

Comments of the Independent Regulatory Review Commission



Department of Agriculture Regulation #2-194 (IRRC #3405)

Milk Sanitation

August 14, 2024

The Independent Regulatory Review Commission (Commission) submits for your consideration the following comments on the proposed rulemaking published in the June 15, 2024 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the Department of Agriculture (Department) to respond to all comments received from us or any other source.

1. Section 59a.2. Definitions. – Statutory authority; Clarity.

The definition of “Grade “A” PMO or PMO” states that it will be “[t]he most current revision of the Grade “A” Pasteurized Milk Ordinance and its appendices, as published by the United States Department of Health and Human Services, Public Health Service and the [United States Food and Drug Administration].” The phrase “most current revision” is unclear. Is the Department referencing the revision current as of the date that the regulation takes effect, or is the Department intending to automatically adopt future revisions? If it is the former, we ask the Department to clarify which specific revision is to be used to define Grade “A” PMO. If it is the latter, we ask the Department to explain how this delegation of authority is lawful.

Additionally, we ask the Department to combine subsections (b) and (c) into one paragraph.

2. Section 59a.5. Standards for Pennsylvania-approved dairy laboratories, official laboratories and other laboratories; reports of results. – Clarity.

Subsection (a)

This subsection provides for general laboratory standards. Under paragraph (a)(4) (regarding 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 publish such approved methods in the *Pennsylvania Bulletin*. We ask the Department to amend the final regulation to clarify that the approved alternate laboratory methods also will be available on the Department’s website.

Subsection (b)

This subsection addresses laboratory reports. Paragraph (b)(3) states that the Department, through publication in the *Pennsylvania Bulletin*, may specify the format in which laboratories must submit test results. We ask the Department to clarify its intent regarding publishing the formatting requirements. Does the Department intend to publish the formatting requirements along with the final regulation? If so, we ask the Department to include the formatting requirements as an appendix or addendum to the final regulation. Additionally, we ask the Department to publish any formatting requirements on its website.

3. Section 59a.6. Approved sampler and weigher/sampler. – Statutory authority; Protection of the public, health, safety, and welfare; Reasonableness.

This new section provides for a person to apply to be certified as an approved sampler or a weigher/sampler.

Subsection (c)

This subsection establishes the criteria for approval of certification. Paragraph (c)(3) states that “[t]he Department may **modify criteria for approval** to be consistent with provisions of the Grade “A” PMO, **in particular** Appendix B (relating to milk sampling, hauling and transportation), which specifies the required training and periodic evaluation of samplers and weighers/samplers.” (Emphasis added.) We have two issues with this proposed language. First, we ask the Department to explain in the preamble to the final rulemaking how it is lawful to change the qualifications for approval in the manner set forth in this paragraph. Second, the phrase “in particular” is non-regulatory language and we ask the Department to either delete or clarify the language.

Subsection (e)

This subsection provides for the duration and renewal of certificates. The provision states that a certificate expires as of January 1 of each calendar year. A commenter asks the Department to align with the Grade “A” Pasteurized Milk Ordinance (Grade “A” PMO), making the length of a certificate two years. We ask the Department to explain why the length of time for the certificate of an approved sampler or weigher/sampler provided in the final regulation is reasonable and protects the public health, safety, and welfare. Additionally, if this standard is more stringent than the federal standards, we ask the Department to revise the final preamble and Regulatory Analysis Form (RAF) to address the need for a more stringent requirement and the impact on the regulated community.

Paragraph (e)(1) states that a person may “[a]pply or reapply by December 31 of the calendar year preceding the year for which certification is requested.” Is this a sufficient and reasonable timeframe for the Department to approve a person to work as an approved sampler or weigher/sampler beginning on January 1?

4. Section 59a.12. Permits. – Clarity; Implementation procedures.

Subsection (b) provides for exceptions from the permit requirement of subsection (a), which states, “A person may not sell milk, milk products or manufactured dairy products within this Commonwealth without having a current, valid permit from the Secretary, unless the person is

exempt from this permit requirement under subsection (b).” The proposed regulation amends the exemption in paragraph (b)(5) to read, “A person producing and selling milk from a single cow. **The registration shall be renewed every 2 years.**” [Emphasis added.] This last sentence does not seem to apply to this provision. We ask the Department to delete the last sentence in paragraph (b)(5) or clarify this provision in the final regulation.

5. Section 59a .110. Somatic cell count. – Protection of the public health, safety, and welfare; Reasonableness.

In subsection (c), the Department proposes to reduce the somatic cells per millimeter from 750,000 to 500,000 for goat/sheep milk. In the preamble, the Department states that this change is requested by the regulated community. Further, the Department explains that “the industry is already requiring these lower counts from the producers: the lower somatic cell counts make the milk easier to pasteurize and process and help to ensure a safer raw milk product.” However, Dairy Farmers of America opposes the reduced limits for somatic cell count per millimeter and asserts that this proposed standard is inconsistent with the Grade “A” PMO. Another commenter also asserts that these standards should be the same as the Grade “A” PMO. We ask the Department to explain in the preamble how the somatic cells per millimeter in the final regulation protects the public health, safety, and welfare. If the standard for somatic cells per millimeter in the final regulation differs from the Grade “A” PMO, we ask the Department to explain the reasonableness of this provision in the preamble to the final regulation. Additionally, if this standard is more stringent than the federal standards, we ask the Department to revise the final preamble and RAF to address the need for a more stringent requirement and the impact on the regulated community.

6. Subchapter F. Raw milk for human consumption. – Reasonableness.

We received comments asking for the expansion of permitted raw milk products and comments opposing raw milk product sales entirely and opposing specifically the expansion of permits for raw butter. In the preamble, the Department explains that the issuance of an additional raw milk butter permit to raw milk permitholders is “in response to the industry-driven initiative to provide more raw milk products.” We ask the Department to explain in the preamble to the final regulation how it determined that it is reasonable to expand permitting for raw butter and only raw butter.

7. Section 59a.402. Raw milk; prohibitions. – Reasonableness.

The Department proposes to add to subsection (a) the following provision: “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.” A commenter opposes this change, stating that buyer’s clubs’ farmers have been exempt. Have buyer’s clubs’ farmers been exempt from the definition of sell? If so, we ask the Department to explain the reasonableness of including buyer’s clubs in the definition of “sell” in this provision and to revise the final preamble and RAF to address any impacts on the regulated community.

8. Compliance with the provisions of the RRA or the regulations of the Commission in promulgating the regulation.

Section 5.2 of the RRA directs the Commission to determine whether a regulation is in the public interest. 71 P.S. § 745.5b. In making this determination, the Commission reviews the information a promulgating agency is required to provide in the Regulatory Analysis Form (RAF) pursuant to Section 5(a) of the RRA. 71 P.S. § 745.5(a).

RAF Question #22 asks the promulgating agency to 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 of the regulated community and local and state governments for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements. The Department did not provide a response to this question in the proposed regulation. We ask the Department to include this information in the final regulatory package.