the applicable temperature, and maintained at that temperature for the corresponding specified time, as set forth

under the definition of “pasteurization” in Section 1. of the Grade “A” PMO (relating to definitions).

Subchapter B. PERMIT REQUIREMENTS

* * * * *

§ 59a.12. Permits.

* * * * *

(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] retail food facility, or any other facility where such products are to be consumed on-premises when the [milk or milk] products have been purchased from a person already in possession of a permit to sell milk, [or] milk products or manufactured dairy products.

(4) [A hotel, restaurant, soda fountain, boarding house or other place 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.]

(Reserved.)

(5) A person producing and selling milk from a single cow [, and exempted from the permit requirement in accordance with the act]. The registration shall be renewed every two-years.

* * * * *

(j) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular section 3[, regarding] (relating to permits), apply to this section to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO). Section 3 of the Grade “A” PMO establishes that to move, including to manufacture, bring into, send into, receive into, sell, offer for sale or store, milk products, as defined in Section 1 of the Grade “A” PMO, in interstate commerce the person must possess a permit issued by the appropriate state regulatory agency. The Department will issue a permit upon verifying the person is a Grade A facility regulated by the appropriate state regulatory agency, and receipt of a copy of their most recent inspection report evidencing compliance.

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

* * * * *

(c) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular section 2[, regarding] (relating to adulterated or misbranded milk and/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, 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 May 21, 2011, shall have until November 21, 2011, to come into compliance with this registration requirement.]

(Reserved.)

(b) *[Approval process.*

(1) A permitholder seeking the Department's approval of a milk, 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, 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.] **(Reserved.)**

(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).] **(Reserved.)**

(d) *Label requirements.* Bottles, containers and packages enclosing milk, milk products or manufactured dairy products offered for sale shall be labeled. The label must [be approved by the Department in accordance with] comply with the labeling provisions of Pennsylvania's Milk

Sanitation Law (act of July 2, 1935, P.L. 589, No. 210) (31 P.S. §§ 645-660g.), Food Safety Act (3 Pa.C.S.A. §§ 5721-5737), Subchapter C (relating to milk sell-by date and best-by date labeling) (3 Pa.C.S.A. §§ 5741-5747), the federal Fair Packaging and Labeling Act (15 U.S.C. §§ 1451-1461) and this section, and contain at minimum the following information:

(1) The common or standardized name of the food.

(2) The net [contents] quantity of contents, which shall be in accordance with the standards provided in 21 CFR 101.7 and 16 CFR Parts 500-503.

(3) The common name of the hooved mammal producing the milk preceding the name of the milk, [or] milk product[,] or manufactured dairy product if the milk, [or] milk product or manufactured dairy 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 or manufactured dairy product is aseptically processed.

(5) The words "keep refrigerated," if the [milk or PMO- defined milk product] milk, milk product or manufactured dairy product is conventionally pasteurized or UHT pasteurized.

(6) The words "Grade 'A'" on the exterior surface, except for bottles, containers and packages of milk, [and] milk products or manufactured dairy 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 the 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] Milk, milk products or manufactured dairy 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, milk product or manufactured dairy product is made by reconstitution or recombination.

(10) The volume or proportion of water, in both standard and metric units, to be added for reconstitution or recombination, if the milk, [or] milk product or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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] sell by date, best by date, or other 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 and inspection requirements for vehicles containing milk, [and] milk products and manufactured dairy product), 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.

(1) Labels containing claims, such as A2A2, organic, kosher, grass-fed and other such marks, words, or endorsements placed upon the label, shall have documentation to support such claims. Such documentation shall be provided to the Department upon request.

(2) Proof of certification issued by a national or third-party accreditation or certification process shall be maintained by the permittee and support the marks, words, or endorsements used on the label. Such proof of certification shall be provided to the Department upon request.

(g) *Reference to applicable provisions of the Grade ‘‘A’’ PMO.* The provisions of the Grade ‘‘A’’ PMO, in particular section 4[, regarding] (relating to 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 a retail food facility, to include retail food stores, restaurants, schools, farmers markets, and roadside stands,

[or similar food facilities] for resale shall be conspicuously and legibly marked in a contrasting color with the designation of the [“sell-by”] “sell by” or “best by” date.[—]

(1) Sell by date. A “sell by” date shall consist of a designation of the month and day of the month after which the product may not be sold or offered for sale, whether expressed in standard fashion (such as “August 15”), [. The designation may be numerical—] numerically (such as “8-15”)[—] or with the use of an abbreviation [for the month,] (such as “AUG 15 or AU 15[.]’’) and either: [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.]

(i) The words “Sell by” or “Not to be sold after” preceding that designation and appearing legibly on the cap or nonglass container; or

(ii) The statement “Not to be sold after the date stamped above” following that designation and appearing legibly on the cap or nonglass container.

(2) Best by date. A “best by” date shall consist of designation of the month and the day of the month, in the same format as required in paragraph (1) of this subsection (a), established by the permitholder as a product quality guideline and the words “Best By,” “Best if Consumed By” or “Best if Used By” preceding that designation and appearing legibly on the cap or nonglass container.

(b) *Prominence of [sell-by]sell by or best by date on label.* The [sell-by] “Sell By” or “Best By” date shall be separate and distinct from any other number, letter or intervening material on the cap or nonglass container.

(b.1) Sell by or best by date limitation. A “Sell By” or “Best By” date may not exceed 17 days beginning after midnight on the day on which the milk was pasteurized, unless the Department approves a longer interval in accordance with the procedure set forth in subsection (f) of this section.

(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] sell by or best by date designated on the cap or nonglass container.

(d) *Exemption.* The following types of pasteurized [dairy] milk [products] are exempt from the requirements of this section, provided that the cap or nonglass 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] milk.

(2) Cultured [dairy products] milk.

(3) Aseptically processed [dairy products] milk.

(4) [Dairy products] Milk that [have] has undergone HTST pasteurization.

(5) Milk sold or offered for retail sale on the same premises at which it was processed.

(e) *Monitoring by the permitholder and the Department.*

(1) Permitholder samples. [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.] All permitholders shall sample and submit milk for testing in accordance with paragraph (2) of this subsection (e), and as often as follows:

(i) Permitholders using sell by or best by dates of 17 days or less. If the permitholder labels milk with a sell by or best by date that is no later than 17 days beginning after midnight on the day on which the milk was pasteurized, the permitholder shall, at intervals of no greater than 12 months and for the highest selling volume of milk type, and each type and volume of container of that highest selling volume of milk type bearing that label information, sample and test in accordance with paragraph (2) of this subsection (e).

(ii) Permitholders using sell by or best by dates of greater than 17 days. If the permitholder labels milk with a sell by or best by date that is greater than 17 days beginning after midnight on the day on which the milk was pasteurized, and that has been approved by the department under subsection (f) of this section (related to applying to the department for approval to use a sell by or best by date greater than 17 days) the permitholder shall, at intervals of no greater than 6 months and for the highest selling volume of milk type, and each type and volume of container of that highest selling volume of milk type bearing that label information, sample and test in accordance with paragraph (2) of this subsection (e).

(1.1) Department monitoring. The Department may, at its discretion, pull regulatory samples from a permitholder or person required to have a permit, at any time during regular business hours, for testing at an official laboratory.

(2) Testing methodology. The permitholder shall submit unopened samples described in paragraph (1) [will be analyzed] for analysis by [the Department or a Pennsylvania-approved dairy laboratory] a laboratory meeting the requirements of section 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results), applying [a] the methodology established in subparagraph (f)(1)(ii) or an approved method established under subsection (a)(4) of section 59a.5 [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]sell by or best by date designated on the retail container.

(3) *Pasteurized milk that exceeds the bacterial limits.*

(i) When any sample pulled under paragraphs (1) or (1.1) of this subsection (e) exceeds the bacterial limits for pasteurized milk described in § 59a.21 (relating to standards) prior to the expiration of the sell by or best by date designated on the retail container, the permitholder shall resample that same product at the next production date, or within 10 days, following receipt of test results, for retesting as established in paragraph (2) of this subsection (e).

(ii) When two or more samples [demonstrate a processor] pulled under paragraphs (1) or (1.1) of this subsection (e) indicate that a permitholder 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] established in section 59a.21 (relating to standards) during the sell by or best by date period the Department will calculate [this revised] a reduced [sell-by]sell by or best by date so that bacterial growth in the milk will not exceed the referenced bacterial limits within that [sell-by] sell by or best by date period if the milk is maintained in accordance with the temperature standards for pasteurized milk in § 59a.21.

(4) *Resumption of use of a sell by or best by date not exceeding 17 days.* A processor may submit three samples from different production days to [the Department] a laboratory meeting the requirements of section 59a.5 (relating to standards for Pennsylvania-approved dairy

laboratories, official laboratories and other laboratories; reports of results) for analysis to obtain approval to resume a 17-day, or less, sell-by period for the product sampled. The Department will approve resumption of a 17-day, or less, 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.

(5) Reapplying to resume a sell by or best by date period greater than 17 days. A permitholder may reapply to the Department to resume a sell by or best by date period greater than 17 days for the product sampled by following the application process established in subsection (f) (relating to applying to the department for approval to use a sell by or best by date greater than 17 days) of this section.

(6) Reporting test results. The Pennsylvania-approved dairy laboratory conducting tests required under this section shall submit all results to the permitholder and the Department as established in section 59a.5.

(f) Applying to the Department for approval to use a sell by or best by date greater than 17 days. A permitholder may apply to the department for approval to use a sell by or best by date that exceeds the 17-day period referenced in subsection (b.1) (relating to sell by or best by date limitation). The department will approve a permitholder’s application by type of milk and the type and volume of the milk container.

(1) Approval process. The permitholder shall apply to the department for approval to use a specific sell by or best by date that is greater than 17 days using a form provided by the Department.

(i) The permitholder must specify on the form by milk type and type and volume of container, each product for which approval is requested, and the specific sell by date or best by date proposed for that product as packaged.

(ii) For each milk type and type and volume of container for which approval is requested, the permitholder must include a report from a laboratory meeting the requirements of § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) that confirms the requirements set forth in 3 Pa.C.S. § 5744(b)(3). The bacterial count required under 3 Pa.C.S. § 5744(b)(3)(ii) shall conform with the bacteriological standards established in section 59a.21(a).

(iii) All testing results shall be maintained by the permitholder for a minimum of two years.

(2) Continuation of approval. The Department's approval under this section shall remain in effect as long as the permitholder continues to complete the periodic sampling and testing required in subsection (e) (relating to monitoring by the permitholder and the Department).

§ 59a.16. Markings, sealing, [and] documentation and inspection requirements for vehicles containing milk, [and] milk products or manufactured dairy products.

(a) *Marking requirements.* A vehicle or milk tank truck containing milk, [or] milk products or manufactured dairy 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, [or] milk products or manufactured dairy 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 or manufactured dairy 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 or manufactured dairy 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:

* * * * *

(12) Grade [of product] “A”, if product is Grade “A”.

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

(e) *Additional documentation.* Milk transport tank trucks transporting bulk milk [and] or manufactured 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, in particular section 4, regarding labeling, apply to this section to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).] **(Reserved)**

(g) Vehicle or Milk Tank Truck Inspection. All vehicles and milk tank trucks transporting raw, heat-treated or pasteurized milk, milk products or manufactured dairy products within this Commonwealth shall be inspected at least once every 24 months, or at a lesser interval where violations have occurred, by the Department or other Department authorized official, or a non-Commonwealth state agency participating in the NCIMS program, and shall comply with standards set forth in the PMO, Appendix B, Section VIII (relating to milk tank truck permitting and inspection).

(h) Reporting and inspection. Haulers and milk plants shall cooperate with the Department by:

(1) Providing an annual report of the vehicles and milk tank trucks described in subsection (g) of this Section, in their fleet on forms supplied by the Department or as otherwise deemed acceptable by the Department.

(2) Making those vehicles and milk tanker trucks available for inspection.

(i) Proof of inspection. Upon compliant inspection the Department will issue an official sticker indicating compliance and setting forth the expiration date of the current valid inspection. The Department shall apply the sticker to each vehicle and milk tanker truck found to be compliant.

(j) Reference to applicable provisions of the Grade “A” PMO. The provisions of the Grade “A” PMO, in particular section 4 (relating to labeling), and Appendix B (relating to milk sampling, hauling and transportation) 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] the Department 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] The milk producer shall have an empty bulk tank for any initial inspection or change of market inspection. All inspections 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 (relating to drug residue testing and farm surveillance) of the Grade “A” PMO [regarding drug residue testing and farm surveillance].

(c) *Notification to the Department 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, in particular section 5[, regarding] (relating to 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[,] or [an out-of-State dairy] laboratory compliant with § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) [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 (relating to drug residue testing and farm surveillance) 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.

* * * * *

(e) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular section 6 (relating to examination of milk and/or milk products) and Appendix N (relating to drug residue testing and farm surveillance), [regarding examination of milk and milk products and drug residue testing and farm surveillance,] apply to this section to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

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§ 59a.19. Standards for Grade “A” milk for pasteurization, ultrapasteurization or aseptic processing.

* * * * *

(b) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular the *Standards for Grade “A” Raw Milk for Pasteurization, Ultrapasteurization or Aseptic Processing* set forth in that document and section 7[, regarding] (relating to standards for Grade “A” milk and milk products) are incorporated by reference as regulations authorized under the act, to the extent they do not conflict with the act or any

provision of this chapter. This includes all of the items listed under the referenced Grade “A” PMO provisions, including the following:

* * * * *

§ 59a.20. Standards for [Grade “A”] pasteurized, ultrapasteurized and aseptically processed milk and [milk] manufactured dairy products.

(a) *Applicability.* The standards prescribed under this section apply to a milk plant processing milk and manufactured dairy products 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, in particular the *Standards for Grade “A” Pasteurized, Ultrapasteurized and Aseptically Processed Milk and Milk Products* and section 7[, regarding] (relating to 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 Articles [Containers], Utensils and Materials
- (15) Item 15p. Protection from Contamination
- (16) Item 16p. Pasteurization and Aseptic Processing and Packaging, Retort Processed after Packaging, and Fermented High Acid, Shelf-Stable Processing and Packaging
- (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 and Practices
- (21) Item 21p. Vehicles
- (22) Item 22p. Surroundings

§ 59a.21. Standards.

(a) *Standards for milk and [milk] manufactured dairy products*. The standards that apply to milk and [milk] manufactured dairy products are as set forth in section 7 (relating to standards for Grade “A” milk and milk products) of the Grade “A” PMO, in Table 1, regarding chemical, physical, bacteriological, and temperature standards except that the Somatic Cell Count for Grade “A” raw milk and manufactured dairy products for pasteurization shall not exceed 500,000 per ml.

(b) *Standards for milk for manufacturing, milk products and manufactured dairy products*. The standards that apply to milk for manufacturing, milk products 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] manufactured dairy products provided that they meet all applicable requirements of Subchapter C.

(c) *Standards for milk products, including 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 (relating to standards for Grade “A” milk and milk products) of the Grade “A” PMO, 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] 6 (relating to the examination of milk and/or milk

products) and Appendix N (relating to drug residue testing and farm surveillance) [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, in particular section 8[, regarding] (relating to 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 and manufactured dairy products which may be sold.

The provisions of the Grade “A” PMO, in particular section 9[, regarding] (relating to milk and/or 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, in particular section 10[, regarding] (relating to transferring; delivery containers; and 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.

* * * * *

(b) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular section 11[, regarding] (relating to milk and/or 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.

* * * * *

(b) *Reference to applicable provisions of the Grade “A” PMO.* The provisions of the Grade “A” PMO, in particular section 12[, regarding] (relating to 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.

The provisions of the Grade “A” PMO, in particular section 13[, regarding] (relating to personnel health), 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 milk₂ [or] milk products or manufactured dairy products, the Department is authorized to require one or more of the following measures:

- (1) The immediate exclusion of that person from handling milk₂ [or] milk products or manufactured dairy products, or the handling of related [milk or milk-product] product contact surfaces, subject to release from this exclusion if in accordance with [Table 5 of section 15] section 13 (relating to personnel health) and section 14 (relating to procedure when infection or high risk of infection is discovered) 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, in particular section [16, regarding] 14 (relating to 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
PURPOSE**

* * * * *

§ 59a.102. Milk permits.

Plants, receiving stations, transfer stations and bulk tank units handling or processing milk for manufacturing of milk products or manufactured 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, manufactured milk products, 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, milk products, or manufactured 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—weighers/samplers.] (Reserved.)

(a) [Weighers/samplers will be evaluated and approved by the Department.] **(Reserved.)**

(b) [The provisions of the Grade “A” PMO, in particular Appendix B, 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).] **(Reserved.)**

§ 59a.105. [Approved milk graders.] (Reserved.)

[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—59a.111.] **(Reserved.)**

§ 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, as set forth in section 59a.107 (relating to appearance and odor), section 59a.109 (relating to bacterial estimate classification, section 59a.110 (relating to somatic cell count), and section 59a.111 (relating to drug residue level).

§ 59a.107. Appearance and odor.

(a) *Industry responsibilities.* Approved samplers shall be responsible for ensuring that raw milk for manufacturing purposes meets the requirements of this section.

(b) *Examination for 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 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 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.] (Reserved.)

(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.] **(Reserved.)**

(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.] **(Reserved.)**

(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.] **(Reserved.)**

(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.] **(Reserved.)**

(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.] **Reserved.**

§ 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 or other laboratory compliant with § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results). The laboratory must report the results to the permitholder.

* * * * *

(c) *Excessive bacteria.* Whenever the bacterial estimate indicates the presence of more than 500,000 bacteria per milliliter, the result shall be noted as a producer 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.

* * * * *

§ 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 or other laboratory compliant with § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other

laboratories; reports of results). The laboratory must report the results to the permitholder.

* * * * *

(c) *Excessive somatic cell count.* Whenever the official test indicates the presence of more than [750,000] 500,000 somatic cells per milliliter (1,500,000/ml for goat/sheep milk), the result shall be noted as a producer violation in the permitholder's records. When two of the last four consecutive bacterial estimates exceed [750,000/ml] 500,000/ml (1,500,000/ml for goat/sheep 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] 500,000 per milliliter (1,500,000/ml for goat/sheep milk), 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] 500,000 per milliliter (1,500,000/ml for goat/sheep milk). 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.* Milk products and [M]manufactured dairy products permitholders shall meet the requirements of this section to confirm their milk products and 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] (relating to 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 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 will be valid for no more than 1 year and may be renewed for additional periods of up to 1 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.

* * * * *

(v) All [S]sample test results, including negative and positive test results, shall be recorded. The test result records shall be retained for 6 months.

* * * * *

(b) *Responsibilities of the Department.*

* * * * *

(2) *Enforcement.*

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(vi) The actions and procedures of the Department will be in accordance with this chapter and Appendix N of the Grade “A” PMO[, regarding] (relating to drug residue testing and farm surveillance).

§ 59a.112. Rejected milk.

(a) *Rejection requirement.* A plant shall reject specific milk from a producer if it fails to meet the requirements 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)] (**Reserved.**)

(2) [The milk has been in a probational (No. 3) sediment content classification for more than 10-calendar days.] (**Reserved.**)

(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] 500,000 per milliliter (1,500,000/ml for goat/sheep 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] Hortvet (0.508° Celsius) 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 with an empty bulk milk tank and have a passing score before the first milk is shipped.

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

* * * * *

(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).] **(Reserved.)**
- (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 (relating to appearance and odor).
- (2) [The requirements of § 59a.108.] **(Reserved.)**

(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).

(d) *Transfer producers*. When a producer discontinues milk delivery to one plant and begins delivery to a different plant, the provisions of the Grade “A” PMO, in particular section 5[, regarding certified industry inspection and change-of-market requirements](relating to inspection of dairy farms and milk plants), apply to the extent described in § 59a.11 (relating to adoption of Grade “A” PMO).

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§ 59a.116. Abnormal milk.

(a) *Certain milk to be excluded from human consumption*. [Cows]Dairy animals which show evidence of the secretion of abnormal milk in one or more quarters or halves based on bacteriological, chemical or physical examination and [cows] dairy animals 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] dairy animals 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] dairy animals treated with or exposed to pesticides not approved for use on dairy [cattle] animals 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] (relating to drug residue testing and farm surveillance).

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

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Subchapter D. FARMS PRODUCING MILK FOR MANUFACTURING

§ 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. The dairy farm shall have an empty bulk tank for inspection and shall have a passing score before the first milk is shipped. To attain a passing score, there may not be 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 every 6 months by an approved inspector, and an accurate record of inspections shall be maintained by each permitholder 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 the 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 or email within 24 hours of the action.

§ 59a.202. Milking facilities and housing.

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(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.

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§ 59a.205. Milkhouse or milkroom.

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(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, insects 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 or
insects.

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§ 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[, regarding] (relating to standards for water sources), and is approved by the Department.

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Subchapter E. MANUFACTURING PLANTS

GENERAL REQUIREMENTS

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§ 59a.302. Buildings.

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(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, self-closing, 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, insects 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.

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(f) *Certain rooms and compartments.*

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(5) *Laboratory.* The permitholder may establish its own laboratory to perform required tests on milk received as milk for manufacturing purposes. The laboratory shall be adequately equipped and maintained and be properly staffed with qualified, trained personnel and 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]§ 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results). If the permitholder does not establish its own laboratory, an existing [approved laboratory] Pennsylvania-approved dairy laboratory or other laboratory compliant with § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) is acceptable if services are conveniently available so that samples and results can be transmitted without delay.

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§ 59a.303. Facilities.

(a) *Water supply.* There must 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 not be 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] every six months, 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.

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§ 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] milk residue or any unsanitary condition.

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§ 59a.308. Raw product storage.

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(e) *Procedures if bacterial counts are high.*

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

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§ 59a.309. Pasteurized, ultrapasteurized or aseptically processed and packaged products.

Pasteurized, ultrapasteurized or aseptically processed and packaged products must conform with the pasteurization standards established at § 59a.[2]7 (relating to [definitions]pasteurization standards). 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 assure proper pasteurization or sterilization of the product. The heat treatment by either process must be sufficient to [i]ensure public health safety and to assure adequate keeping quality, [yet] while 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, milk products or manufactured dairy products during manufacturing. Substances and ingredients used in the processing or manufacturing of a milk, milk product or manufactured 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—399i), applicable regulations under 21 CFR, Chapter I, Subchapter B. and applicable Commonwealth statutes and regulations as to their composition and wholesomeness.

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§ 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 records shall be maintained for examination at the plant or receiving station where performed:

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

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

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§ 59a.314. Packaging and general identification.

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

- (1) The size, style and type of packaging used for milk, milk products, and 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 milk, milk products, and manufactured dairy products shall be selected which 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 milk, milk products or manufactured dairy products or cutting and repackaging dairy products require 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 milk, milk products, or manufactured 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 must 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 other products and items in the same room with [foreign to] milk, milk products, and manufactured dairy products [in the same room], to prevent impairment or damage to the milk, milk products or manufactured 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 must be placed on shelves, dunnage or pallets and properly identified. It must 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.

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§ 59a.317. Federal Food Safety regulations.

(a) The Department adopts all federal regulations related to food as dictated by the Pennsylvania Food Safety Act (3 Pa.C.S.A. § 5733(f)) including all applicable enforcement provisions.

(b) Permitholders shall comply with Food Facility registration requirements established in 21 CFR Ch.1, Subch. A, Pt. 1, Subpart H (relating to registration of food facilities).

(c) Permitholders shall comply with the requirements of 21 CFR Ch.1, Subch. B, Pt. 117 (relating to current good manufacturing practices, hazard analysis, and risk-based preventive controls for human food regulations).

(d) Permitholders shall comply with applicable provisions and requirements under 7 CFR Subt. B, Ch. 1, Subch. C, Part 58 (relating to grading and inspection, general specifications for approved plants and standards for grades of dairy products).

**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.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 21 CFR 177.1520 (relating to 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 manufactured dairy product may not be used for the bulk handling of [dairy] these 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] palletizing or dry storage areas.

* * * * *

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

(1) *Product.* The packaged dry [milk] product must 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 must 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 must be placed on dunnage or pallets and arranged in an orderly manner for accessibility and cleaning of the room. Supplies must be kept enclosed in their original wrapping material until used. After removal of supplies from their original containers, they must 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.

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

Milk, milk products, and manufactured dairy products [and], to include dry milk products shall be subject to inspection an 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 dairy laboratory meeting standards established in § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) at least once each month for the purpose of assuring that the product meets the requirements of subsection (b). The dry milk plant shall have each subplot of approximately 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.

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

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§ 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, other than the cream for production of raw milk butter as described in § 59a.402 (relating to raw milk; prohibitions), with respect to which pasteurization requirements are not applicable, shall be pasteurized at a temperature of at least 165° F and held continuously in a vat at that temperature at least 30 minutes, pasteurized by the 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.

* * * * *

**SUPPLEMENTAL REQUIREMENTS FOR
PLANTS MANUFACTURING AND**

**PACKAGING CHEESE, PASTEURIZED PROCESS CHEESE AND RELATED
PRODUCTS**

§ 59a.371. Rooms and compartments.

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(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. [tion.]

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§ 59a.372. Equipment and utensils.

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

(n) Grinders or shredders. Product contact surfaces shall be of corrosion resistant material, and of a construction to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces, and shall be kept in good repair.

(o) Cookers. Cookers shall meet the following standards:

(1) The cookers shall be the steam jacketed or direct steam type.

(2) The cookers shall be constructed of stainless steel or other equally corrosion resistant material.

(3) All product contact surfaces shall be readily and easily accessible for cleaning.

(4) Each cooker shall be equipped with an indicating thermometer and a temperature recording device.

(5) Steam check valves on direct steam type cookers shall be mounted flush with the cooker wall, constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily and easily cleaned.

(6) If direct steam is applied to the product, only culinary steam shall be used.

(p) Fillers. The filler valves and head shall be kept in good repair and be capable of accurate measurements. The hoppers of all fillers shall meet the following standards:

(1) Be covered, but such covers may have sight ports.

(2) May, where necessary, have an agitator to prevent buildup on the side wall.

§ 59a.373. Operations and operating procedures.

(a) Cheese from pasteurized milk.

(1) When 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] in accordance with the standards established at § 59a.7. (relating to pasteurization standards) of this chapter.

(2) [HTST pasteurization] Pasteurization units must 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.

(1) When the cheese is labeled as “heat treated,” “unpasteurized,” “raw milk” or “for manufacturing,” the milk may be raw or heated at a temperature below pasteurization.

(2) 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.

(3) Cheese to be labeled as “raw aged” shall meet the following requirements:

(i) The cheese is a standardized cheese identified in 21 CFR Part 133, Subpart B (relating to requirements for specific standardized cheese and related products).

(ii) The standards set forth in 21 CFR, Ch.1, Subch. B, Part 133, Subpart B, must allow that type of cheese to be manufactured from raw milk.

(iii) Laboratory test results verifying the cheese conforms with all applicable CFR standards shall be made available to the Department.

* * * * *

(c.1) Forming containers.

(1) When lined or unlined containers are assembled and stored it shall be done in a sanitary manner to prevent contamination.

(2) Procedures must be in place for the handling of containers between forming and filling that prevent contamination of the product contact surfaces.

(3) Preforming and assembling of pouch liners and containers shall be based on production needs and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

(c.2) 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 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.

(d) *Packaging and repackaging.* Packaging rindless cheese or cutting and repackaging all styles of bulk cheese requires a high level of sanitation 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.

(d.1) *Trimming and cleaning.* The natural cheese shall be cleaned so that it is free of all nonedible portions. Paraffin and bandages as well as rind surfaces, mold or other unclean areas deemed unwholesome shall be removed.

(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, to include the wording “raw milk,” “made with raw milk,” or similar identifying language, the number of days the cheese aged, and other information that may be required.

**SUPPLEMENTAL REQUIREMENTS FOR
PLANTS MANUFACTURING, PROCESSING
AND PACKAGING [PASTEURIZED PROCESS CHEESE] MILK PRODUCTS, TO
INCLUDE ICE CREAM, FROZEN DESSERTS 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] milk products must 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.]

(Reserved.)

(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.] **(Reserved.)**

(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.] **(Reserved.)**

(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.] **(Reserved.)**

§ 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.] **(Reserved.)**

(b) [*Cooking the batch.* Each batch of cheese within the cooker, including the optional ingredients, shall be thoroughly commingled, 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.] **(Reserved.)**

(c) [*Forming containers.* Containers either lined or unlined shall be assembled and stored in a sanitary manner to prevent contamination. Procedures must be in place for the handling of containers between forming and filling that 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.] **(Reserved.)**

(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 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.] **(Reserved.)**

(d.1) Pasteurization of milk products.

(1) All milk products shall be pasteurized.

(2) HTST, UHT and BATCH pasteurization units shall be equipped with the proper controls and equipment to complete the pasteurization process. Where milk is held more than 2 hours between time of receipt or heat treatment and setting, it shall be cooled to 45° Fahrenheit or lower during the entire time period.

(d.2) Purchase of pasteurized mixes for production of milk products. Permitholders may purchase a pasteurized frozen dessert or ice cream mix from a permitted facility for further production of a milk product.

(d.3) Filling Containers.

(1) Mechanical fillers. Both gravity and vacuum type fillers shall be of sanitary design and all product contact surfaces, if metal, shall be made of stainless steel or equally corrosion resistant material. Certain evaporated milk fillers having brass parts may be approved if free from corroded surfaces and kept in good repair. Fillers shall be designed in a manner to assure they will not contaminate or detract from the quality of the product in any way.

(2) Manual fillers. Manual filling shall be done in a sanitary manner in order to prevent contamination of the product contact surfaces of containers. The containers shall be kept sanitary and may not contaminate or detract from the quality of the product in any way.

(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 subplot number.

(f) Freezer storage. Freezer storage shall comply with the following:

(1) The room shall be maintained at a temperature of 0° Fahrenheit or lower.

(2) Air circulation must be sufficient to preclude odors and maintain uniform storage temperatures throughout the freezer.

(g) Sampling. Milk products shall be sampled by an approved sampler and tested in accordance with § 59a.21(c) of this chapter.

(h) Inspections. Milk product manufacturers will be inspected by the Department every 6 months.

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Subchapter F. RAW MILK FOR HUMAN CONSUMPTION

§ 59a.401. Raw milk; general.

This subchapter prescribes the permitting, testing and inspection requirements that are applicable to persons seeking to sell raw milk and raw milk butter 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. The term “sell” also includes selling, exchanging, or delivering to a consumer who is a member of a “buyer’s club,” cow herd share agreement or other type of membership purchasing group.

(b) *Actions authorized under a raw milk permit.*

(1) A raw milk permit authorizes the permitholder to lawfully produce and sell (within this Commonwealth) raw whole milk for human consumption. The permit only authorizes the sale of raw milk that has been produced by the permitholder. [It also authorizes the permitholder to

obtain an additional permit, issued by the Department under authority of 21 CFR Part 133 (relating to cheese and related cheese products), authorizing the sale of cheese manufactured from raw milk if all of the following apply:

(1) The cheese is a standardized cheese identified in 21 CFR Part 133, Subpart B (relating to requirements for specific standardized cheese and related products).

(2) The standards for that cheese allow for it to be manufactured from raw milk.]

(2) A raw milk permitholder may obtain an additional permit, issued by the Department, authorizing the production and sale of raw milk butter manufactured from raw milk if that raw milk butter is produced in compliance with the supplemental requirements for plants manufacturing, processing and packaging butter and related products presented in § 59a.361 (relating to rooms and compartments), § 59a.362 (relating to equipment and utensils) and § 59a.363 (relating to operations and operating procedures) and any other provision of this chapter relating to the production of butter, other than a provision or requirement relating to pasteurization under section 59a.7 (relating to pasteurization standards). The additional permit only authorizes the sale of raw milk butter that has been manufactured by the permitholder from raw milk that has been produced by the permitholder.

(c) *Compliance with testing and documentation requirements.* A person may not sell raw milk or raw milk butter for human consumption without being in compliance with the testing and documentation requirements of this section.

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

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(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 and tested and analyzed by a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to Standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results)[or the Department for analysis].

* * * * *

§ 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” 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, in particular the *Standards for Grade “A” Raw Milk for Pasteurization, Ultrapasteurization or Aseptic Processing* and section 7[, regarding] (relating to standards for Grade “A” milk and milk products), are incorporated by reference as regulations authorized under the act, to the extent they do not conflict with the act or this subchapter. This includes the items listed under the referenced Grade “A” PMO provisions, including the following:

* * * * *

§ 59a.408. Regular testing of raw milk and raw milk butter for human consumption.

(a) *Responsibility.* A raw milk or raw milk butter permitholder shall be responsible to arrange for the regular sampling and testing required with respect to the raw milk and raw milk butter permit, and to pay for this testing.

(b) *Testing laboratories.* Raw milk or raw milk butter samples submitted for testing shall be analyzed at [an official laboratory or] a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to Standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results).

(c) *Raw Milk and Raw Milk Butter Testing schedule and standards.* A person holding a raw milk [permitholder] permit or raw milk butter permit or both, shall coordinate the testing of raw milk and raw milk butter for human consumption on the following schedule, and the raw milk and raw milk butter samples must 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	Bacterial count	Bacteria may not be present in excess of 20,000 <u>cfu</u> per milliliter. <i>Note:</i> Tested in

with the tests for coliform count and for the presence of drugs (including growth inhibitors), described in this subsection

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 cfu 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] 500,000/milliliter (1,500,000/ml for goat/sheep milk).

At least twice each month, in conjunction with the tests for bacterial count and for coliform count,

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

described in this subsection

Health and Human Services, Food and Drug Administration.

From a sample drawn from the bulk tank, test for presence of the following

Once every 6 months

pathogenic bacteria: *Salmonellae, Listeria monocytogenes, Camphylobacter* and *E. Coli* 0157:H7

There may be no pathogenic bacteria present.

(d) Raw milk butter testing schedule and standards. In addition to the raw milk utilized for raw milk butter meeting the requirements of the testing schedule and standards in subsection (c), a raw milk butter permitholder shall coordinate and assure the testing of raw milk butter every six months for bacterial count, coliform, and yeast and mold count. The product(s) shall meet the most current microbiological standards outlined in 7 CFR 58.345 (relating to butter). Current standards include:

- (1) Bacterial count not exceeding 100 cfu per gram.
- (2) Coliform count not exceeding 10 cfu per gram.
- (3) Yeast and Mold count not exceeding 20 cfu per gram.

§ 59a.409. Violations of raw milk testing standards.

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(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, and then have an approved sampler collect a sample and submit it to a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) 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 with an empty tank between samples, and submit it to a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) 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 and with an empty tank between samples, 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.

(e) Raw milk butter not meeting testing standards. When two or more raw milk butter samples exceed the microbiological limits referenced in § 59a.408(d), the permitholder must cease production of the raw milk butter until the permitholder can demonstrate, through additional sample testing on two different production dates, that the raw milk butter meets the microbiological standards referenced in § 59a.408 (relating to regular testing of raw milk and raw milk butter for human consumption).

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§ 59a.411. Label content review by the Department.

(a) Raw milk and packaged raw milk butter in containers owned by the raw milk permitholder.

(1) General label statements. If raw milk or raw milk butter for human consumption is prepackaged for sale in containers that are owned by the raw milk permitholder, and where applicable the raw milk butter 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 or raw milk butter, comply with section 59a.14 (relating to labeling: bottles, containers and packages of milk, milk products or manufactured dairy products), and at a minimum include the fluid volume, for raw milk, or the net weight, for raw milk butter, as well as the name and address of the distributor or producer, the raw milk permit number under which the raw milk was produced, and for raw milk butter, the additional raw milk butter permit number under which the raw milk butter was produced, 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.* In addition to the information 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 and raw milk butter, [has] have not been processed to remove pathogens that can cause illness. The consumption of raw milk or raw milk butter 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.

(3) *Label requirement: raw 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”] sell by or “best by” date.[—]

(A) Sell by date. A “sell by” date shall consist of a designation of the month and day of the month after which the raw milk may not be sold or offered for sale, whether expressed in standard fashion (such as “August 15”), numerically (such as “8-15”) or with use of an abbreviation (such as “AUG 15” or “AU 15”)[. 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] and either 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.

(B) Best by date. A “best by” date shall consist of designation of the month and the day of the month, in the same format as required in Clause (A) of this section, established by the permitholder as a product quality guideline and the words “Best By,” “Best if Consumed By” or “Best if Used By” preceding that designation.

(ii) *Prominence of [sell-by] sell by or best by date on label.* The [sell-by] sell by or best 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 or best-by date designated on the container.

(iv) *Monitoring by the permitholder and the Department.*

(A) *Department.* The Department will periodically sample containers of raw milk, and raw milk butter for human consumption, that is in the possession of the raw milk permitholder or a distributor. This sampling may occur at any time before the raw milk, or raw milk butter is delivered to the customer. [The Department will take at least one sample of raw milk from each raw milk permitholder each calendar year.]

(A.1.) *Permitholders.* The permitholder shall, at intervals of no greater than 12 months sample and test in accordance with § 59a.15(e)(2) (relating to testing methodology).

(B) The samples described in clauses (A) and (A.1.) shall be analyzed by [the Department or] a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to Standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results), to determine whether bacterial and coliform test results exceed the bacterial limits for raw milk described in the Raw Milk Testing Schedule and Standards in § 59a.408 (relating to regular testing of raw milk and raw milk butter for human consumption) prior to the expiration of the [sell-by]sell by or best by date designated on the raw milk container.

(B.1.) When any sample pulled under clause (A.1) exceeds the bacterial or coliform limits for raw milk described in 59a.408 (relating to regular testing of raw milk and raw milk butter for human consumption), the permitholder shall resample at the next production date, or within 10 days, following receipt of test results, for retesting as described in clause (B).

(C) When two or more samples, pulled under clause (A) or (A.1.), demonstrate a raw milk permitholder cannot produce raw milk for human consumption that remains consistently within the bacterial and coliform limits referenced in clause (B) through the [sell-by]sell by or best by date marked on the container, the Department will require a raw milk permitholder to use a shorter [sell-by]sell by or best by date specified by the Department. The Department will calculate this revised [sell-by]sell by or best by date so that bacterial growth in the raw milk will not exceed the referenced bacterial limits within that [sell-by]sell by or best by period if the raw milk is maintained in accordance with the temperature requirements for raw milk in the Raw Milk Testing Schedule and Standards in § 59a.408.

(D) A raw milk permitholder may submit samples to [the Department] a Pennsylvania-approved dairy laboratory, official laboratory, or other laboratory meeting the requirements of § 59a.5 (relating to standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results) for analysis to obtain approval to resume a specific [sell-by] sell by or best by period for the raw milk sampled. The Department will approve resumption of a specific [sell-by]sell by or best by period when analysis of at least three [a] samples from three different production days demonstrates that bacterial growth in the raw milk will not exceed the referenced bacterial and coliform limits within that [sell-by]sell by or best by period if the raw milk is maintained in accordance with the temperature requirements for raw milk in the Raw Milk Testing Schedule and Standards in § 59a.408.

* * * * *

(c) Label statements for raw milk butter. Raw milk butter shall be packaged or wrapped prior to sale with a label identifying the name and address of the distributor or producer, date of manufacture code, and the raw milk and raw milk butter permit number under which the raw milk butter was produced and shall conform with the labeling requirements of subsection (a)(1) and (2) of this section.

§ 59a.412. Inspection, sampling and testing by the Department.

A raw milk permitholder, and a raw milk butter additional 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 Safety Act or any other applicable statute or regulation. If a raw milk or raw milk butter permitholder fails to allow this inspection

and sampling by the Department, the Department may take steps to revoke or suspend the raw milk permit or the raw milk butter permit, or both.

§ 59a.413. Enforcement: Suspension or revocation of a raw milk or raw milk butter permit.

(a) *General.* The Department may take action to suspend or revoke a raw milk permit, raw milk butter permit, or both, 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 or raw milk butter permitholder with at least 5 days advance written notice of a [raw milk permit] revocation or suspension of their raw milk permit, raw milk butter permit, or both. This written notice will be sent by certified mail. The Department may supplement the notice by providing the permitholder the written notice by personal service or other means. The written notice must 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 shall be submitted to the Department.

(2) If the basis for a proposed [raw milk permit] suspension or revocation of the raw milk permit, raw milk butter permit, or both, is that pathogenic bacteria have been detected in the raw milk or raw milk butter, or foreign substances are present in the raw milk or raw milk butter, or any condition exists when consumption of raw milk or raw milk butter produced and sold prior to revocation or suspension of the raw milk or raw milk butter permit may pose a threat to the health or safety of those persons who consume it, the Department will immediately notify the raw milk or raw milk butter permitholder, or both, and request that it voluntarily cease all sales of raw milk, raw milk butter, or both—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 or raw milk butter permit holder to cease sales of raw milk, raw milk butter, or both, for human consumption if required under § 59a.409 (relating to violations of raw milk testing standards).

(i) If a raw milk permit holder or raw milk butter permit holder, or both, complies with a request that it voluntarily cease raw milk sales, the Department will consider this cooperation a mitigating factor as it determines any penalty or sanction relating to the violation.

(ii) If a raw milk permit holder or raw milk butter permit holder, or both, does not choose to comply with a request that it voluntarily cease [raw milk sales,] the sale of raw milk, raw milk butter, or both, the Department will do the following:

(A) Apprise the Department of Health and any local health department having jurisdiction of the situation, and recommend these entities take lawful action to ensure that sales of raw milk or raw milk butter, or both, 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 of raw milk or raw milk butter, or both.

(C) Arrange for an administrative hearing before a hearing examiner, if the raw milk permit holder or raw milk butter permit holder 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 permit holder or raw milk butter permit holder, or both, does not request a hearing on the proposed permit suspension or revocation.

(E) Recommend to the raw milk permitholder or raw milk butter permitholder, or both, that it inform its customers that it has been asked by the Department to voluntarily cease the sale of raw milk, raw milk butter, or both, [sales] and provide these customers the basis for the Department's request.

(c) *Ownership of raw milk permit or raw milk butter permit.* A raw milk permit or a raw milk butter 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, or a raw milk butter permit, or both, 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 or raw milk butter permit, or both, shall immediately return or surrender that raw milk permit, raw milk butter permit, or both, to the Department. In the case of a permit suspension, the Department will promptly return the raw milk permit, raw milk butter permit, or both, to the permitholder at the end of the suspension period.

* * * * *

Subchapter G. MISCELLANEOUS PROVISIONS

§ 59a.501. Interrelatedness with the Retail Food Facility Safety Act and the Food Safety Act.

The subject matter of the act and this chapter overlaps with the subject matter of the Retail Food Facility Safety Act (3 Pa.C.S.A. §§ 5701-5714) and the Food Safety Act (3 Pa.C.S.A. §§ 5721-5737) [(repealed)] and the applicable regulations promulgated under authority of [that] each statute [in] at Chapters 37 through 59a of Title 7 of the Pennsylvania Code [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 Retail Food Facility Safety Act or the Food Safety Act

or [its] their attendant regulations with respect to milk, milk products, manufactured dairy products or any other foods.



COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

Via electronic mail: irrc@irrc.state.pa.us

May 28, 2024

Independent Regulatory Review Commission
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: NOTICE OF PROPOSED RULEMAKING
Department of Agriculture
7 PA. CODE CH. 59a
Milk Sanitation
I.D. No. 2-194

Dear Sir or Madam:

Please find enclosed copies of the Face Sheet, Preamble, Annex "A" and Regulatory Analysis Form with respect to the above proposed regulation.

Copies of these documents have been submitted to the majority and minority chairpersons of the House and Senate Agriculture and Rural Affairs Committees and to the Legislative Reference Bureau on this date.

The proposed regulation will be published in the June 15, 2024 edition of the *Pennsylvania Bulletin*. If I may be of further information, please advise.

Sincerely,

A handwritten signature in blue ink that reads "David C. Kennedy".

David C. Kennedy
Assistant Counsel

Enclosures

Black, Angela M

From: Zeiders, Destiny <DZeiders@pahouse.net>
Sent: Tuesday, May 28, 2024 12:40 PM
To: Black, Angela M
Cc: Kennedy, David C. (AG); Rudman, Stephen; Youker, Darrin
Subject: RE: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations

Agreed and received.
Thanks
Destiny

RECEIVED

Independent Regulatory
Review Commission

From: Black, Angela M <anblack@pa.gov>
Sent: Tuesday, May 28, 2024 12:37 PM
To: Zeiders, Destiny <DZeiders@pahouse.net>
Cc: Kennedy, David C. (AG) <dkennedy@pa.gov>; Rudman, Stephen <srudman@pa.gov>; Youker, Darrin <dyouker@pa.gov>
Subject: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations
Importance: High

May 28, 2024

SENT ON BEHALF OF ASSISTANT COUNSEL DAVID C. KENNEDY

Good Afternoon Ms. Zeiders:

On behalf of the Department of Agriculture, attached for review by the House Agriculture and Rural Affairs Committee Majority Chair Pashinski is a complete regulatory package of proposed rulemaking #2-194. Thank you for agreeing to receive this submission electronically. Please confirm receipt of this rulemaking today, so I can confirm submission with IRRC.

If you have any questions, please advise.

Thank you,
Angie-

Angela M. Black | Legal Office Administrator |
Litigation Referrals and Delegations Coordinator | Office Manager
Pennsylvania Department of Agriculture
Governor's Office of General Counsel
2301 North Cameron Street | Hbg PA 17110
Phone: 717.783.0587 | Fax: 717.787.1270
anblack@pa.gov
www.agriculture.pa.gov

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Black, Angela M

From: Kerry Golden <Kgolden@pahousegop.com>
Sent: Tuesday, May 28, 2024 12:47 PM
To: Black, Angela M
Cc: Kennedy, David C. (AG); Rudman, Stephen; Youker, Darrin
Subject: RE: [EXTERNAL]: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations

Hello Angie,

On behalf of Chairman Moul, I have received Proposed Rulemaking #2-194.

Cheers,
Kerry

Ms. Kerry Golden | Executive Director (R)
Agriculture and Rural Affairs Committee
Manager | Department of Policy and Legislative Services
Pennsylvania House of Representatives
331 Ryan Office Building
(717) 787-3396 | kgolden@pahousegop.com

RECEIVED

Independent Regulatory
Review Commission

May 28, 2024

From: Black, Angela M <anblack@pa.gov>
Sent: Tuesday, May 28, 2024 12:38 PM
To: Kerry Golden <Kgolden@pahousegop.com>
Cc: Kennedy, David C. (AG) <dkennedy@pa.gov>; Rudman, Stephen <srudman@pa.gov>; Youker, Darrin <dyouker@pa.gov>
Subject: [EXTERNAL]: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations
Importance: High

SENT ON BEHALF OF ASSISTANT COUNSEL DAVID C. KENNEDY

Good Afternoon Ms. Golden:

On behalf of the Department of Agriculture, attached for review by the House Agriculture and Rural Affairs Committee Minority Chair Moul is a complete regulatory package of proposed rulemaking #2-194. Thank you for agreeing to receive this submission electronically. Please confirm receipt of this rulemaking today, so I can confirm submission with IRRC.

If you have any questions, please advise.

Thank you,
Angie-

Angela M. Black | Legal Office Administrator|
Litigation Referrals and Delegations Coordinator|Office Manager
Pennsylvania Department of Agriculture
Governor's Office of General Counsel

Black, Angela M

From: Evans, William <william.evans@pasenate.com>
Sent: Tuesday, May 28, 2024 12:53 PM
To: Black, Angela M
Subject: RE: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations

Received –

RECEIVED

Bill Evans

Independent Regulatory
Review Commission

From: Black, Angela M <anblack@pa.gov> May 28, 2024
Sent: Tuesday, May 28, 2024 12:39 PM
To: Evans, William <william.evans@pasenate.com>
Cc: Kennedy, David C. (AG) <dkennedy@pa.gov>; Rudman, Stephen <srudman@pa.gov>; Youker, Darrin <dyouker@pa.gov>
Subject: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations
Importance: High

■ EXTERNAL EMAIL ■

SENT ON BEHALF OF ASSISTANT COUNSEL DAVID C. KENNEDY

Good Afternoon Mr. Evans:

On behalf of the Department of Agriculture, attached for review by the Senate Agriculture and Rural Affairs Committee Minority Chair Schwank is a complete regulatory package of proposed rulemaking #2-194. Thank you for agreeing to receive this submission electronically. Please confirm receipt of this rulemaking today, so I can confirm submission with IRRC.

If you have any questions, please advise.

Thank you,
Angie-

Angela M. Black | Legal Office Administrator|
Litigation Referrals and Delegations Coordinator|Office Manager
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Black, Angela M

From: Guthrie, Lily <lguthrie@pasen.gov>
Sent: Tuesday, May 28, 2024 1:57 PM
To: Black, Angela M
Cc: Kennedy, David C. (AG); Rudman, Stephen; Youker, Darrin
Subject: RE: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations

Received. Thank you!

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Independent Regulatory
Review Commission

From: Black, Angela M <anblack@pa.gov>
Sent: Tuesday, May 28, 2024 12:38 PM
To: Guthrie, Lily <lguthrie@pasen.gov>
Cc: Kennedy, David C. (AG) <dkennedy@pa.gov>; Rudman, Stephen <srudman@pa.gov>; Youker, Darrin <dyouker@pa.gov>
Subject: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations
Importance: High

May 28, 2024

● CAUTION : External Email ●

SENT ON BEHALF OF ASSISTANT COUNSEL DAVID C. KENNEDY

Good Afternoon Ms. Guthrie:

On behalf of the Department of Agriculture, attached for review by the Senate Agriculture and Rural Affairs Committee Majority Chair Vogel is a complete regulatory package of proposed rulemaking #2-194. Thank you for agreeing to receive this submission electronically. Please confirm receipt of this rulemaking today, so I can confirm submission with IRRC.

If you have any questions, please advise.

Thank you,
Angie-

Angela M. Black | Legal Office Administrator|
Litigation Referrals and Delegations Coordinator|Office Manager
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Black, Angela M

Independent Regulatory
Review Commission

From: Bulletin <bulletin@palrb.us>
Sent: Tuesday, May 28, 2024 1:16 PM
To: Black, Angela M
Cc: Kennedy, David C. (AG); Garonzi, Sophea
Subject: [External] RE: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations

May 28, 2024

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Thank you, Angela.

Yes, we have received Proposed Rulemaking #2-194 and it is scheduled for publication in the June 15th issue.

Take care,

Ernest L. Engvall | Legal Assistant
eengvall@palrb.us | 717.783.1530
Legislative Reference Bureau
Code and Bulletin Office

From: Black, Angela M <anblack@pa.gov>
Sent: Tuesday, May 28, 2024 12:41 PM
To: Bulletin <bulletin@palrb.us>
Cc: Kennedy, David C. (AG) <dkennedy@pa.gov>; Garonzi, Sophea <sgaronzi@pa.gov>
Subject: Agriculture - Proposed Rulemaking #2-194 - Milk Sanitation Regulations
Importance: High

SENT ON BEHALF OF ASSISTANT COUNSEL DAVID C. KENNEDY

Good Afternoon Sir or Madam:

Attached please find a pdf packet containing the above-referenced Notice of Proposed Rulemaking (cover letter, signed face sheet, Preamble and Annex A). Also attached are Word versions of the Preamble and Annex A. I am respectfully requesting that you publish this regulation in the **June 15, 2024** edition of the *Pa. Bulletin*. Please confirm receipt of this rulemaking today, so I can confirm submission with IRRC.

If you have any question, please advise.

Thank you,
Angie-

Angela M. Black | Legal Office Administrator|
Litigation Referrals and Delegations Coordinator|Office Manager
Pennsylvania Department of Agriculture
Governor’s Office of General Counsel