

# Regulatory Analysis Form

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(1) Agency

Department of Agriculture

INDUSTRIAL REVIEW COMMISSION

(2) I.D. Number (Governor's Office Use)

2-141

IRRC Number: 3293

(3) Short Title

Milk Sanitation

(4) PA Code Cite

7 Pa. Code Chapter 59

(5) Agency Contacts & Telephone Numbers

Primary Contact: James C. Dell 717-787-4316

Secondary Contact: Bobby McLean 717-787-4315

(6) Type of Rulemaking (check one)

Proposed Rulemaking

Final Order Adopting Regulation **XXXXX**

Final Order, Proposed Rulemaking Omitted

(7) Is a 120-Day Emergency Certification Attached?

No: **XXXXX**

Yes: By the Attorney General

Yes: By the Governor

(8) Briefly explain the regulation in clear and non-technical language.

The regulation amends 7 Pa. Code §59.22 (relating to milk dating) by extending the "sell-by" date that must appear on containers of pasteurized milk by three (3) days. That section currently requires containers of pasteurized milk to bear a "sell by" date that does not exceed 14 days from midnight of the date upon which the milk was pasteurized. The proposed amendment will change that 14-day limit to 17 days. It also exempts certain highly-processed pasteurized dairy products from the sell-by date requirement, and defines several related terms in § 59.1 (relating to definitions). These terms include "aseptically processed dairy products" and "higher heat shorter time pasteurization." The regulation also describes the role of the Pennsylvania Department of Agriculture ("PDA") in monitoring dairy products to ensure they remain within acceptable bacterial limits for pasteurized milk.

(9) State the statutory authority for the regulation and any relevant state or federal court decisions.

The statutory authority for this regulation is the Act of July 2, 1935 (P.L. 589, No. 210) (31 P.S. §§ 645-660f), which authorizes PDA to regulate the production, processing, storage and packaging of milk to safeguard human health.

## Regulatory Analysis Form

(10) Is the regulation mandated by any federal or state law or court order, or federal regulation? If yes, cite the specific law, case or regulation, and any deadlines for action.

No federal or state statute, law or regulation mandates this regulation

(11) Explain the compelling public interest that justifies the regulation. What is the problem it addresses?

The public has an interest in maintaining the vitality of the Commonwealth's dairy industry. The nature of the industry is changing. Modern processing and refrigeration have increased the distribution range of the average milk processor from 100-150 miles to 300-400 miles. Modern processing and refrigeration also allow for the production of pasteurized milk that can remain on-the-shelf for longer periods of time without bacterial growth exceeding acceptable limits. The regulation will follow the trend among states to extend sell-by dates for pasteurized milk - whether by designating a maximum sell-by period (as this regulation will do) or allowing individual producers to demonstrate their pasteurization and refrigeration processes result in dairy products that remain within acceptable bacterial limits for the period in which they are marketed to consumers.

The regulation should make Pennsylvania-produced dairy products more competitive in interstate commerce.

(12) State the public health, safety, and environmental or general welfare risks associated with non-regulation.

There are no public health, safety or environmental risks associated with non-regulation.

(13) Describe who will benefit from the regulation. (Quantify the benefits as completely as possible and approximate the number of people who will benefit.)

The Commonwealth's dairy industry will benefit by this regulation in that it will make the Commonwealth's pasteurized milk more competitive in interstate commerce. The milk "sell by" date also provides processors with a tool by which to insure consistent turnover of their inventories. Milk retailers will also benefit from this regulation in that, by extending the "sell by" date from 14 days to 17 days, the retailers will have an additional three days within which to turn over their milk inventories.

## Regulatory Analysis Form

(14) Describe who will be adversely affected by the regulation. (Quantify the adverse effects as completely as possible and approximate the number of people who will be adversely affected.)

This regulation is not expected to have an adverse affect on any person or entity.

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

The Commonwealth's milk processors will be required to comply with this regulation. It is significant that the regulation establishes a maximum "sell by" date, and that individual milk processors remain free to establish "sell by" dates of less than 17 days, if they wish.

(16) Describe the communications with and input from the public in the development and drafting of the regulation. List the persons and/or groups who were involved, if applicable.

The regulation has been adopted largely at the behest of the Commonwealth's dairy industry. The Pennsylvania Association of Milk Dealers petitioned PDA for this regulatory change. A meeting with representatives of the Commonwealth's dairy industry was held at the Pennsylvania Association of Milk Dealers, which submitted a letter of petition (dated November 2, 2001), seeking the change that will be accomplished by the regulation.

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

The regulation is not expected to impose any costs upon milk processors. Although it is expected to result in savings to milk processors, which will make their product (pasteurized milk) more competitive in interstate commerce. That more competitive price will benefit the consumers. PDA is unable to provide a specific estimate of these savings.

## **Regulatory Analysis Form**

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

The regulation is not expected to result in appreciable costs or saving to local governments, nor is it expected to result in the need for new legal, accounting or consultant procedures.

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

The regulation is not expected to result in any costs or savings with respect to state government, nor is it expected to result in the need for new legal, accounting or consultant procedures.

## Regulatory Analysis Form

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

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
<b>SAVINGS:</b>	\$	\$	\$	\$	\$	\$
Regulated	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
<b>COSTS:</b>						
Regulated	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
<b>REVENUE LOSSES:</b>						
Regulated	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

(20a) Explain how the cost estimates were derived.

The regulation is not expected to result in any costs or savings with respect to the regulated community, local government or state government.

## Regulatory Analysis Form

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

Program	FY -3	FY -2	FY -1	Current FY
Milk Dating	0	0	0	0

(21) Using the cost-benefit information provided above, explain how the benefits of the regulation outweigh the adverse effects and costs.

This regulation will impose no new costs on the Commonwealth's dairy industry, but will make Pennsylvania-produced pasteurized milk more competitive in interstate commerce and will benefit the consumer with the most competitive milk product price. There are no appreciable costs associated with implementation. Although the regulation calls for PDA to take milk samples and conduct bacteriological testing of these samples, PDA already does this type of sampling and testing on a routine basis as part of its statutory responsibilities.

(22) Describe the non-regulatory alternatives considered and the costs associated with those alternatives. Provide the reasons for their dismissal.

No non-regulatory alternatives were considered. The regulation amends a pre-existing regulation.

(23) Describe alternative regulatory schemes considered and the costs associated with those schemes. Provide the reasons for their dismissal.

No alternative regulatory schemes were considered. The only procedure by which to revise the pasteurized milk sell-by date is through revision of the current regulation.

## Regulatory Analysis Form

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

There are no federal standards dealing with establishing "sell by" dates for pasteurized milk.

(25) How does this regulation compare with those of other states? Will the regulation put Pennsylvania at a competitive disadvantage with other states?

This regulation will not put Pennsylvania at a competitive disadvantage with other states. On the contrary, its purpose is to make the Commonwealth's dairy industry more competitive in interstate commerce by extending the pasteurized milk "sell by" date to bring it into closer conformity with neighboring states.

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

No. This regulation is not expected to have an adverse affect on any person or entity.

(27) Will any public hearings or informational meetings be scheduled? Please provide the dates, times, and locations, if available.

No public hearings or informational meetings will be scheduled. The regulation was drafted largely at the behest of the Commonwealth's dairy industry. The Pennsylvania Association of Milk Dealers petitioned PDA for this regulatory change. A meeting with representatives of the Commonwealth's dairy industry was held at the Pennsylvania Association of Milk Dealers, which submitted a letter of petition to PDA on November 2, 2001.

Interested persons were afforded the opportunity to offer comments on the proposed regulation during the promulgation process described in the Regulatory Review Act. Only the Independent Regulatory Review Commission and the Pennsylvania Association of Milk Dealers offered comments.

## Regulatory Analysis Form

(28) Will the regulation change existing reporting, record keeping, or other paperwork requirements? Describe the changes and attach copies of forms or reports which will be required as a result of implementation, if available.

No. The regulation will not change existing reporting or record keeping requirements.

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

No such special provisions have been developed.

(30) What is the anticipated effective date of the regulation; the date by which compliance with the regulation will be required; and the date by which any required permits, licenses or other approvals must be obtained?

The regulation will take immediate effect upon final publication in the *Pennsylvania Bulletin*.

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

Although no sunset date has been set for this regulation, its efficacy will be reviewed on an ongoing basis.



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REVIEW DIVISION

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

By: \_\_\_\_\_  
(Deputy Attorney General)

DATE OF APPROVAL \_\_\_\_\_

Check if applicable  
Copy not approved. Objections attached.

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

(AGENCY) \_\_\_\_\_

DOCUMENT/FISCAL NOTE NO. 2-141

DATE OF ADOPTION 5/1/03

BY Dennis C Wolff  
Dennis C Wolff, Acting Secretary

TITLE \_\_\_\_\_  
EXECUTIVE OFFICER CHAIRMAN OR SECRETARY

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

BY \_\_\_\_\_

DATE OF APPROVAL

6/18/03  
Exec. (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 59

Milk Sanitation

# FINAL RULEMAKING

## DEPARTMENT OF AGRICULTURE

### [7 PA CODE CH. 59]

#### *Milk Sanitation*

The Department of Agriculture (Department) hereby revises several provisions of 7 Pa. Code Chapter 59 (relating to milk sanitation). The revisions: (1) reformat and add several new defined terms to § 59.1 (relating to definitions); and (2) revise § 59.22 (relating to milk dating) to extend the current 14-day maximum "sell-by" period for pasteurized milk to 17 days, clarify the exceptions to that sell-by date requirement and describe the milk quality sampling and testing that will be performed by the Department. The revisions read as set forth in Annex "A."

#### *Statutory Authority*

The act of July 2, 1935 (P.L.589, No. 210)(31 P.S. §§ 645-660), as amended (Act) provides the legal authority for this regulation. In particular, section 21 of the act (31 P.S. § 660e) makes the Department generally responsible for the safety and wholesomeness of the milk supply and allows the Department to exclude milk from commerce if it fails to meet the requirements of the Act, and section 19 of the act (31 P.S. § 660c) authorizes the Department to regulate for the proper enforcement of the Act.

#### *Need for the Regulation*

The primary purpose of the final-form regulation is to amend § 59.22 (relating to milk dating) to extend the maximum sell-by date for pasteurized milk by three days. The current maximum sell-by date is 14 days beginning after midnight of the date of pasteurization. Modern processing and refrigeration allow for the production of pasteurized milk that can remain on-the-shelf for longer periods of time without bacterial growth exceeding acceptable limits. The final-form regulation follows the trend among states to extend sell-by dates for pasteurized milk - whether by designating a maximum sell-by period (as the final-form regulation does) or allowing individual producers to demonstrate their pasteurization and refrigeration processes result in dairy products that remain within acceptable bacterial limits for the period in which they are marketed to consumers.

The final-form regulation also reformats § 59.1 (relating to definitions). The section was divided into two subsections - one containing "general definitions" and the other containing definitions related to "milk and milk products." The final-form regulation deletes these subsection designations and combines the two sets of terms and definitions into a single, more readable set.

The final-form regulation also revises § 59.1 by adding definitions of "aseptically processed dairy products" and "higher heat shorter time pasteurization," two terms describing relatively recent advances in the processing of dairy products. These processes result in milk with a longer shelf life than milk processed through typical pasteurization processes. Section 59.22(d) of the final-form regulation exempts milk processed through either of these methods (and several other methods) from the sell-by date requirements described in that section.

Section 59.22 of the final-form regulation describes the process by which the Department will sample and analyze pasteurized milk to ensure it does not exceed bacterial limits prescribed by regulation.

In summary, the Department is satisfied there is a need for the revisions accomplished by this final-form regulation.

### *Comments*

Notice of Proposed Rulemaking was published at 32 *Pennsylvania Bulletin* 4717 (September 28, 2002), and provided for a 30-day public comment period. Comments were received from the Pennsylvania Association of Milk Dealers and the Independent Regulatory Review Commission (IRRC).

*Comment:* The Pennsylvania Association of Milk Dealers represents the substantial majority of companies which process beverage milk sold in Pennsylvania, and offered its strong support for the increase in the maximum milk sell-by date to 17 days from date of pasteurization. The commentator believes the change will "... help the industry adapt to the changing marketplace and grow stronger."

*Response:* The Department accepts the comment without further response.

*Comment:* IRRC noted that proposed § 59.22(e) (relating to milk dating) made reference to the Department "periodically" sampling containers of pasteurized milk, and suggested the final-form regulation include a specific time frame for this "periodic" sampling.

*Response:* The Department accepts this suggestion, and has implemented it in § 59.22(e)(1) of the final-form regulation by specifying this "periodic" sampling shall be at least one product from each processor or distributor each year. As a result of this comment and the other comments offered by IRRC, the Department divided § 59.22(e) into four paragraphs, dealing with: (1) sampling requirements; (2) testing requirements; (3) the imposition of maximum sell-by dates of less than 17 days; and (4) resumption of 17-day maximum sell-by periods. This reformatting adds clarity to the section.

*Comment:* Proposed § 59.22(e) provided that the Department might require a milk processor to use a maximum sell-by date of something less than 17 days if two or

more samples demonstrated the processor could not produce pasteurized milk that remained consistently within acceptable bacterial limits during a 17-day sell-by period. IRRC recommended the final-form regulation describe the procedure by which such a milk processor could reestablish a 17-day sell-by date for its pasteurized milk.

*Response:* The Department accepts IRRC's recommendation, and has implemented it in paragraphs 59.22(e)(2) and (3). The new language also clarifies that the analysis of samples is to be conducted by a "Pennsylvania approved dairy laboratory" – a term defined in § 59.1.

*Comment:* On a subject closely related to the previous comment, IRRC requested the final-form regulation specify how the Department will establish a specific maximum sell-by date for a milk processor that cannot produce pasteurized milk that merits a 17-day maximum sell-by date.

*Response:* The Department has revised the final-form regulation to implement this request, in paragraphs 59.22(e)(3) and (4), to reflect that predicted bacterial growth shall determine the appropriate sell-by date.

#### ***Fiscal Impact***

The final-form regulation does not impose any costs and has no fiscal impact upon the Commonwealth, political subdivisions or the general public.

The final-form regulation has no adverse fiscal impact upon the private sector. The extension of the maximum sell-by date for pasteurized milk is expected to have a favorable economic impact upon milk processors and milk retailers. These economic impacts cannot be readily quantified, though.

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#### ***Paperwork Requirements***

The final-form regulation does not appreciably increase the paperwork burden of the Department, local government units, milk producers, milk distributors or other affected entities.

#### ***Contact Person***

Further information is available by contacting the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: James Dell. Telephone: (717) 787-4316.

#### ***Regulatory Review***

Under § 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), the Department submitted a copy of the Notice of Proposed Rulemaking published at 32 *Pennsylvania Bulletin* 4717 (September 28, 2002) on September 18, 2002 to the Independent

Regulatory Review Commission and to the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs for review and comment. In compliance with § 5(b.1), the Department also provided the Commission and the Committees with copies of all comments received, as well as other documentation.

In preparing this final-form regulation, the Department has considered all comments received from the Commission, the Committees and the public.

This final-form regulation was \_\_\_\_\_ (approved or deemed approved) by the House Agricultural and Rural Affairs Committee on \_\_\_\_\_, 2003, was \_\_\_\_\_ (approved or deemed approved) by the Senate Agriculture and Rural Affairs Committee on \_\_\_\_\_, 2003, and was approved by the Commission on \_\_\_\_\_, 2003.

### ***Findings***

The Department of Agriculture finds the following:

1. Public notice of its intention to adopt the regulation encompassed by this Order has been given under §§ 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240)(45 P.S. §§ 1201 and 1202) and their attendant regulations at 1 Pa. Code §§ 7.1 and 7.2.
2. A public comment period was provided as required by law and all comments received were considered.
3. The modifications that were made to this regulation in response to comments received do not enlarge the purpose of the proposed regulation published at 32 *Pennsylvania Bulletin* 4717 (September 28, 2002).
4. The adoption of the regulation in the manner provided in this Order is necessary and appropriate for the administration of the authorizing statute.

### ***Order***

The Department of Agriculture, acting under authority of the authorizing statute, orders the following:

1. The regulations of the Department of Agriculture at 7 Pa. Code Chapter 59 (relating to milk sanitation) are adopted as set forth at Annex "A" hereto.
2. The Secretary of Agriculture shall submit this Order, 32 *Pennsylvania Bulletin* 4717 (September 28, 2002) and Annex "A" hereto to the Office of General Counsel and to the Office of Attorney General for approval as required by law.

3. The Secretary of Agriculture shall certify this Order, 32 *Pennsylvania Bulletin* 4717 (September 28, 2002) and Annex "A" hereto and deposit them with the Legislative Reference Bureau as required by law.

4. This Order shall take effect upon publication in the *Pennsylvania Bulletin*.

DENNIS C WOLFF,  
*Acting Secretary*

Annex A

TITLE 7. AGRICULTURE  
PART 3. BUREAU OF FOOD SAFETY AND  
LABORATORY SERVICES  
Subpart B. LIQUID FOODS  
CHAPTER 59. MILK SANITATION  
Subchapter A. PRELIMINARY PROVISIONS

TERMS AND APPLICATIONS

§ 59.1. Definitions.

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

\* \* \*

*Aseptically processed dairy products* -Milk and milk products which are packaged in hermetically sealed containers allowing storage for long periods of time without refrigeration.

\* \* \*

*Certified milk*—Milk from dairy farms operated in accordance with “Methods and Standards for the Production and Distribution of Certified Milk,” last adopted by the American Association of Medical Milk Commissioners, Inc., the production and handling of which shall be certified by a commission instituted in compliance therewith.

\* \* \*

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

\* \* \*

*Dry milk and whey products*—Products which have been produced for use in pasteurized milk or milk products and which have been manufactured under this chapter.

\* \* \*

*Higher heat shorter time pasteurization* – A process through which every particle of a dairy product is heated to between 191°F and 212°F at holding times between 1.0 and 0.1 seconds before packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

\* \* \*

Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk—The product resulting from the treatment of milk, lowfat milk, or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of lactose to glucose or galactose, or both, so that the remaining lactose is less than 30% of the lactose in milk, lowfat milk, or skim milk.

\* \* \*

Milk—The natural lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats.

\* \* \*

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

\* \* \*

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

\* \* \*

Pasteurized concentrated dairy products—Includes homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section.

Pasteurized frozen milk concentrate—A frozen dairy product with a composition of milkfat and milk solids not fat in such proportions that, when a given volume of concentrate is mixed with a given volume of water, the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.

Pasteurized low-sodium milk or low-sodium lowfat milk or low-sodium skim milk—The product resulting from the treatment of milk, lowfat milk, or skim milk by a process of passing the milk, lowfat milk, or skim milk through an ion exchange resin process or by any process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.



\* \* \*

*Raw milk*—Raw milk is milk which conforms with the relevant provisions of this chapter and may be sold to consumers without further treatment or processing.

\* \* \*

[(b) *Milk and milk products*. The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:]

[*Certified milk*—Milk from dairy farms operated in accordance with “Methods and Standards for the Production and Distribution of Certified Milk,” last adopted by the American Association of Medical Milk Commissioners, Inc., the production and handling of which shall be certified by a commission instituted in compliance therewith.]

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

[*Dry milk and whey products*—Products which have been produced for use in pasteurized milk or milk products and which have been manufactured under the provision of this chapter.]

[*Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk*—The product resulting from the treatment of milk, lowfat milk, or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of lactose to glucose or galactose, or both, so that the remaining lactose is less than 30% of the lactose in milk, lowfat milk, or skim milk.]

[*Milk*—The natural lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats.]

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

[*Milk products*—Ice cream, ice cream mix, custard ice cream, French ice cream, frozen custard, ice milk, sherbet, and other similar frozen and semifrozen products and all dairy products used in the manufacture thereof.]

[*Pasteurized concentrated dairy products*—Includes homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section.]

[*Pasteurized frozen milk concentrate*—A frozen dairy product with a composition of milkfat and milk solids not fat in such proportions that, when a given volume of

concentrate is mixed with a given volume of water, the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.]

[*Pasteurized low-sodium milk or low-sodium lowfat milk or low-sodium skim milk*—The product resulting from the treatment of milk, lowfat milk, or skim milk by a process of passing the milk, lowfat milk, or skim milk through an ion exchange resin process or by any process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.]

[*Raw milk*—Raw milk is milk which conforms with the relevant provisions of this chapter and may be sold to consumers without further treatment or processing.]

## LABELING

### § 59.22. Milk dating.

(a) *Label requirement.* The cap or non-glass container of pasteurized milk held in retail food stores, restaurants, schools, or similar food establishments for resale shall be conspicuously and legibly marked in a contrasting color with the designation of the "sell-by" date - the month and day of the month after which the product may not be sold or offered for sale. The designation may be numerical – such as “8-15” – or with the use of an abbreviation for the month, such as “AUG 15 or AU 15.” The words “Sell by” or “Not to be sold after” shall precede the designation of the date, or the statement “Not to be sold after the date stamped above” shall appear legibly on the container. This designation of the date shall not exceed [14] 17 days beginning after midnight on the day on which the [dairy products were] milk was pasteurized. [Stores, as used in this subsection, include any mercantile establishments which offer milk for sale except on premises where processed.]

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

(c) *Prohibition.* Pasteurized milk may not be sold [after the date designated on the container] or offered for sale if either of the following occurs:

(1) The milk is sold or offered for sale after the sell-by date designated on the container.

(2) Without regard to the sell-by date designated on the container, the milk exceeds the bacterial limits for pasteurized milk described in § 59.52 (relating to table).

(d) *Exemption.* [Sterile, ultra-pasteurized and cultured dairy products are exempt from the dating requirements.] The following pasteurized dairy products are exempt from the requirements of this section:

(1) Ultra-pasteurized dairy products.

(2) Cultured dairy products.

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

processed.

(e) Monitoring by the Department.

(1) The Department will periodically sample containers of pasteurized milk in the possession of the processor or distributor. This sampling may occur at any time before the pasteurized milk is delivered to the store or the customer. THE DEPARTMENT WILL SAMPLE AT LEAST ONE MILK PRODUCT FROM EACH PROCESSOR EACH CALENDAR YEAR.

(2) The samples DESCRIBED IN PARAGRAPH (1) shall be analyzed BY A PENNSYLVANIA APPROVED DAIRY LABORATORY, APPLYING A METHODOLOGY SET FORTH IN THE MOST CURRENT EDITION OF DAIRY PRACTICES COUNCIL GUIDELINE NO. 10, ENTITLED "GUIDELINES FOR MAINTAINING AND TESTING FLUID MILK SHELF LIFE," to determine whether the bacterial test results exceed the bacterial limits for pasteurized milk described in § 59.52 (relating to table) prior to the expiration of the sell-by date designated on the retail container.

(3) When two or more samples demonstrate a processor cannot produce pasteurized milk that remains consistently within the ~~referenced~~ bacterial limits REFERENCED IN PARAGRAPH (2) during a 17-day sell-by period, the Department will require a processor to use a sell-by date of something less than the 17-day period described in subsection (a). THE DEPARTMENT WILL CALCULATE THIS REVISED SELL-BY DATE SUCH 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 § 59.52 (RELATING TO TABLE).

(4) A PROCESSOR MAY SUBMIT SAMPLES TO THE DEPARTMENT FOR ANALYSIS IN ORDER TO OBTAIN APPROVAL TO RESUME A 17-DAY SELL-BY PERIOD FOR THE PRODUCT SAMPLED. THE DEPARTMENT WILL APPROVE RESUMPTION OF A 17-DAY SELL-BY PERIOD WHEN ANALYSIS OF A SAMPLE DEMONSTRATES THAT BACTERIAL GROWTH IN THE MILK WILL NOT EXCEED THE REFERENCED BACTERIAL LIMITS WITHIN THAT SELL-BY PERIOD IF THE MILK IS MAINTAINED IN ACCORDANCE WITH THE TEMPERATURE STANDARDS FOR PASTEURIZED MILK IN § 59.52 (RELATING TO TABLE).

\* \* \*

# PROPOSED RULEMAKING

## DEPARTMENT OF AGRICULTURE

[7 PA. CODE CH. 59]

### Milk Sanitation

The Department of Agriculture (Department) proposes to amend §§ 59.1 and 59.22 (relating to definitions; and milk dating) to read as set forth in Annex A.

#### *Statutory Authority*

The act of July 2, 1935 (act) (P. L. 589, No. 210) (31 P. S. §§ 645—660g) provides the legal authority for this proposed rulemaking. In particular, section 21 of the act (31 P. S. § 660e) makes the Department generally responsible for the safety and wholesomeness of the milk supply and allows the Department to exclude milk from commerce if it fails to meet the requirements of the act, and section 19 of the act (31 P. S. § 660c) authorizes the Department to regulate for the proper enforcement of the act.

#### *Purpose*

The primary purpose of the proposed rulemaking is to amend § 59.22 to extend the maximum sell-by date for pasteurized milk by 3 days. The current maximum sell-by date is 14 days beginning after midnight of the date of pasteurization. Modern processing and refrigeration allows for the production of pasteurized milk that can remain on-the-shelf for longer periods of time without bacterial growth exceeding acceptable limits. The proposed rulemaking will follow the trend among states to extend sell-by dates for pasteurized milk—whether by designating a maximum sell-by period (as the proposed rulemaking would do) or allowing individual producers to demonstrate their pasteurization and refrigeration processes result in dairy products that remain within acceptable bacterial limits for the period in which they are marketed to consumers.

The proposed rulemaking would also reformat § 59.1. The section is currently divided into two subsections—one containing “general definitions” and the other containing definitions related to “milk and milk products.” The proposed rulemaking would delete these subsection designations and combine the two sets of terms and definitions into a single, more readable set.

In addition, proposed § 59.1 would add definitions of “aseptically processed dairy products” and “higher heat shorter time pasteurization,” two terms describing relatively recent advances in the processing of dairy products. These processes result in milk with a longer shelf life than milk processed through typical pasteurization processes. Proposed § 59.22(d) would exempt milk processed through either of these methods (and several other methods) from the sell-by date requirements described in that section.

Proposed § 59.22 would also describe the process by which the Department would sample and analyze pasteurized milk to ensure it does not exceed bacterial limits prescribed by regulation.

#### *Background*

The Department has increased the maximum “sell-by” date for pasteurized milk several times in recent years, to

keep pace with developments in the fluid milk industry. The nature of the fluid milk industry is changing. The number of milk processing plants and milk distributing plants has declined significantly. Where the average plant once distributed its pasteurized milk in a 100-150 mile radius, the average modern plant’s distribution radius is between 300 and 400 miles. Although these plants are fewer in number, they tend to be larger, more modern and more efficient. Modern processing, refrigeration and transportation gives pasteurized milk a longer shelf life than it has had in the past.

The milk “sell-by” date that appears on a container of pasteurized milk does not control the time within which the milk may be consumed, only the time within which it may be sold. All pasteurized milk supports bacterial growth that, in time, affects the flavor of the milk. Although the bacteria in milk does not pose a threat to the health of people who drink it, there is a general consumer expectation that milk will have a certain crisp, consistent taste.

Although the proposed rulemaking would extend the maximum sell-by date for pasteurized milk, a milk plant would have the discretion to use a shorter sell-by period. This exercise of discretion might be driven by a milk plant’s desire to meet a particular consumer taste preference, or by the processing, refrigeration and transportation system through which the milk is delivered to the consumer.

#### *Need for the Proposed Rulemaking*

The proposed rulemaking is necessary to keep Commonwealth-produced pasteurized milk competitive in interstate commerce. The proposed increase in the maximum sell-by date for pasteurized milk is justified by advances in processing, packaging and transportation that result in pasteurized milk with a longer shelf life.

The Department is satisfied of the need for the proposed rulemaking and believes the document is consistent with the principles outlined in Executive Order 1996-1, “Regulatory Review and Promulgation.”

#### *Overview of the Major Provisions of the Proposed Rulemaking*

Section 59.22 would be amended by extending the maximum sell-by date for pasteurized milk by 3 days. In addition, subsection (c) would be revised to clarify the sell-by date requirement. Subsection (d) would list the types of dairy products that are exempt from the sell-by date requirements. Subsection (e) would describe the sampling and testing that would be undertaken by the Department to ensure the bacterial levels of milk remain within acceptable limits for the duration of the sell-by period set forth on the milk container.

#### *Affected Individuals and Organizations*

The Commonwealth’s dairy industry will benefit from this proposed rulemaking in that it will make this Commonwealth’s pasteurized milk more competitive in interstate commerce. The milk sell by date also provides processors with a tool by which to insure consistent turnover of their inventories. Milk retailers will also benefit from this proposed rulemaking in that, by extending the sell-by date from 14 days to 17 days, the retailers will have an additional 3 days within which to turn over their milk inventories. This proposed rulemaking is not expected to have an adverse affect on any person or entity.

*Fiscal Impact*

The proposed rulemaking would impose no costs and have no fiscal impact on the Commonwealth, political subdivisions or the general public.

The proposed rulemaking would impose no costs and have no adverse fiscal impact upon the private sector. The extension of the maximum sell-by date for pasteurized milk is expected to have a favorable economic impact upon milk processors and milk retailers. None of these favorable economic impacts can be readily quantified, though.

*Paperwork Requirements*

The proposed rulemaking would not appreciably increase the paperwork burden of the Department, local government units, milk producers, milk distributors or other affected entities.

*Effective Date*

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

*Sunset Date*

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

*Public Comment Period/Contact Person*

Interested persons are invited to submit written comments regarding the proposed rulemaking within 30 days following publication in the *Pennsylvania Bulletin*. Comments shall be submitted to the Department of Agriculture, Bureau of Food Safety and Laboratory Services, 2301 North Cameron Street, Harrisburg, PA 17110-9408, Attention: James C. Dell.

*Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P. S. § 745.5(a)), on September 18, 2002, the Department submitted a copy of this proposed rulemaking to the Independent Regulatory Review Commission (IRRC) and the Chairpersons of the House and Senate Standing Committees on Agriculture and Rural Affairs. In addition to submitting the proposed rulemaking, the Department has provided IRRC and the Committees with a copy of a detailed Regulatory Analysis Form prepared by the Department in compliance with Executive Order 1996-1. A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, if IRRC has objections to any portion of the proposed rulemaking, it will notify the Department within 10 days of the close of the Committees' review period. The notification shall specify the regulatory review criteria that have not been met by the portion of the proposed rulemaking to which an objection is made. The Regulatory Review Act specifies detailed procedures for review, prior to final publication of the rulemaking, by the Department, the General Assembly and the Governor of objections raised.

SAMUEL E. HAYES, Jr.,  
*Secretary*

**Fiscal Note:** 2-141. No fiscal impact; (8) recommends adoption.

Annex A

TITLE 7. AGRICULTURE  
PART III. BUREAU OF FOOD SAFETY AND  
LABORATORY SERVICES

Subpart B. LIQUID FOODS

CHAPTER 59. MILK SANITATION

Subchapter A. PRELIMINARY PROVISIONS

TERMS AND APPLICATION

§ 59.1. Definitions.

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

\* \* \* \* \*

*Aseptically processed dairy products*—Milk and milk products which are packaged in hermetically sealed containers allowing storage for long periods of time without refrigeration.

\* \* \* \* \*

*Certified milk*—Milk from dairy farms operated in accordance with "Methods and Standards for the Production and Distribution of Certified Milk," last adopted by the American Association of Medical Milk Commissioners, Inc., the production and handling of which shall be certified by a commission instituted in compliance therewith.

\* \* \* \* \*

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

\* \* \* \* \*

*Dry milk and whey products*—Products which have been produced for use in pasteurized milk or milk products and which have been manufactured under this chapter.

\* \* \* \* \*

*Higher heat shorter time pasteurization*—A process through which every particle of a dairy product is heated to between 191°F and 212°F at holding times between 1.0 and 0.1 seconds before packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

\* \* \* \* \*

*Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk*—The product resulting from the treatment of milk, lowfat milk or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of lactose to glucose or galactose, or both, so that the remaining lactose is less than 30% of the lactose in milk, lowfat milk or skim milk.

\* \* \* \* \*

*Milk*—The natural lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats.

\* \* \* \* \*

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

\* \* \* \* \*

**Milk products**—Ice cream, ice cream mix, custard ice cream, French ice cream, frozen custard, ice milk, sherbet, and other similar frozen and semifrozen products and all dairy products used in the manufacture thereof.

\* \* \* \* \*

**Pasteurized concentrated dairy products**—Includes homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section.

**Pasteurized frozen milk concentrate**—A frozen dairy product with a composition of milkfat and milk solids not fat in proportions so that, when a given volume of concentrate is mixed with a given volume of water, the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported and sold in the frozen state.

**Pasteurized low-sodium milk or low-sodium lowfat milk or low-sodium skim milk**—The product resulting from the treatment of milk, lowfat milk or skim milk by a process of passing the milk, lowfat milk or skim milk through an ion exchange resin process or by any process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

\* \* \* \* \*

**Raw milk**—Raw milk is milk which conforms with the relevant provisions of this chapter and may be sold to consumers without further treatment or processing.

\* \* \* \* \*

[ (b) **Milk and milk products.** The following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

**Certified milk**—Milk from dairy farms operated in accordance with "Methods and Standards for the Production and Distribution of Certified Milk," last adopted by the American Association of Medical Milk Commissioners, Inc., the production and handling of which shall be certified by a commission instituted in compliance therewith.

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

**Dry milk and whey products**—Products which have been produced for use in pasteurized milk or milk products and which have been manufactured under the provision of this chapter.

**Lactose-reduced milk or lactose-reduced lowfat milk or lactose-reduced skim milk**—The product resulting from the treatment of milk, lowfat milk,

or skim milk by the addition of safe and suitable enzymes to convert sufficient amounts of lactose to glucose or galactose, or both, so that the remaining lactose is less than 30% of the lactose in milk, lowfat milk, or skim milk.

**Milk**—The natural lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows or goats.

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

**Milk products**—Ice cream, ice cream mix, custard ice cream, French ice cream, frozen custard, ice milk, sherbet, and other similar frozen and semifrozen products and all dairy products used in the manufacture thereof.

**Pasteurized concentrated dairy products**—Includes homogenized concentrated milk, concentrated skim milk, concentrated lowfat milk, and similar concentrated products made from concentrated milk or concentrated skim milk, which, when combined with potable water in accordance with instructions printed on the container, conform with the definitions of the corresponding dairy products in this section.

**Pasteurized frozen milk concentrate**—A frozen dairy product with a composition of milkfat and milk solids not fat in such proportions that, when a given volume of concentrate is mixed with a given volume of water, the reconstituted product conforms to the milkfat and milk solids not fat requirements of whole milk. In the manufacturing process, water may be used to adjust the primary concentrate to the final desired concentration. The adjusted primary concentrate is pasteurized, packaged, and immediately frozen. This product is stored, transported, and sold in the frozen state.

**Pasteurized low-sodium milk or low-sodium lowfat milk or low-sodium skim milk**—The product resulting from the treatment of milk, lowfat milk, or skim milk by a process of passing the milk, lowfat milk, or skim milk through an ion exchange resin process or by any process which has been recognized by the Food and Drug Administration that effectively reduces the sodium content of the product to less than 10 milligrams in 100 milliliters.

**Raw milk**—Raw milk is milk which conforms with the relevant provisions of this chapter and may be sold to consumers without further treatment or processing. ]

LABELING

§ 59.22. Milk dating.

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

[ 14 ] 17 days beginning after midnight on the day on which the [ dairy products were ] milk was pasteurized. [ Stores, as used in this subsection, include mercantile establishments which offer milk for sale except on premises where processed. ]

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

(c) *Prohibition.* Pasteurized milk may not be sold [ after the date designated on the container. ] or offered for sale if either of the following occurs:

(1) The milk is sold or offered for sale after the sell-by date designated on the container.

(2) Without regard to the sell-by date designated on the container, the milk exceeds the bacterial limits for pasteurized milk described in § 59.52 (relating to table).

(d) *Exemption.* [ Sterile, ultra-pasteurized and cultured dairy products are exempt from the dating requirements. ] The following pasteurized dairy products are exempt from the requirements of this section:

(1) Ultra-pasteurized dairy products.

(2) Cultured dairy products.

(3) Aseptically processed dairy products.

(4) Dairy products that have undergone higher heat shorter time pasteurization.

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

(e) *Monitoring by the Department.* 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 samples shall be analyzed to determine whether the bacterial test results exceed the bacterial limits for pasteurized milk described in § 59.52 (relating to table) prior to the expiration of the sell-by date designated on the retail container. When two or more samples demonstrate a processor cannot produce pasteurized milk that remains consistently within the referenced bacterial limits 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).

COMMONWEALTH OF PENNSYLVANIA



GOVERNOR'S OFFICE OF GENERAL COUNSEL  
DEPARTMENT OF AGRICULTURE  
2301 N. Cameron Street • Room 201  
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OFFICE OF CHIEF COUNSEL

July 2, 2003

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Independent Regulatory Review Commission  
333 Market Street  
14<sup>th</sup> Floor  
Harrisburg, PA 17120

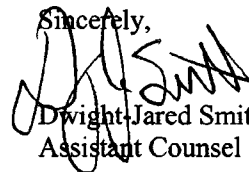
**Re: FINAL-FORM REGULATION**  
**Department of Agriculture**  
**Bureau of Food Safety and Laboratory Services**  
**I.D. No. 2-141**  
**7 Pa. Code Chapter 59**  
**Proposed Rulemaking: 32 Pa. Bulletin 4717 (September 28, 2002)**  
**Approved by Office of General Counsel: June 18, 2003**

Dear Sirs:

Please find enclosed a copy of the above-referenced final-form regulation. This material includes copies of the Preamble and Annex "A". Copies of the Notice of Proposed Rulemaking and Regulatory Analysis Form are also enclosed. I respectfully request the Independent Regulatory Review Commission review and approve the above-referenced final-form regulation in accordance with the requirements and procedures of the Regulatory Review Act.

This Department's responses to the comments received from the public, the Legislature and the Independent Regulatory Review Commission with respect to the proposed regulation are set forth in the Preamble to the final-form regulation. Copies of this final-form regulation have been delivered to the appropriate Legislative Committees (the House and Senate Agricultural and Rural Affairs Committees), and have been mailed or delivered to each commentator on this date. In response to the requirement (at 71 P.S. § 745.5a(b) and 1 Pa. Code § 307.2(c)(7)) that this Department provide the names and addresses of commentators who requested additional information on the final-form regulation, the Department hereby relates that no commentators have made this request.

The Department will provide you with any assistance you may require to facilitate a thorough review of this final-form regulation. Thank you for your attention to this matter.

Sincerely,  
  
Dwight Jared Smith  
Assistant Counsel

Enclosures



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

I.D. NUMBER: 2-141  
 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  
 2003 JUL -2 PM 3:03  
 INDEPENDENT REGULATORY REVIEW COMMISSION

**FILING OF REGULATION**

DATE	SIGNATURE	DESIGNATION
7/2/03	<u>C. Zimm</u>	HERSHEY HOUSE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7/2/03	<u>S. Ireland</u>	DALEY
7/2/03	<u>C. Boyer</u>	WAUGH SENATE COMMITTEE ON AGRICULTURE & RURAL AFFAIRS
7/2/03	<u>Judith M. Eagle</u>	O'PAKE
7/2/03	<u>Elena Page</u>	INDEPENDENT REGULATORY REVIEW COMMISSION
		ATTORNEY GENERAL
		LEGISLATIVE REFERENCE BUREAU

June 19, 2003