



To: Members of the State Board of Health

From: Bradley Turpin, Milk and Corrections Program Manager, Division of Environmental Health and Sustainability

Sean C. Scott, Deputy Director, Division of Environmental Health and Sustainability

Cary E. Ruble, Regulation Development and Enforcement Coordinator, Division of Environmental Health and Sustainability

Through: Jeff Lawrence, Director
Division of Environmental Health and Sustainability (jL)

Date: January 16, 2019

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations* with a request for a rulemaking hearing to be set for March 20, 2019

The Division of Environmental Health and Sustainability (“division”) is proposing revisions to 6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*, and is requesting that the Board of Health schedule a rulemaking hearing to consider adoption of the proposed amendments at the March 20, 2019, Board of Health meeting.

6 CCR 1010-4 was last amended by the Board of Health in November 2016. In compliance with Executive Order D 2012-002 and the State Administrative Procedure Act, §24-4-103.3, C.R.S., the department has conducted the biennial review of 6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*. Based on this review, the department is recommending amendments to update and align the state milk and dairy regulation with recently revised federal regulations through incorporation by reference.

The amended and proposed regulation continues the incorporation by reference of the requirements and provisions of U.S. Food & Drug Administration’s (FDA’s) *Grade “A” Pasteurized Milk Ordinance, 2017 Revision (PMO)*; *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), 2017 Revision (Procedures)*; and *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2017 Revision (Methods)*. The PMO, Procedures, and Methods also serve as the official documents setting forth the sanitation requirements that govern the processing, packaging, sale, and interstate shipment of Grade “A” milk and dairy products. An electronic copy of these documents and the proposed regulation are available for review on the division website:

- <https://www.colorado.gov/pacific/cdphe/dehs-active-stakeholder-processes>

Also, the 2017 PMO, Procedures, and Methods are posted and available for review on the following FDA website:

- <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm>

Adoption of the updated 2017 PMO, Procedures, and Methods will ensure that Colorado's Grade "A" and manufactured milk and dairy sanitation programs are in conformance with the latest national standards, thereby, permitting Colorado milk and dairy products to move freely in interstate commerce, and maintaining the efficiency and effectiveness of the rulemaking process. The division has engaged stakeholders and to date, none have expressed concern with the proposed amendments to the *Colorado Milk and Dairy Regulations*.

The division appreciates the Board's consideration.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*

Basis and Purpose.

Revisions to *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4 would incorporate by reference and adopt U.S. Food and Drug Administration's (FDA's) *Grade "A" Pasteurized Milk Ordinance, 2017 Revision (PMO)*; *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2017 Revision (Procedures)*; and *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2017 Revision (Methods)*. 6 CCR 1010-4 was last amended by the Board of Health in November 2016.

The PMO, Methods, and Procedures are formally revised every two years at the National Conference on Interstate Milk Shipments (NCIMS). The NCIMS brings together state and federal regulatory agencies with industry and academia to discuss and vote on the proposed changes to the current version of the PMO and supporting documents. The division's milk and dairy program manager, Bradley Turpin, is Colorado's voting delegate at NCIMS and last attended the conference in May 2017.

The on-going incorporation by reference of the PMO, Methods, and Procedures aligns nationally accepted standards already acknowledged and accepted by industry. Proposed amendments to the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4, recognize technological advances, milk plant environment changes, clarification of sampling and testing requirements, and the finalized alignment of the Pasteurized Milk Ordinance (PMO) with the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food. The amended regulation will maintain Colorado's conformance with the federal requirements adopted by other states, thereby, permitting freedom in the movement of milk and dairy products not only within Colorado, but also nationally and internationally, in accordance with the terms of:

- A. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *Grade "A" Pasteurized Milk Ordinance (Includes provisions from the Grade "A" Condensed and Dry Milk Products and Condensed and Dry Whey - Supplement I to the Grade "A" PMO), 2017 Revision (PMO)*, including supplements, administrative procedures, appendices, and coded Food and Drug Administration Interpretative Memoranda;
- B. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration and the National Conference on Interstate Milk Shipments, *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2017 Revision (Procedures)*; and
- C. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *Methods of Making Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service Containers and/or Closures for Milk and/or Milk Products Manufacturers, 2017 Revision (Methods)*.

The continued incorporation by reference of these federal milk and dairy sanitation standards into the proposed regulation translates new knowledge, technology and methodologies into effective and practicable public health practices. The PMO, Procedures, and Methods are developed by FDA with assistance of state and local milk regulatory agencies and all segments of the dairy industry and educational and research institutions, for adoption by states for the purpose of assuring uniformity and effectiveness in conducting their milk and dairy programs.

Specific Statutory Authority.

Statutes that require or authorize rulemaking: Sections 25-1.5-104(1)(b)(I), 25-5.5-103, 25-5.5-107(5) and (6), 25-5.5-205, 25-5.5-309, and 25-5.5-310, C.R.S.

Is this rulemaking due to a change in state statute?

Yes, the bill number is _____. Rules are ___ authorized ___ required.
 No

Does this rulemaking incorporate materials by reference?

Yes, FDA's PMO, Methods, and Procedures, 2017 Revisions

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm>

No

Does this rulemaking create or modify fines or fees?

Yes
 No

Does the proposed rule create (or increase) a state mandate on local government?

No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Grade "A" milk producers	18	C
Licensed milk and dairy plant samplers	203	C
Milk and dairy product manufacturers	21	C
Farms (121 Grade "A" and 9 non-Grade "A")	130	C
Transport firms (193 tanker trucks)	21	C
Licensed haulers	217	C
Consulting/engineering firms	~6	C
Colorado Department of Public Health and Environment	~1,600	S
Colorado Department of Agriculture	~300	S
Retail Food Establishments	~23,000	S
Milk and dairy consumers in Colorado	~5 million	S/B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

- C = individuals/entities that implement or apply the rule.
- CLG = local governments that must implement the rule in order to remain in compliance with the law. (NA)
- S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
- B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed or be at-risk because of the rule, the "C" or "CLG" category individuals/entities that implement or apply the rule, or "S" category individuals/entities that are interested in the rule or its implementation.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Non-economic outcomes

Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes for each affected class of persons by the relationship category:

- C: Colorado's milk and dairy industry is already subject to the federal milk and dairy product requirements proposed for incorporation by reference in the revised rule. The proposed incorporation by reference of FDA's 2017 PMO, Methods, and Procedures continues public health protections while providing industry clarification for consistent interpretation of milk and dairy products regulations

through alignment with current and nationally accepted federal standards. No non-favorable non-economic outcomes for the milk and dairy industry were identified.

- S: The PMO, Procedures, and Methods are developed and revised by FDA with the assistance of state and local milk regulatory agencies, the dairy industry and educational and research institutions for the purpose of assuring uniformity and effectiveness in state milk sanitation programs. The 2017 PMO, Procedures, and Methods also serve as the official documents setting forth the most current sanitation requirements that govern the processing, packaging, sale, and interstate shipment of Colorado milk and dairy products. Also, incorporation by reference of the PMO and supplemental documents maintains the efficiency and effectiveness of the biennial rulemaking process. No non-favorable non-economic outcomes are anticipated for the state regulatory agencies or retail milk and dairy suppliers.
- B: The approximately five million potential consumers of milk and dairy products inside Colorado, will benefit from the proposed rule revision by ensuring that the processing, packaging, sale, and interstate shipment of milk and dairy products are in accordance with the current sanitation standards required by FDA's 2017 PMO, Methods, and Procedures. No non-favorable non-economic outcomes were identified for the milk and dairy consumer.

Economic outcomes

Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

- C: At this time, there are no known or foreseen increases in cost to Colorado's milk and dairy industry. Colorado milk and dairy businesses affected by this regulation are already subject to the federal requirements proposed for incorporation.

Please describe any anticipated financial costs or benefits to or monitored by these individuals/entities.

- S: No costs will be incurred by state regulatory agencies or retail food establishments as a result of the proposed rule revision. A cost savings to both Colorado state regulatory agencies and milk and dairy stakeholders will be realized through the efficiency of the biennial rulemaking process and consistent interpretation and application of federal milk and dairy sanitation requirements.
 - B: Consumers of milk and dairy products in Colorado and worldwide benefit from the continuation of milk and dairy sanitation practices this amended rule provides. No costs will be incurred by the milk and dairy consumer as a result of the proposed rulemaking.
3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.
- A. Anticipated CDPHE personal services, operating costs or other expenditures: None
- Anticipated CDPHE Revenues: None

- B. Anticipated personal services, operating costs or other expenditures by another state agency: None

Anticipated Revenues for another state agency: None

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Check mark all that apply:

- Inaction is not an option because the statute requires rules be promulgated.
- The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
- The proposed revisions appropriately maintain alignment with other states or national standards.
- The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.
- The proposed revisions implement stakeholder feedback.
- The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities Goal 2, Increase Efficiency, Effectiveness and Elegance Goal 3, Improve Employee Engagement Goal 4, Promote health equity and environmental justice Goal 5, Prepare and respond to emerging issues, and Comply with statutory mandates and funding obligations
--

Strategies to support these goals:

- Substance Abuse (Goal 1)
- Mental Health (Goal 1, 2, 3 and 4)
- Obesity (Goal 1)
- Immunization (Goal 1)
- Air Quality (Goal 1)
- Water Quality (Goal 1)
- Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
- Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
- Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
- Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)
- Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)
- Other favorable and unfavorable consequences of inaction: None

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Incorporation by reference and adoption of FDA's 2017 PMO, Methods, and Procedures, continues levels of milk and dairy sanitation practices in place and maintains the allowance for the interstate shipment of Colorado milk and dairy products. The proposed rulemaking is the least costly and intrusive method for achieving the purpose of the rule. The specific revisions to FDA's PMO, Methods, and Procedures proposed in this rulemaking were developed in conjunction with a national stakeholder group at the 2017 NCIMS. Through the continued incorporation by reference of current federal regulations and the resulting efficiencies in the rulemaking process, the proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, and are the most feasible manner to achieve compliance with statute. The minimal short-term administrative costs associated with the biennial rulemaking process is far out-weighed by the operational efficiencies and continued protection of human health. The department will update the incorporation by reference as needed to remain current.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

No alternate rules or alternatives to the proposed rulemaking were considered. Current regulations incorporate by reference the 2015 version of the PMO, Methods and Procedures. Therefore, adoption of the updated 2017 federal regulation is considered the most effective and efficient approach to rulemaking while protecting public health and allowing Colorado businesses to continue sell their milk and dairy products in interstate commerce. Incorporation and implementation of the federal milk and dairy regulations will ensure short- and long-term consistency in the application of these requirements in Colorado.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

In May 2017, the division's milk and dairy program manager attended the NCIMS. The NCIMS provides an opportunity for state milk and dairy delegates to provide feedback and vote on proposed, science-based changes to FDA's PMO, Methods, and Procedures. Amendments passed by state delegates at the May 2017 NCIMS are represented in the federal regulations proposed for incorporation by reference into the new rule. The continued incorporation by reference of current federal milk and dairy products regulation will be a benefit to the department, the regulated community and the public, both in the short-term and long-term.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:

The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

Organization	Representative Name and Title (if known)
AGPROfessionals	Thomas Haren
AMCOR PET Packaging - North America	Chris Maes
Aurora Organic Dairy	Peggy Colfelt
Aurora Organic Dairy	Katie Speidel
Aurora Organic Dairy	Juan Velez
Boren Trucking	Ricky Boren
CDPHE	Labertta Cano
CDPHE	Ben Chouaf
CDPHE	Jeff Groff
CDPHE - DEHS	Ryan Allen
CDPHE - DEHS	Jeff Lawrence
CDPHE - DEHS	Jacob Lofgren
CDPHE - DEHS	Samantha Monell
CDPHE - DEHS	Cary Ruble
CDPHE - DEHS	Sean Scott
CDPHE - DEHS	Bradley Turpin
CO Department of Agriculture	Maggie Baldwin
Colorado Dairy Supply	Joel Lederman
Colorado Department of Agriculture	Keith Roehr, DVM
Colorado Department of Agriculture	Nick Streigel, DVM
Corsentino Dairy	Brett Corsetino
Dairy Engineering	Bob Bullus
Dairy Engineering	Walt Powell
Dairy Farmers of America	Tim Houck
Dairy Farmers Of America	Andrew Kidd
Dairy Farmers of America	Thomas Kovacic
Dairy Farmers Of America	Cathy McManaman
Dairy Farmers of America	Marie teVelde
Dairy Farmers of America	Jill Waite
Dairy Farmers of America, Inc. Ft. Morgan Plant	Tony Rosso
Dairy Specialists	Kelly Smith
Dairy Specialists	Randy Sorenson
Dean Foods Company	Roger Hooi
Dean Foods Company	John Sanford
Empire Dairy	Norm & Britt Dinis
Graff Dairy	Dave Nichols
Hx Butterfield/Camelot Camel Dairy	Kyle Hendrix
Juniper Valley Farm	Will McConnell
Juniper Valley Farm	Larea Schmutzler
Kraft Family Dairies, LLC	Chris & Mary Kraft

La Luna Dairy	Jon Slutsky
Leprino Foods	Mark Cramer
Leprino Foods	Scott Hall
Leprino Foods	Brad Maier
Leprino Foods - Denver	Edith Wilkin
Leprino Foods - Fort Morgan	Chris Alonzo
Leprino Foods - Greeley	Erick Murray
Longmont Dairy Plant	Dan Boyd
Mars Milky Way Dairy	Eldon Marrs
Meadow Gold Dairies – Englewood	Randy Kaufman
Meadow Gold Dairy - Greeley	Rick Adams
Mile High Dairy	Wes Bangma
Mini-Moos Dairy	Rob and Amy Anderson
Morning Fresh Dairy	Rob Graves
Mountain View Foods	Tyler Dixon
Noosa Yoghurt	Dave Davis
Pirnie Services	Russ Pirnie
Queso Campesino	Dan Harris
Queso Campesino	Abel Robles
Rich Thompson Trucking, Inc.	Tammie Niemoth
Rocking W Cheese	John Gibson
Royal Crest Dairy	Todd Watson
Safeway Stores, Inc. Milk Plant	Karl Guderian
Schwartz and Sons Trucking	Dan Schwartz
Sinton Dairy Foods Co. LLC	Katie Gray
Sinton Dairy Foods Co. LLC	Dennis Nowell
Western Culture Farmstead	David Miller
Western Dairy Association	Scott Dutcher
Western Dairy Transport	Phil Redd

FDA's PMO, Methods, and Procedures are formally revised every two years at the National Conference on Interstate Milk Shipments (NCIMS). The NCIMS stakeholder process brings together state and federal regulatory agencies with industry and academia to discuss and vote on the proposed changes to the current version of the PMO. The NCIMS stakeholder process provides regulatory consistency to the milk and dairy industry nationwide. The division's milk and dairy program manager, Bradley Turpin, is Colorado's voting delegate at NCIMS and last attended the conference in May 2017. Only state delegates have the ability to vote on and pass changes to the federal regulation. A summary of the NCIMS changes made to the 2017 revision of the PMO, Methods, and Procedures is provided.

On October 30, 2018, following the publication of FDA's revised 2017 PMO, Methods, and Procedures, the division initiated Colorado's stakeholder outreach communications and solicited contributions to the proposed revisions. Based on subsequent conversations with stakeholders and the receipt of multiple letters of support, consensus on the revised and proposed regulation was achieved, including the incorporation by reference of FDA's 2017 PMO, Methods, and Procedures. All documents associated with stakeholder engagement were made available on the department's web site.

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

- Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.
- Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

In order to maintain alignment with current federal milk and dairy regulations, the division began preparations for this rulemaking through participation at the NCIMS in May 2017. The NCIMS provides an opportunity for state milk and dairy delegates to provide feedback and vote on proposed changes to FDA's PMO, Methods, and Procedures. Amendments passed at the May 2017 NCIMS are represented in the federal regulations proposed for incorporation by reference into the new rule. Since the current *Colorado Milk and Dairy Products Regulations* are recognized and understood by the involved and effected stakeholders and reflect current federal rules, there were no significant factual or policy issues encountered. Consensus on the proposed regulation, including the incorporation by reference of FDA's 2017 PMO, Methods and Procedures, was achieved.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	X	Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
X	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.

	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
X	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other: _____ _____		Other: _____ _____

SUMMARY OF CHANGES TO THE PMO, 2017 REVISION

The following Proposals were passed or passed as amended by state delegates at the 2017 NCIMS and addressed changes to the PMO, Procedures, Methods, or Forms:

- 113. Clarifies the 96-hour deadline on a tanker with respect to cleaning and the start time for sample usage on a direct load farm passed as amended. Provides much needed clarity for the industry in defining both "first use" and the collection time for "Universal" milk samples.
- 114. Modifies the requirement for state regulatory agencies to test the caustic strength in soaker-type bottle washers from a monthly to a quarterly frequency.
- 115. Removes the requirement to sanitize single service glass containers at dairy plant filling single service glass containers.
- 118. Makes minor editorial changes and to remove confusing and/or unnecessary wording from various portions of the PMO.
- 120. Corrects inaccurate language in ITEM 16p(B),2,c in which the description of the control for flow promoting devices references flow through the "holder" instead of the "FDD".
- 121. Eliminates language in three (3) notes in Appendix I-Pasteurization Equipment and Controls - Tests of the PMO. It also makes a correction to the text in the three (3) notes related to the slope of the holding tube to be consistent with the text in Item 16p(B).
- 127. Removes an unnecessary restriction on the location of flow promoting devices in systems using meter based timing systems.
- 129. Allows a centralized filtered air manifold system that distributes air under pressure to multiple locations where this centralized air manifold system is cleaned in place.
- 130. Provides a technology update to the PMO regarding programmable logic controllers.

134. Updates Appendix O-Vitamin Fortification of Fluid Milk Products of the PMO to align it with the Federal Register announcement that amended 21 CFR 172.380 to allow manufacturers to fortify milk with vitamin D3 at a level not to exceed 84 international units (IU) per 100 g (800 IU (20 mcg)/quart) when named with a nutrient content claim for vitamin D3 and a standardized term in accordance with 21 CFR 130.10.
206. Revises the PMO Section 6 to include the BactoCount IBC (BCC) and the BactoCount IBCm (BCMC) as alternate methods to enumerate bacteria in raw milk.
207. Updates the definitions of "Bulk Milk Hauler/Sampler", "Dairy Plant Sampler" and "Industry Plant Sampler" within Section I Definitions of the PMO to be more up-to-date with the sampling activities that these samplers are allowed to conduct within the PMO.
212. Broadens the requirement of using a watch to assure proper agitation time as stated in Appendix B.
213. Changes the wording in the Hauler section, Appendix B, from rinsing the dipper to cleaning the dipper to make the language consistent with the requirements for the sampling equipment in the PMO and with the Bulk Milk Hauler/Sampler Evaluation Report (Form 2399a).
214. Allows for the use of pulsed light as a method of sanitizing single service containers as required in Section 7 Item 12p.
215. Clarifies the bacteriological sampling and testing requirements within Appendix G. of the PMO for individual water supplies and Category I water that is used for potable water purposes, which has been reclaimed from milk and milk product and from heat exchangers or compressors in a milk plant.
216. Approves use of the AccuPoint® Advanced Alkaline Phosphatase electronic test for the detection of alkaline phosphatase in pasteurized fluid dairy products (all matrices defined within M-a-98).
217. Appendix N section VI, pertaining to testing for non-beta-lactam antibiotics with test methods that have not been evaluated by FDA and accepted by the NCIMS, is moved into a new appendix (Appendix T).
219. Approval (addition to m-a-85 latest revision) for BetaStar® Advanced for Beta-lactams for the use of detecting beta-lactam drug residues in raw, commingled bovine milk.
220. Approval (addition to m-a-85 latest revision) for the use of the BetaStar® Advanced for Tetracyclines test to detect tetracycline drug residues in raw, commingled bovine milk.
223. Clarifies the use of "future farm pickups", "further farm pickups" and "future pickups".

224. Clarifies that test kits may still be used to test for these drugs that have zero tolerance levels and do not have an established target testing level, as it is not possible for a commercially available test method to have a detection limit less than zero.
225. Clarifies language related to the documented agreement when using non-Beta lactam test kits that have not been evaluated by FDA and accepted by the NCIMS.
226. Corrects conflicting language in Appendix N section VI pertaining to testing for non-Beta lactam drug residues.
228. Clarifies the sampling frequency requirements for Grade "A" raw milk and Grade "A" milk and/or milk products that are not produced on a continuous monthly basis.
230. Provides clarity, consistency and uniformity to the text contained within the MMSR and also requests that the Chair assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA to conduct a comprehensive and thorough review of the MMSR.
241. Approves the 3M™ Petrifilm™ Rapid Aerobic Count Plate method as a new method for the enumeration of aerobic bacteria in milk products. Also updates M-a-98-10 Table 3 with the matrices validated with the new method.
243. Seeks clarification in FDA/NCIMS 2400 Cultural Procedures - General Requirements regarding the storage of Petrifilm.
301. Requests a two (2) year extension of the NCIMS Aseptic Program Committee's (APC) pilot program to specifically address Grade "A" fermented high-acid shelf stable milk and/or milk products.
303. Provides clarity, consistency and uniformity to the text contained within the Procedures document; Requests that the Chair assign to the NCIMS MMSR Committee and HACCP Implementation Committee to work with FDA to conduct a comprehensive and thorough review of the Procedures.
306. Makes editorial corrections to SRO and LEO certification and related procedures as cited in the Procedures document. Clarifies that FDA may certify Sampling Surveillance Officers (SSOs); Clarifies that a certified SSO for a specified category may delegate to designated Sampling Surveillance Officers (dSSOs).
307. Calls for, on the part of FDA, greater information sharing with and oversight by the NCIMS Executive Board regarding evaluations and ultimate determinations of milk safety program equivalence in other countries.
309. Limits members of NCIMS Councils to serving through five (5) consecutive biennial meetings of the Conference.

- JC-2. Building upon the work conducted at the 2015 conference through the Joint Council proposals, this proposal finalizes the alignment of the Pasteurized Milk Ordinance (PMO) with the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food.

- JC-4. Building upon the work conducted at the 2015 conference through the Joint Council proposals, this proposal finalizes the alignment of the Pasteurized Milk Ordinance (PMO) Appendix K with the Food Safety Modernization Act (FSMA) Final Rule for Preventive Controls for Human Food. It also aligns Appendix K with the proposal being submitted by Liaison Committee.

1 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2
3 Division of Environmental Health and Sustainability

4
5 6 CCR 1010-4

6
7 COLORADO MILK AND DAIRY PRODUCTS REGULATIONS

8
9 Adopted by the Board of Health on _____; effective, _____

10
11 4.1 Authority

12
13 This regulation is adopted pursuant to Section 25-1.5-104(1)(b)(I), 25-5.5-103, 25-5.5-107(5),
14 and (6), 25-5.5-205, 25-5.5-309, and 25-5.5-310, Colorado Revised Statute (C.R.S.) and is
15 consistent with the requirements of the State Administrative Procedure Act, Section 24-4-101,
16 *et seq.*, C.R.S.

17
18 4.2 Scope and Purpose

19
20 A. This regulation shall govern:

- 21
22 1. Dairy sanitation, the processing, packaging, transportation and sale of Grade
23 "A" milk and milk products, and represents the state and federal standard for
24 Grade "A" milk sanitation;
25
26 2. Sanitary production of milk for manufacturing purposes including its
27 transportation, grading, use, processing, and the packaging, labeling and
28 storage of dairy products made there from;
29
30 3. Licensure and inspection of dairy farms and dairy plants for the production and
31 sale of milk or dairy products for manufacturing purposes;
32
33 4. Retention of appropriate documentation and records by plants licensed
34 hereunder;
35
36 5. Licensure of qualified milk or dairy product samplers and testers.

37
38 B. Section 4.7 of this regulation incorporates by reference the *Grade "A" Pasteurized*
39 *Milk Ordinance 2015-2017 Revision*, including supplements, provisions, administrative
40 procedures and appendices (PMO), *Procedures Governing the Cooperative State-Public*
41 *Health Service/Food and Drug Administration Program of the National Conference on*
42 *Interstate Milk Shipments 2015-2017 Revision* (Procedures), and *Methods of Making*
43 *Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service*
44 *Containers and/or Closures for Milk and/or Milk Products Manufacturers 2015-2017*
45 *Revision* (Methods) in effect as of this date.

46
47 4.3 Applicability

48
49 A. Pursuant to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., this regulation shall
50 apply to dairy plants, dairy farms, processing plants, receiving stations and other
51 facilities or establishments handling, transporting or selling any Grade "A" milk and

52 dairy products for human consumption.

- 53
- 54 B. The PMO shall apply to dairy sanitation and the labeling and grading of milk pursuant
55 to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., in so far as it is consistent with
56 Colorado statutes and regulations, except that: In the PMO as indicated, "State of
57 Colorado" shall be inserted in all footnotes numbered (2).
- 58
- 59 C. The PMO shall apply to the production of raw milk and cream for manufacturing
60 purposes, butter, raw aged cheeses, pasteurized cheese and cheese products, frozen
61 desserts, ice cream, pasteurized ice cream, dry whole milk, nonfat dry milk, dry
62 buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk
63 (excluding sweetened condensed milk), condensed skim milk, cottage cheese, dry curd
64 cottage cheese, low fat cottage cheese, and other such products for human
65 consumption, as may be otherwise designated. These products may be produced from
66 cow, goat, sheep, camel or other milk producing animals.
- 67
- 68 D. The PMO shall apply to the production, transportation, processing, handling,
69 sampling, examination, labeling, and sale of milk and dairy products; the
70 inspection of dairy farms, milk tank trucks, milk plants, receiving stations, transfer
71 stations, milk tank truck cleaning facilities, and bulk milk hauler/samplers.
- 72
- 73 E. The PMO shall apply to the issuing and revocation of licenses to milk and dairy
74 producers, dairy farms, bulk milk hauler/samplers, milk tank trucks, milk
75 transportation companies, milk plants, receiving stations, transfer stations, milk
76 tank truck cleaning facilities, haulers, and distributors; and the fixing of penalties.
- 77
- 78 F. The department shall utilize the PMO or other department approved methods as
79 appropriate to assure that non-Grade "A" manufactured milk and dairy products are in
80 compliance with Section 25-5.5-101, *et seq.*, C.R.S.

81

82 4.4 Definitions

83

- 84 A. For the purpose of these rules and regulations:
- 85
- 86 1. Jurisdiction (as used in the PMO) means the State of Colorado.
- 87
- 88 2. Ordinance (as used in the PMO) means the regulations of the State of Colorado.
- 89
- 90 3. Regulatory Agency means the Colorado Department of Public Health and
91 Environment and its authorized representative.
- 92
- 93 4. Sale means the transfer of manufactured milk and dairy products from one
94 individual, partnership, or corporation to another individual, partnership, or
95 corporation in exchange for cash or any other contractual obligation to pay for
96 the product.
- 97

98 4.5 License Requirements

99

100 Any person desiring to operate a dairy farm, milk or dairy plant or receiving station or to
101 sample or test milk or cream for the purpose of payment in this state, before undertaking
102 such operation, shall make application to and, if approved, be licensed by the Department in
103 accordance with Section 25-5.5-107, C.R.S.

104 4.6 Denial and Suspension of Licenses

105
106 All denials, suspensions or revocations of licenses shall be conducted in accordance with the
107 provisions of Sections 24-4-104 and 24-4-105, C.R.S.

108
109 4.7 Incorporation by Reference

110
111 A. Throughout these regulations, standards and requirements of outside organizations
112 have been adopted and incorporated by reference. The material incorporated by
113 reference cited herein includes only those versions that were in effect as of 20152017,
114 and not later amendments to the incorporated materials. These rules incorporate by
115 reference:

- 116
117 1. U.S. Department of Health and Human Services, Public Health Service/Food
118 and Drug Administration, *Grade "A" Pasteurized Milk Ordinance (Includes*
119 *provisions from the Grade "A" Condensed and Dry Milk Products and*
120 *Condensed and Dry Whey - Supplement I to the Grade "A" PMO 2015-2017*
121 *Revision)*, including supplements, administrative procedures, appendices, and
122 coded Food and Drug Administration Interpretative Memoranda (PMO);
123
124 2. U.S. Department of Health and Human Services, Public Health Service/Food
125 and Drug Administration and the National Conference On Interstate Milk
126 Shipments, *Procedures Governing the Cooperative State-Public Health*
127 *Service/Food and Drug Administration Program of the National Conference on*
128 *Interstate Milk Shipments 2015-2017 Revision* (Procedures); and,
129
130 3. U.S. Department of Health and Human Services, Public Health Service/Food
131 and Drug Administration, *Methods of Making Sanitation Ratings of Milk*
132 *Shippers and the Certifications/Listings of Single-Service Containers and/or*
133 *Closures for Milk and/or Milk Products Manufacturers 2015 2017 Revision*
134 *(Methods)*.

135
136 B. The Division of Environmental Health and Sustainability shall maintain certified copies
137 of the complete text of the incorporated materials, which shall be available for public
138 inspection during regular business hours, and shall provide certified copies of the
139 materials at cost upon request. For information regarding how the incorporated
140 materials may be obtained or examined, contact:

141
142 Division Director
143 Division of Environmental Health and Sustainability
144 Colorado Department of Public Health and Environment
145 4300 Cherry Creek Drive South
146 Denver, Colorado 80246-1530

147
148 C. The incorporated materials are available at:

149
150 <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm>

151
152 www.colorado.gov/pacific/cdphe/milk-and-dairy-regulations.