Person(s) Preparing Statement: Brian R.

Telephone: 225-342-7514

Rouge, LA 70821 Return Address: 628 N 4th Street, Baton

**Department:** Louisiana Department of Health, Office of Public Health

Rule Title: Regulation of Milk Products

Updated Citations

Effective Date: January 20, 2017

SUMMARY (Use complete sentences) In accordance with Section 953 of Title 49 of the Louisiana Revised Statues, there is hereby submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE.

# ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The Louisiana Department of Health (LDH), Office of Public Health (OPH) proposes to amend Title 51, Part VII<mark>, Section 101</mark> of the Public Health Sanitary Code related to Pasteurized Milk Section 101, the proposed rule modifies a number of definitions to specify appropriate citations of other documents, including the Code of Federal Regulations, the Shippers. Regulation of Milk Products. Ordinance, The proposed rule change is essentially technical. and Methods of Making Sanitation Ratings of Milk 5

the state or local governmental units. The proposed rule changes will result in an estimated cost of \$373 to publish the notice of intent and final fule in the *Louisiana* proposed rule. It is not anticipated that the proposed action will result in any implementation costs Register. OPH has sufficient funds in its annual operating budget to implement the

# = ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS.

units anticipated as a result of promulgating the proposed rule change. There are no anticipated effects on revenue collections of state or local governmental

= ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary).

groups as a result of the proposed rule change There are no estimated costs or benefits to any affected persons or non-governmental

<u>.</u>

**ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary).**There are no effects on competition and employment anticipated as a result of these proposed rule changes.

3 M. Beth Scalco, Assistant Secretary DHH/Office of Public Health in S Ve

> Legislative Fiscal Officer or Designee

Evan Brass

Date of Signature

Date of Signature

10

Legislative Fiscal Office 1 0 2017

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

In Section 101 of Part VII of Title 51, the proposed rule modifies a number of definitions to specify appropriate citations of other documents, including the Code of Federal Regulations, the Pasteurized Milk Ordinance, and Methods of Making Sanitation Ratings of Milk Shippers.

Summarize the circumstances which require this action. If the action is required by federal regulations, attach a copy of the applicable regulations. The changes to the legal citations are required in order for the citations to reference the most current version (as of this writing) of the Pasteurized Milk Ordinance as well as portions of the Code of Federal Regulations. The changes and void due to this technicality. demonstrated to be incorrect, the compliance activities could be rendered null proceedings against a regulated entity and the citations in the regulations are necessary because if the department is required to initiate enforcement are

## Ē Compliance with Act 11 of the 1986 First Extraordinary Session:

- 3 Will the proposed rule change result in any increase in the expenditure of funds? If so, specify amount and source of funding. Yes, OPH is expected to expend \$373 in operating expenses to pay the Office of the State Register to publish the Notice of Intent and Final Rule in the Louisiana Register.
- <u>N</u> If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

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	If no, provide justification as to why this rule change	If yes, attach documentation.
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OPH currently has sufficient funds to implement the proposed action.

# FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

#### ₽ ACTION COSTS N PROPOSED TO STATE AGENCIES RESULTING FROM THE

-

-What is the anticipated increase (decrease) in costs to implement the proposed action?

Costs	FY 2016-2017	FY 2017-2018	FY 2018 - 2019
Personal Services	\$0	\$0	\$0
Operating Expenses	\$373	\$0	\$0
Professional Services	\$0	\$0	\$0
Other Charges	\$0	\$0	\$0
Equipment	\$0	\$0	\$0
TOTAL	\$373	\$0	\$0
Major Repair/Construction	0\$	\$0	\$0
POSITIONS	\$0	\$0	\$0

'n Provide a narrative explanation of the costs or savings shown in "A.1", including the increase or reduction in workload or additional paperwork (number of new forms, additional documentation, etc.) anticipated as a result of the implementation of the proposed action. Describe all data, to publish the Notice of Intent and Final Rule in the Louisiana assumptions, and methods used in calculating these costs and 2 pages of Final Rule at \$213 per page. The proposed rule changes will result in an estimated cost of \$373 Register. This is based on an estimated 3 pages of Notice of Intent

ယ change. Sources of funding for implementing the proposed rule or rule

Source         FY 2016-2017         FY 2017-2018         FY 2018 - 2019           Agency Gen. Fund         \$373         \$0         \$0           Agency Self Gen.         \$0         \$0         \$0           Dedicated         \$0         \$0         \$0           Federal         \$0         \$0         \$0           Other (Specify)         \$0         \$0         \$0           Total         \$373         \$0         \$0				
id       \$373       \$0         \$0       \$0       \$0         \$0       \$0       \$0         \$0       \$0       \$0         \$373       \$0       \$0	Source	FY 2016-2017	FY 2017-2018	FY 2018 - 2019
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sated       \$0       \$0         ral       \$0       \$0         (Specify)       \$0       \$0         \$373       \$0	Agency Self Gen.	\$0	\$0	\$0
ral \$0 \$0   S0   Compared to the state of th	Dedicated	\$0	\$0	\$0
(Specify) \$0 \$0	Federal	\$0	\$0	\$0
\$373 \$0	Other (Specify)	\$0	\$0	\$0
	Total	\$373	\$0	\$0

4 Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

action. Yes, OPH currently has sufficient funds to implement the proposed

# ĒΩ COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

:-Provide an estimate of the anticipated impact of the proposed action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact. governmental units No impact is anticipated by these proposed actions local

Ŋ which will be affected by these Indicate the sources of funding of the local governmental unit costs or savings.

#### = EFFECT ON REVENUE COLLECTIONS OF GOVERNMENTAL UNITS. STATE AND LOCAL

⋗ proposed action? What increase (decrease) in revenues can be anticipated from the

REVENUE INCREASE/ DECREASE	FY 2016-2017	FY 2017-2018	FY 2018 - 2019
State General Fund	\$0	\$0	\$0
Agency Self-Gen.	\$0	\$0	\$0
Restricted*	\$0	\$0	\$0
Federal Funds	\$0	\$0	\$0
Local Funds	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

<sup>\*</sup>Specify particular fund being impacted.

œ changes No increase of decrease in revenues is anticipated as a result of these methods used in calculating these increases or decreases Provide a narrative explanation of each increase or decrease revenues shown in "A". Describe all data, assumptions, and

# Ħ COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS.

⋗ What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

stakeholders. The rule change is not anticipated to result in costs or benefits to any

Ē their groups. See III A. on receipts and/or income resulting from this rule or rule change to Also provide an estimate and a narrative description of any impact

### 7 **EFFECTS ON COMPETITION AND EMPLOYMENT**

estimates. Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include summary of any data, assumptions and methods used in making these Include a

these rule changes There are no effects on competition and employment anticipated as a result of

Person(s) Preparing Statement: Brian R.

Telephone: 225-342-7514

Rouge, LA 70821

Return Address: 628 N 4th Street, Baton

Department: Louisiana Department of Health,

Office of Public Health

Rule Title: Regulation of Milk Products

**Updated Citations** 

Effective Date: January 20, 2017

# SUMMARY (Use complete sentences)

submitted a fiscal and economic impact statement on the rule proposed for adoption, repeal or amendment. THE FOLLOWING STATEMENTS SUMMARIZE ATTACHED WORKSHEETS I THROUGH IV AND WILL BE PUBLISHED IN THE LOUISIANA REGISTER WITH THE PROPOSED AGENCY RULE In accordance with Section 953 of Title 49 of the Louisiana Revised Statues, there is hereby

ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The Louisiana Department of Health (LDH), Office of Public Health (OPH) proposes to amend Title 51, Part VII, Section 101 of the Public Health Sanitary Code related to Section 101, the proposed rule modifies a number of definitions to specify appropriate citations of other documents, including the Code of Federal Regulations, the Shippers Pasteurized Regulation of Milk Products. Sik Ordinance, ts, including the and Methods The proposed rule change is essentially technical. of Making Sanitation Ratings Δik 5

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ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NON-GOVERNMENTAL GROUPS (Summary).

There are no estimated costs or benefits to any affected persons or non-governmental groups as a result of the proposed rule change.

# Ξ. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary).

proposed rule changes There are 0 effects on competition and employment anticipated as a result of these

DHH/Office of Public Health	M. Beth Scalco, Assistant Secretary
Г	etary   edislative Fiscal

Officer or Designee

of Signature

of Signature

Person(s) Preparing Statement: Brian R. Department: Louisiana Department of Health,

Telephone: 225-342-7514

Return Address: 628 N 4th Street, Baton

Rouge, LA 70821

Rule Title: Regulation of Milk Products Updated Citations

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PERSONS OR NON-GOVERNMENTAL GROUPS (Summary).
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DHH/Office of Public Health	M. Beth Scalco, Assistant Secretary	
Public Health	sistant Secretary	
	Legislative Fiscal Officer or Designee	
	or Designe	

Date 으 Signature

of Signature

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- <u>(N</u> If the answer to (1) above is yes, has the Legislature specifically appropriated the funds necessary for the associated expenditure increase?

(b) X No. If no, provide justification as to why this rule change	(a)	Yes.	=	yes,	attach c	Yes. If yes, attach documentation.	n.			•	•	•
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OPH currently has sufficient funds to implement the proposed action

# FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

### P COSTS OR SAVINGS ACTION PROPOSED TO STATE AGENCIES RESULTING FROM THE

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Costs	FY 2016-2017	FY 2017-2018	FY 2018 - 2019
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TOTAL	\$373	\$0	\$0
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ယ Sources of funding for implementing the proposed rule or rule

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Agency Gen. Fund	\$373	\$0	\$0
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Dedicated	\$0	\$0	\$0
Federal	\$0	\$0	\$0
Other (Specify)	\$0	\$0	\$0
Total	\$373	\$0	\$0

4 Does your agency currently have sufficient funds to implement the proposed action? If not, how and when do you anticipate obtaining such funds?

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### Ē COST OR SAVINGS TO LOCAL GOVERNMENTAL UNITS RESULTING FROM THE ACTION PROPOSED.

governmental units action on local governmental units, including adjustments in workload and paperwork requirements. Describe all data, assumptions and methods used in calculating this impact. No impact is anticipated by these proposed actions local Provide an estimate of the anticipated impact of the proposed

7 which will be affected by these costs or savings. Indicate the sources of funding of the local governmental unit

#### = EFFECT ON REVENUE COLLECTIONS OF GOVERNMENTAL UNITS. STATE AND LOCAL

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Local Funds	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

Specify particular fund being impacted.

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Also provide an estimate and a narrative description of any impact on receipts and/or income resulting from this rule or rule change to their groups.

œ

<u>.</u> EFFECTS ON COMPETITION AND EMPLOYMENT

summary of any data, assumptions and methods competition and employment in the public and private sectors. Include competition and employment in the public and private sectors. Include Identify and provide estimates of the impact of the proposed action on

**estimates.**There are no effects on competition and employment anticipated as a result of these rule changes.

#### Department of Health

Office of Public Health

Regulation of Dairy Products

(LAC 51:VII.101)

These amendments are being proposed to update the references to the most current version of the federal Food and Drug Administration's Pasteurized Milk Ordinance (PMO) as well as revising certain references to the Code of Federal Regulations (CFR) cited in the text. Such amendments are required in order for LDH-OPH to be able to enforce the 2015 PMO regulations over the production and distribution of milk and dairy products. Under the authority of R.S. 40:4 and 40:5, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the state health officer, acting through the Louisiana Department of Health, Office of Public Health (LDH-OPH), intends to amend Part VII (Dairy Products Regulations) of Title 51.

#### Title 51

#### PUBLIC HEALTH—SANITARY CODE Part VII. Dairy Products Regulations

#### Chapter 1. §101. De Milk and Dairy Products

§101. Definitions

A. Unless otherwise specifically provided herein, the following words and terms used in this Part of the Sanitary Code, and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as ×

\*

Code of Federal Regulations (CFR)—Except as otherwise indicated, the April 1, 2010 edition, as amended, of Title 21 (21 CFR = Food and Drugs) and the January 1, 2010 edition, as amended, of Title 7 (7 CFR = Agriculture) of the document, so titled and published by the United States Office of the Federal Register, National Archives and Records Administration.

Good Manufacturing Practices (GMP)—practices used in the manufacturing, packing, or holding of dairy products that comply with the requirements contained in this Part and in 21 CFR 110 and 21 CFR 117 as revised on April 1. 2016, when applicable.

http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM290758.pdf)
\* \* \* \* Methods of Making Sanitation Ratings of Milk Shippers—2007 Revision, as amended, published by the U.S. Department of Health and Human Services, Public Health Service, FDA; (Internet URL address:

PMO-Service/Food and Drug Administration. the 20092015 Edition, as amended, of the Grade "A" Pasteurized Milk Ordinance, Public Health

AUTHORITY NOTE: The first source of authority for promulgation of the Sanitary Code is R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40. This Part is promulgated in accordance with specific provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5.A.(2)(3)(5)(7) (15)(17) and R.S. 40:922. HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1258 (June 2002), amended LR 37:2633 (September 2011), LR 38:2793 (November 2012), amended by the Louisiana Department of Health, Office of Public Health, LR 43:

Person(s) Preparing Statement: Brian R.

Telephone: 225-342-7514

Rouge, LA 70821 Return Address: 628 N 4th Street, Baton

**Department:** Louisiana Department of Health

Office of Public Health

Rule Title: Regulation of Milk Products

**Updated Citations** 

Effective Date: January 20, 2017

# **SUMMARY** (Use complete sentences)

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# **GOVERNMENTAL UNITS (Summary) ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL**

The Louisiana Department of Health (LDH), Office of Public Health (OPH) proposes to amend Title 51, Part VII of the Public Health Sanitary Code related to Regulation of Milk

Ratings of Milk Shippers. Regulations, In Section 101 of Part VII of Title 51, the proposed rule modifies a number of definitions specify appropriate citations of other documents, the Pasteurized Milk Ordinance, and Methods of Making including the Code of Federal Sanitation

Additionally, in LAC51:VII.525, 527, 923, and 2907, language referring to the former Louisiana State Plumbing Code (LAC51:XIV) has been replaced with references to the relevant sections of LAC17:I (Uniform Construction Code), which superseded the relevant sections of LAC17:I (Uniform Construction Code), which support former plumbing code effective January 1, 2016 (see LR 41: 2545-2575).

Minor grammatical errors in the text are also proposed for correction

costs to local governmental units. The proposed rule changes will result in an estimated cost of \$373 to publish the notice of intent and final fule in the *Louisiana Register*. OPH It is not anticipated that the proposed action will result in any significant implementation has sufficient funds in its annual operating budget to implement the proposed rule

# = ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS.

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### ≡ **ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED** PERSONS OR NON-GOVERNMENTAL GROUPS (Summary).

continued routine operations of the Milk and Dairy Unit of the Office of Public Health There are no estimated costs or benefits to this change to any stakeholders The proposed rule change is essentially administrative and necessary for the

# <u>-</u> ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary).

proposed rule changes. There are no effects on competition and employment anticipated as a result of these

M. Beth Scalco, Assistant Secretary

DHH/Office of Public Health

Legislative Fiscal Officer or Designee

2017

Date of Signature

Date R of Signature

MAR 17 2017

The following information is required in order to assist the Legislative Fiscal Office in its review of the fiscal and economic impact statement and to assist the appropriate legislative oversight subcommittee in its deliberations on the proposed rule.

Provide a brief summary of the content of the rule (if proposed for adoption or repeal) or a brief summary of the change in the rule (if proposed for amendment). Attach a copy of the notice of intent and a copy of the rule proposed for initial adoption or repeal (or, in the case of a rule change, copies of both the current and proposed rules with amended portions indicated).

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# FISCAL AND ECONOMIC IMPACT STATEMENT WORKSHEET

### Þ COSTS OR SAVINGS ACTION PROPOSED TO STATE AGENCIES RESULTING FROM THE

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TOTAL	\$373	\$0	\$0
Major Repair/Construction	\$0	\$0	\$0
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REVENUE INCREASE/ DECREASE	FY 2016-2017	FY 2017-2018	FY 2018 - 2019
State General Fund	\$0	\$0	\$0
Agency Self-Gen.	\$0	\$0	\$0
Restricted*	\$0	\$0	\$0
Federal Funds	\$0	\$0	\$0
Local Funds	\$0	\$0	\$0
TOTAL	\$0	\$0	\$0

<sup>\*</sup>Specify particular fund being impacted.

Ω Provide a narrative explanation of each increase or decrease revenues shown in "A". Describe all data, assumptions, and methods used in calculating these increases or decreases. changes No increase of decrease in revenues is anticipated as a result of these

# ≡ COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS.

Þ What persons or non-governmental groups would be directly affected by the proposed action? For each, provide an estimate and a narrative description of any effect on costs, including workload adjustments and additional paperwork (number of new forms, additional documentation, etc.), they may have to incur as a result of the proposed action.

stakeholders The rule change is not anticipated to result in costs or benefits to any

Ē See III A. their groups. on receipts and/or income resulting from this rule or rule change to Also provide an estimate and a narrative description of any impact

### Ζ. **EFFECTS ON COMPETITION AND EMPLOYMENT**

summary of any data, assumptions and methods used in making these Identify and provide estimates of the impact of the proposed action on competition and employment in the public and private sectors. Include estimates. Include ۵

these rule changes There are no effects on competition and employment anticipated as a result of