

Regulatory Analysis Form

(Completed by Promulgating Agency)

**INDEPENDENT REGULATORY
REVIEW COMMISSION**

(All Comments submitted on this regulation will appear on IRRC's website)

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(1) Agency

Pennsylvania Department of Agriculture

(2) Agency Number: 02

Identification Number: 191

IRRC Number:
3210

(3) PA Code Cite: 7 Pa Code § 59a.402

(4) Short Title: Milk Sanitation

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

Primary Contact: Dwight Smith, 717-787-8744, dwsmith@pa.gov

Secondary Contact: Lydia Johnson, 717-787-4315, lydijohnso@pa.gov

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

- Proposed Regulation
- Final Regulation
- Final Omitted Regulation

- Emergency Certification Regulation;
 - Certification by the Governor
 - Certification by the Attorney General

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

The Food and Drug Administration's (FDA's) regulations (at 21 CFR Part 133, Subpart B) are promulgated under authority of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), and establish standardized definitions and requirements for 72 different kinds of cheese. These same Federal regulations allow for 57 of these standardized cheeses to be produced from raw (unpasteurized) milk.

The Department of Agriculture's (Department's) current regulation for raw milk cheese is more restrictive than the Federal standards. The regulation will bring Pennsylvania into alignment with FDA standards and allow for the production of cheese from raw milk if: (a) the type of cheese that is being produced is a standardized cheese under FDA's standards; and (b) FDA's standards allow that type of standardized cheese to be produced from raw milk.

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

The act of July 2, 1935 (P.L. 589, No 210) (31 P.S. §§ 645-660g), as amended, commonly referred to as the Milk Sanitation Law, establishes the powers and duties of the Department with respect to milk sanitation, and (at 31 P.S. § 660c) authorizes the Department to adopt the regulations necessary to administer the provisions of that statute. The regulation is also authorized under the Food Safety Act (3 Pa.C.S. §§ 5721-5737), which: (1) authorizes the Department to promulgate regulations and food

standards necessary for enforcement of that statute; (2) defines certain "Federal acts" as including the Federal Food, Drug, and Cosmetic Act – the statute under which FDA's regulations establishing standardized cheeses are promulgated; and (3) encourages consistency between the Department's food safety regulations and those defined Federal acts and their attendant regulations (at 3 Pa.C.S. §§ 5733(a), 5722 and 5736(a), respectively).

(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.

No, the regulation is not mandated by any federal or state law or court order, or federal regulation. There are no relevant state or federal court decisions.

(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 regulation is needed to bring Pennsylvania's standards for raw milk cheese into alignment with FDA standards and, by so doing, to benefit Pennsylvania's raw milk cheese manufacturers and consumers.

The Department is aware that there has been some confusion among Pennsylvania's raw milk cheese manufacturers as to the types of standardized raw milk cheese that can lawfully be produced in Pennsylvania. The Department is satisfied the FDA's raw milk cheese standards are reasonable and represent the current state of food science with respect to the safe production of raw milk cheeses. There is no practical reason for PDA's raw milk cheese standards to be any more stringent than these FDA raw milk cheese standards.

The current regulation at 7 Pa. Code § 59a.402(b) (relating to raw milk; prohibitions) provides holders of Department-issued raw milk permits the option to obtain an additional permit "... authorizing the sale of aged cheese manufactured from raw milk." That provision references the standards set forth at 21 CFR Section 133.150 (relating to hard cheeses) as the applicable standards for this raw milk cheese production. In summary, this FDA standard requires that if raw milk is used to manufacture hard cheese: (a) the cheese must have a moisture content of no more than 39%; (b) the cheese solids must contain at least 50% milkfat; and (c) the cheese must be aged for at least 60 days at 35°F or higher.

In practice, although 57 of the 72 FDA standardized cheeses can be produced from raw milk, only 9 of these 57 cheeses can meet the requirements of 21 CFR Section 133.150 presented in the preceding paragraph. The regulation will allow Pennsylvania's cheese manufacturers to produce all 57 of the FDA standardized cheeses that can be manufactured from raw milk, and to better compete in the interstate and intrastate marketplace.

The beneficiaries of this regulation will be those Pennsylvania cheese manufacturers who produce cheese from raw milk. There are approximately 90 such manufacturers at present, and their numbers will likely increase after the regulation takes effect. These manufacturers will be able to market a greater variety of raw milk cheeses and will be able to compete with raw milk cheeses from other states. The value of the benefits of this regulation to raw milk cheese manufacturers cannot be readily quantified.

The regulation will also benefit consumers, to the extent there will be a wider variety of Pennsylvania-produced raw milk cheeses in the marketplace. The value of the benefits of this regulation to raw milk cheese consumers cannot be readily quantified.

(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, the provisions of the regulation are not more stringent than federal standards. To the contrary, the regulation will bring Pennsylvania's standards with respect to raw milk cheese into complete alignment with federal (FDA) standards.

(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 regulation will put Pennsylvania's raw milk cheese manufacturers on equal or similar regulatory footing with respect to their counterparts in other States. The statutes or regulations of other major commercial and artisanal cheese producing states (such as New York, Vermont, Maine, Wisconsin and California) are either in alignment with the FDA standards for raw milk cheese or require that raw milk cheese be refrigerated at no less than 35°F for at least 60 days (per 7 CFR 58.439). The regulation will: (a) bring Pennsylvania's standards with respect to cheese that is manufactured from raw milk into alignment with FDA standards on this subject; (b) increase the variety of standardized cheeses that can be produced in Pennsylvania from raw milk; and (c) make Pennsylvania's raw milk cheese manufacturers more competitive in interstate commerce.

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

No, the regulation will not affect any other regulations of the Department or another state agency.

(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 regulation is prompted by comments and recommendations from individual Pennsylvania cheese manufacturers and the Pennsylvania Cheese Guild, an umbrella organization representing approximately 20 of the approximately 90 raw milk cheese manufacturers in the Commonwealth.

(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 size standards presented in the United States Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121 (relating to Small Business Size Regulations) are the size standards that determine whether a business is a "small business" for purposes of the Regulatory Review Act. The applicable standards track with the North American Industry Classification System (NAICS) Codes, and are at 13 CFR § 121.201, in a chart titled *Small Business Size Standards by NAICS Industry*. The Department believes the following standards from that chart are applicable to the businesses and small businesses impacted by the regulation:

- Sector 11 (relating to Agriculture, Forestry, Fishing and Hunting), Subsector 112 (relating to Animal Production and aquaculture), provides that a dairy cattle and milk production operation is a small business if its annual receipts are *\$750,000 or less*.
- Sector 31 (relating to Manufacturing), Subsector 311 (relating to food manufacturing) categorizes various types of food manufacturing operations and provides that a cheese manufacturing operation is a small business if its annual receipts are *\$1,250,000 or less*.

As stated in Response No. 10, above, there are approximately 90 Pennsylvania cheese manufacturers who manufacture cheese from raw milk. For purposes of this small business impact analysis, the Department assumes that *all* these impacted businesses are "small businesses" under the Federal standards described above.

The impact of the regulation on the small businesses described above will be positive. It will allow Pennsylvania's cheese manufacturers to produce a greater variety of standardized cheeses from raw milk and to better compete in the marketplace. The Department is not able to provide an estimate of the dollar value of this positive benefit since it cannot estimate how much standardized cheese from raw milk will be produced, the types that will be produced, production costs and the market conditions that will drive product pricing.

(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.

Persons who manufacture cheese from raw milk will be required to comply with the regulation. As stated, these are approximately 90 in number, and the regulation is expected to increase this number.

(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 financial, economic and social impact of the regulation will be entirely positive. It will bring Pennsylvania's regulatory requirements into alignment with FDA regulations addressing the various standardized cheeses that can be manufacture from raw milk. Persons who manufacturer cheese from raw milk will be able to produce and market a wider variety of standardized cheeses, and should realize economic benefit from this expansion of the market. The dollar value of this benefit cannot be readily quantified.

Also, consumers will benefit from being able to buy more varieties of locally-produced raw milk cheese.

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

The regulation will not impose any new costs or adverse effects upon the regulated community (approximately 90 persons who manufacture cheese from raw milk). It is expected to benefit the regulated community by allowing it to produce and market a wider array of FDA-standardized cheeses from raw milk. These benefits cannot be readily quantified but - given that there are *no* costs - the regulation's benefits will certainly outweigh its costs.

Also, although the value of benefits to consumers cannot be readily quantified, there will be no adverse effects on consumers from this 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 is not expected to impose costs on the regulated community or to result in savings to the regulated community.

(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.

The regulation is not expected to result in costs or savings to local governments.

(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.

The regulation is not expected to result in costs or savings to state government.

(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.

The regulation will not result in new legal, accounting, consulting, reporting, recordkeeping requirements, or other paperwork. The persons who are currently making raw milk cheese under authority of Department-issued permits are the same group that will be producing the expanded variety of standardized raw milk cheeses when the final-form regulation is promulgated. No new permits or paperwork will be necessary.

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

No new forms will be required for implementation of the regulation. Persons who produce raw milk cheese do so under authority of Department-issued permits, and when the final-form regulation is promulgated these same producers will be able to lawfully produce the expanded variety of raw milk cheeses described in the regulation under authority of those same permits, without any additional paperwork. For informational purposes, samples of a milk permit and the application for a milk permit are attached to this document as Attachment "A."

(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.**

No forms are required for implementation of the regulation. See Answer No. 22a. For informational purposes, samples of a milk permit and the application for a milk permit are attached to this document as Attachment "A."

(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	0	0	0	0	0	0
Total Savings	0	0	0	0	0	0
COSTS:						
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 Costs	0	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community	0	0	0	0	0	0
Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Revenue Losses	0	0	0	0	0	0

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

Program	FY -3 2015-16	FY -2 2016-17	FY -1 2017-18	Current FY 2018-19
Food Safety Inspection Program	\$10,864,387	\$11,317,930	\$12,480,429	\$2,173,461

(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 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.

The regulation will not have an adverse impact on small business, obviating the need for the small business impact statement described above.

(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, since the regulation will not generate any adverse impact among affected groups or persons.

(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 least burdensome acceptable regulatory alternative has been selected.

(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.

The regulation will have no adverse impact on small businesses, obviating the need for the analysis described above.

(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.

Data is not the basis for the regulation, obviating the need for the referenced description.

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

- | | |
|---|----------------------------------|
| A. The length of the public comment period: | 30 days |
| B. The date or dates on which any public meetings or hearings will be held: | No public meetings will be held. |
| C. The expected date of delivery of the final-form regulation: | April 2019 |
| D. The expected effective date of the final-form regulation:
final-form regulation in the PA Bulletin | upon publication of the |
| E. The expected date by which compliance with the final-form regulation will be required:
final-form regulation in the PA Bulletin | upon publication of the |
| F. The expected date by which required permits, licenses or other approvals must be obtained:
final-form regulation in the PA Bulletin | upon publication of the |

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

The Department will evaluate the efficacy of the regulation on an ongoing basis.

Attachment “A”

Samples of a Milk Permit and the Application for a Milk Permit

(In Response to Questions 22, 22a and 22b, above)

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF AGRICULTURE
BUREAU OF FOOD SAFETY AND LABORATORY SERVICES
DIVISION OF MILK SANITATION

Facility ID: FIPS: Permit Expires: 8/31/2018 Effective Date: 9/1/2017
Business Name: Owner(s): Business Address:

Permit Type:	Operation Type:
Raw Bottler	Producer Handler
	Raw Milk
	Raw Milk Sales/Off Premises
	Raw Milk Sales/On Premises
Manufacturing Plant	Manufactured Cheese Aged 60 Days
	Manufactured Dairy Products
	MFG Frozen Desserts

Richard P. Kelly

Director

PERMIT IS NON-TRANSFERABLE



pennsylvania
 DEPARTMENT OF AGRICULTURE
 BUREAU OF FOOD SAFETY AND LABORATORY SERVICES

2301 North Cameron Street, Room 112

Harrisburg, PA 17110

APPLICATION FOR PERMIT TO Sell Milk and/or Milk Products

From September 1, 20 17 to August 31, 20 18

Please complete pages 1 through 3 of this form and sign and date the bottom of the third page and return it to the address listed

Facility ID Number : _____ (to be completed by PA Dept. of Ag)

FIPS Number : _____

Company Name and Physical Address:

Company Name: _____

Street Address: _____ City: _____

State: _____ Zip Code: _____

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: _____

Contact Name/Title: _____

Phone Number: _____ Emergency Phone: _____

County in which Facility is located: _____

Check ALL that indicate the type of permit you are applying for:

- Raw Farm (plan to sell raw milk on Farm it was produced)
- Raw Bottler (plan to bottle raw milk and sell off farm)
- Milk Processor Grade A (plan to pasteurize grade A milk/milk products)
- Milk processor Non Grade A (plan to pasteurize Non-grade A Milk, milk products)
- Manufacturing Plant (plan to manufacture dairy products)
- Receiving Station Transfer Station Wash Station
- Single service Container Manufacturer Distributor
- Bulk Tank Unit (BTU)* Organic (must attach copy of organic certification)

*Number of farms in the Bulk Tank Unit (BTU): _____

List all other sources of milk or dairy products you are receiving at this plant or location:

<u>Name</u>	<u>Address</u>	<u>Products</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

Please check all the operation type(s) that describe your operation does:

- Produce Raw Milk-Cows Produce Raw Milk- Goats Produce Raw Milk-Sheep
- Raw milk Sales/on premises Raw Milk sales/Off Premises MFG Frozen desserts
- Manufacturing Grade Milk for Pasteurization(BTU) Grade A Milk for Pasteurization (BTU)
- Pasteurizes Grade A-Cow Pasteurizes Grade A Milk-Goats Pasteurizes Grade A Milk-Sheep
- Grade A UltraPasteurized Milk Grade A Aseptically Processed & Packaged products
- Pasteurizes Milk-Cows (Non-A) Pasteurizes Milk – Goats (Non-A) Pasteurizes Milk-Sheep (Non-A)

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE
BUREAU

(Pursuant to Commonwealth Documents Law)

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DO NOT WRITE IN THIS SPACE

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

By: _____
(Deputy Attorney General)

DATE OF APPROVAL

Check if applicable
Copy not approved. Objections attached.

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

(AGENCY)

DOCUMENT/FISCAL NOTE NO. 2-181

DATE OF ADOPTION 1/11/2019

BY Russell C Redding
RUSSELL C. REDDING

TITLE
SECRETARY
Pennsylvania Department of Agriculture

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

BY B. L. Engler

MAY 06 2019
DATE OF APPROVAL

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

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

Notice of Final Rulemaking

Title 7 – AGRICULTURE
7 Pa. Code Chapter 59a

Milk Sanitation

NOTICE OF FINAL-FORM RULEMAKING

DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 59a]

Milk Sanitation

The Department of Agriculture (Department) amends § 59a.402 (relating to raw milk; prohibitions) to read as set forth in Annex A.

Effective Date

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

Authority

This final-form 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, which establishes the powers and duties of the Department with respect to milk sanitation. Section 19 of the act (at 31 P.S. § 660c) authorizes the Department to adopt the regulations necessary to administer the act. This final-form rulemaking is also authorized under 3 Pa.C.S. §§ 5721-5737 (relating to Food Safety Act), which: 1) authorizes the Department to promulgate regulations and food standards necessary for enforcement of 3 Pa.C.S. §§ 5721-5737; 2) defines certain “Federal acts” as including the Federal Food, Drug, and Cosmetic Act (21 U.S.C.A. §§ 301 – 399i); and 3) encourages consistency among the Department’s food safety regulations and those defined Federal acts and their attendant regulations. See 3 Pa.C.S. §§ 5722, 5733(a) and 5736(a) (relating to definitions; rules and regulations; and construction of subchapter).

Background and Summary

The United States Food and Drug Administration’s (FDA) regulations in 21 CFR Part 133, Subpart B (relating to requirements for specific standardized cheese and related products) were promulgated under authority of the Federal Food, Drug, and Cosmetic Act, and establish standardized definitions and requirements for 72 different kinds of cheese. These same Federal regulations allow for 57 of these standardized cheeses to be produced from raw (unpasteurized) milk.

Section 59a.402 addresses the types of cheese that can be produced from raw milk, and is more restrictive than 21 CFR Part 133, Subpart B. The Department is satisfied that the FDA’s raw milk cheese standards are reasonable and represent the current state of food science with respect to the safe production of raw milk cheeses. There is no practical reason for the Department’s raw milk cheese standards to be any more stringent than the FDA’s raw milk cheese standards. This final-form rulemaking will also further the objective of 3 Pa.C.S. §§ 5721-5737 to make the Department’s food regulations consistent with the FDA’s food safety regulations.

This final-form regulation will revise § 59a.402 to allow the holder of a raw milk permit to obtain an additional permit from the Department, authorizing the manufacture and sale of cheese from raw milk if: 1) the type of cheese that is being produced is a standardized cheese under the FDA's standards; and 2) the FDA's standards allow that type of standardized cheese to be produced from raw milk. This revision will bring the Commonwealth into alignment with FDA standards and allow the manufacture and sale of cheese from raw milk to the full extent allowed under the FDA standards. It will also allow manufacturers of raw milk cheese to market a greater variety of raw milk cheeses and provide consumers a wider selection of these cheeses.

Response to Comments

Notice of proposed rulemaking was published at 48 Pa.B. 4761 (August 4, 2018), with a 30-day public comment period.

The Department received a total of 10 comments from the public. The commentators included the Pennsylvania Cheese Guild, the Pennsylvania Farm Bureau, Oldways Cheese Coalition, the Real Food Consumer Coalition and six individuals. Each of these commentators offered support for the proposed rulemaking as written, without recommending any revisions. Commentators noted the benefits of aligning the Commonwealth's raw milk cheese standards with existing Federal standards of identity for cheese, and believe the rulemaking will bring economic benefits to the raw milk cheese industry and provide consumers a wider variety of raw milk cheeses in the marketplace.

The Department appreciates these comments and agrees with the sentiments expressed by the commentators.

The Independent Regulatory Review Commission had no objections, comments or recommendations to offer on the proposed rulemaking.

Fiscal Impact

Commonwealth

This final-form rulemaking will have no fiscal impact on this Commonwealth.

Political Subdivisions

This final-form rulemaking will have no fiscal impact on political subdivisions.

Private Sector

This final-form rulemaking will have some fiscal impact on the private sector. Businesses that manufacture raw milk cheese will benefit from being able to market a greater variety of raw milk cheeses. There are approximately 90 of these manufacturers.

General Public

This final-form rulemaking will have no appreciable impact on the general public, other than to make a greater variety of Pennsylvania-made raw milk cheeses available to consumers.

Paperwork Requirements

This final-form rulemaking will not add to paperwork requirements for any entity or the Department. The persons who are currently making raw milk cheese under authority of Department-issued permits are the same group that will be producing the expanded variety of standardized raw milk cheeses when the final-form regulation is promulgated. New permits or paperwork will not be necessary.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on July 25, 2018, the Department submitted a copy of the proposed rulemaking, published at 48 Pa.B. 4761, to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Agriculture and Rural Affairs Committees for review and comment.

Under section 5(c) of the Regulatory Review Act, the Department is required to submit to IRRC and the referenced Legislative Standing Committees copies of comments received during the public comment period, as well as other documents when requested. The Department provide the required copies of comments it received. No other documents were requested by the Legislative Standing Committees.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on _____, the final-form rulemaking was deemed approved by the House and Senate Agriculture and Rural Affairs Committees. IRRC did not comment on, make recommendations regarding or object to any portion of the proposed rulemaking, and the Department did not make any changes to the proposed rulemaking. Thus, under section 5.1(e) of the Regulatory Review Act (71 P.S. § 745.5a(e)), IRRC met on _____ and the final-form regulation was deemed approved pursuant to section 5(g) of the Regulatory Review Act.

Additional Information

Additional information may be obtained from Lydia Johnson, Ph.D., Director, Bureau of Food Safety and Laboratory Services, Pennsylvania Department of Agriculture, 2301 North Cameron Street, Harrisburg, PA 17110-9408, (717) 787-4315.

Findings

The Department finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

- (2) A public comment period was provided as required by law.
- (3) The amendments to the regulations of the Department are necessary and appropriate for the administration of the authorizing statute.

Order

The Department, acting under its authorizing statute, orders that:

(a) The regulations of the Department, 7 Pa. Code Chapter 59a, are amended by amending § 59a.402 to read as set forth in Annex A.

(b) The Department shall submit a copy of this final-form regulation to the Office of the Attorney General and the Office of General Counsel for approval as required by law.

(c) The Department shall submit this final-form regulation to IRRC and the committees as required by law.

(d) The Department shall certify this final-form regulation and deposit it with the Legislative Reference Bureau as required by law.

(e) The final-form regulation shall take effect immediately upon publication in the *Pennsylvania Bulletin*.

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

Subchapter F. RAW MILK FOR HUMAN CONSUMPTION

§ 59a.402. Raw milk; prohibitions.

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

(b) *Actions authorized under a raw milk permit.* A raw milk permit authorizes the permitholder to lawfully produce and sell (within this Commonwealth) raw whole milk for human consumption. It also authorizes the permitholder to obtain an additional permit, issued by the Department under authority of [21 CFR 133.150 (relating to hard cheeses), authorizing the sale of aged cheese manufactured from raw milk.] 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.

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



COMMONWEALTH OF PENNSYLVANIA
GOVERNOR'S OFFICE OF GENERAL COUNSEL

May 10, 2019

Independent Regulatory Review Commission
ATTN: David Sumner, Executive Director
333 Market Street, 14th Floor
Harrisburg, PA 17101

RE: NOTICE OF FINAL RULEMAKING
Department of Agriculture
7 Pa. Code Chapter 59a
Milk Sanitation
I.D. No. 2-191
Proposed Rulemaking: 48 Pa. Bulletin 4761 (August 4, 2018)
Approved by Office of General Counsel: May 6, 2019

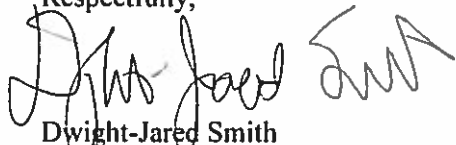
Dear Mr. Sumner:

Please find enclosed a copy of the above-referenced final-form regulation (Face Sheet, Preamble and Annex A). Copies of the Regulatory Analysis Form and Notice of Proposed Rulemaking are also enclosed. This material is submitted to you in accordance with the Regulatory Review Act (at 71 P.S. § 745.5a(a)).

No objections, comments or recommendations were received from the General Assembly with respect to the proposed rulemaking. The Department's responses to the several comments received from the public with respect to the proposed rulemaking are set forth in the enclosed Preamble and Annex "A" document. These comments all supported the proposed regulation and did not recommend any changes. None of the commentators requested additional information regarding the final-form regulation or the text of the final-form regulation.

I respectfully request the Commission's approval of this final-form regulation. The Department will provide any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your consideration of this document.

Respectfully,



Dwight-Jared Smith
Assistant Counsel

Enclosures

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**


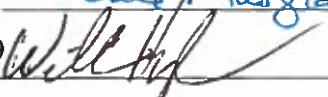



I.D. NUMBER: 2-191
SUBJECT: MILK SANITATION
AGENCY: DEPARTMENT OF AGRICULTURE

TYPE OF REGULATION

- Proposed Regulation
- X Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

**RECEIVED
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FILING OF REGULATION

<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
<i>HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS</i>		
5-10-19		MAJORITY CHAIR <u>Causer</u>
5-10-19		MINORITY CHAIR <u>Pashinski</u>
<i>SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS</i>		
5-10-19		MAJORITY CHAIR <u>Vogel</u>
5-10-19		MINORITY CHAIR <u>Schwank</u>
5-10-19		<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
_____	_____	<i>ATTORNEY GENERAL</i> (for Final Omitted only)
_____	_____	<i>LEGISLATIVE REFERENCE BUREAU</i> (for Proposed only)