

**COLORADO****Department of Public
Health & Environment**

To: Members of the State Board of Health

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

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

Date: November 18, 2020

Subject: **Rulemaking Hearing**
Proposed Amendments to 6 CCR 1010-4, *Colorado Milk and Dairy Products Regulations*, for the rulemaking to occur in November 2020

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 adopt the revised regulation at the November 18, 2020, Board of Health meeting.

6 CCR 1010-4 was last amended by the Board of Health in March 2019. In compliance with 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, 2019 Revision (PMO)*; *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments (NCIMS), 2019 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, 2019 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 2019 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 2019 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, 2019 Revision (PMO)*; *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2019 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, 2019 Revision (Methods)*. 6 CCR 1010-4 was last amended by the Board of Health in March 2019.

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 corrections program manager, Bradley Turpin, is Colorado's voting delegate at NCIMS and the program last attended the conference in April and May 2019.

Over five billions pounds (~580 million gallons) of raw milk for processing is produced in Colorado each year. 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 that allow for the collection of representative milk samples on-farm and the use of UV disinfection in the production of pasteurized equivalent water. Other significant proposals were passed at the 2019 NCIMS that created efficiencies in regard to plant inspections by allowing a state rating to qualify in place of a PHS/FDA rating and the introduction of a compliance-based program evaluation process that could reduce a state's program evaluation frequency. 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), 2019 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, 2019 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, 2019 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 include proposed rule language that incorporates materials by reference?

Yes, FDA's PMO, Methods, and Procedures, 2019 Revisions
<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm>
 No

Does this rulemaking include proposed rule language to 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 processors	19	C
Licensed milk and dairy plant samplers	214	C
Milk and dairy product manufacturers	21	C
Farms (121 Grade "A" and 9 manufacture grade)	130	C
Transport firms (193 tanker trucks)	21	C
Licensed haulers	263	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	~5.8 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.

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.

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 2019 PMO, Methods, and Procedures favorably continues public health protections for the short and long-term 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 2019 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: Over five billion pounds (~580 million gallons) of raw milk for processing is produced in Colorado each year. Over 5.8 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 2019 PMO, Methods, and Procedures. No non-favorable non-economic outcomes were identified for the milk and dairy consumer.
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.

Along with the costs and benefits discussed above, the proposed revisions:

- Comply with a statutory mandate to promulgate rules.
 Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
 Maintain alignment with other states or national standards.
 Implement a Regulatory Efficiency Review (rule review) result
 Improve public and environmental health practice.
 Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

<p>1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO₂e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO₂e per year by June 30, 2020 and to 113.144 million metric tons of CO₂e by June 30, 2023.</p> <p><input type="checkbox"/> Contributes to the blueprint for pollution reduction <input type="checkbox"/> Reduces carbon dioxide from transportation <input type="checkbox"/> Reduces methane emissions from oil and gas industry <input type="checkbox"/> Reduces carbon dioxide emissions from electricity sector</p>
<p>2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.</p> <p><input type="checkbox"/> Reduces volatile organic compounds (VOC) and oxides of nitrogen (NO_x) from the oil and gas industry. <input type="checkbox"/> Supports local agencies and COGCC in oil and gas regulations. <input type="checkbox"/> Reduces VOC and NO_x emissions from non-oil and gas contributors</p>
<p>3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.</p> <p><input checked="" type="checkbox"/> Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. <input type="checkbox"/> Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. <input type="checkbox"/> Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.</p>

<p>4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023.</p> <p>___ Ensures access to breastfeeding-friendly environments.</p>
<p>5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <p>___ Reverses the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <p>___ Performs targeted programming to increase immunization rates.</p> <p>___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).</p>
<p>6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.</p> <p>___ Creates a roadmap to address suicide in Colorado.</p> <p>___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate.</p> <p>___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries.</p> <p>___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.</p>
<p>7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.</p> <p>___ Conducts a gap assessment.</p> <p>___ Updates existing plans to address identified gaps.</p> <p>___ Develops and conducts various exercises to close gaps.</p>
<p>8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.</p> <p>___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident.</p> <p>___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.</p> <p>___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.</p>
<p>9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023.</p>

<p><input type="checkbox"/> Implements the CDPHE Digital Transformation Plan.</p> <p><input checked="" type="checkbox"/> Optimizes processes prior to digitizing them.</p> <p><input checked="" type="checkbox"/> Improves data dissemination and interoperability methods and timeliness.</p>
<p>10. Reduce CDPHE’s Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.</p> <p><input type="checkbox"/> Reduces emissions from employee commuting</p> <p><input type="checkbox"/> Reduces emissions from CDPHE operations</p>
<p>11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.</p> <p><input type="checkbox"/> Used a budget equity assessment</p>

Advance CDPHE Division-level strategic priorities.

- Goal - Develop and execute a successful legislative initiative to modernize milk program funding in 2020, or future years if necessary. Fees should be increased to lessen the program’s demand on the General Fund.
- Goal - Budget Plan- Seek funding increase to the milk program via legislation to ensure dollars provided to the program support the necessary FTE to deliver federally required program services.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include: NA

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 2019 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 2019 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 cost 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 2017 version of the PMO, Methods and Procedures. Therefore, adoption of the updated 2019 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 April and May 2019, the division's milk and dairy program 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 2019 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
AGPROfessionals	Chad TeVelde
AMCOR PET Packaging - North America	Chris Maes
Aurora Organic Dairy	Peggy Colfelt
Aurora Organic Dairy	Juan Valez
Aurora Organic Dairy	Katie Speidel
Boren Trucking	Ricky Boren
CDPHE	Ben Chouaf
CDPHE	Jeff Groff
CDPHE	Labertta Cano
CDPHE - DEHS	Sean Scott
CDPHE - DEHS	Jeff Lawrence
CDPHE - DEHS	Cary Ruble
CDPHE - DEHS	Jacob Lofgren
CDPHE - DEHS	Brad Turpin
CDPHE - DEHS	Samantha Monell
CDPHE - DEHS	Ryan Allen
CDPHE - DEHS	Hayden Wailes
CDPHE - DEHS	Rachel Warnell
Chapin Dairy	Foy Chapin
Colorado Dairy Supply	Joel Lederman
Colorado Dept of Agriculture	Maggie Baldwin
Colorado Dept of Agriculture	Keith Roehr, DVM
Colorado Livestock Association	Jessica Lemmel
Colorado Livestock Association	Bill Hammerich
Colorado State University - Dept. of Animal Sciences	Noa Roman-Muniz
Corsentino Dairy	Brett Corsentino
Cream Bean Berry	Katie Burford
Dairy Engineering	Walt Powell
Dairy Farmers of America	Tim Houck
Dairy Farmers Of America	Cathy Krueger
Dairy Farmers of America	Thomas Kovacik
Dairy Farmers Of America	Andrew Kidd
Dairy Farmers of America	Jill Waite
Dairy Farmers of America	Marie teVelde
Dairy Farmers of America, Inc. Ft. Morgan Plant	Tony Rosso
Dairy Farmers of America, Inc. Ft. Morgan Plant	Vince Mooney
Dairy Max	Bill Keating
Dairy Resources of the West	Keith Benner
Dairy Specialists	Randy Sorenson
Dairy Specialists	Kelly Smith

Dairy Specialists	Paul Berdell
Dean Foods Company	John Sanford
Dean Foods Company	Roger Hooi
Empire Dairy	Heidi Jordan
Empire Dairy	Norm and Britt Dinis
Foss Dairy Farm, LLLP	Robin Meireis
Fruition Farms Dairy and Creamery	Jimmy Warren
Graff Dairy	Dave Nichols
Haystack Mountain Goat Dairy	Charles Hellmer
Hx Butterfield/Camelot Camel Dairy	Kyle Hendrix
James Ranch Artisan Cheese	Dan James
Jumpin' Good Goat Dairy	Dawn Jump
Juniper Valley Farm	Will McConnell
Juniper Valley Farm	Larea Schmutzler
Kraft Family Dairies, LLC	Chris and Mary Kraft
Kroger Mountain View	Whitney Wisma
Kroger Mountain View	Douglas Richards
La Luna Dairy	Jon Slutsky
Laz Ewe 2 Bar Dairy	Jennifer Knoblauch
Leprino Foods	Scott Hall
Leprino Foods	Brad Maier
Leprino Foods	Jason Eckert
Leprino Foods	Jon Alby
Leprino Foods	Mark Cramer
Leprino Foods	Larry Rasmussen
Leprino Foods - Denver	Edith Wilkin
Leprino Foods - Fort Morgan	Chirs Alonzo
Leprino Foods - Greeley	Erick Murray
Leprino Foods - Greeley	Dustin Long
Longmont Dairy Plant	Dan Boyd
Marrs Milky Way Dairy	Eldon Marrs
Meadow Gold Dairies	Randy Kaufman
Meadow Gold Dairies	Ryan Johnson
Mile High Dairy	Wes Bangma
Mini-Moos Dairy	Rob and Amy Anderson
Morning Fresh Dairy	Rob Graves
MouCo Cheese Company, Inc.	Robert Poland
Noosa Yoghurt	Dave Davis
Philpott Goat Dairy	Vallorie Philpott
Pirnie Services	Russ Pirnie
Queso Campesino	Dan Harris
Queso Campesino	Able Robles
Rich Thompson Trucking, Inc.	Tammie Niemoth
Rockin' W Cheese	John Gibson
Royal Crest Dairy	Todd Watson
Russell Stover Candies LLC	Paul Minerich
Safeway Stores, Inc. Milk Plant	Karl Guderian
Schwartz and Sons Trucking	Dan Schwartz
Sinton Dairy Foods Co. LLC	Sheryl Grider
Third Bowl Homemade Ice Cream	Kendall Tankersly
USDA	Emily Prisco
Western Culture Farmstead	David Miller
Western Dairy Transport	Phil Redd
Zubal Goat Dairy	Tom and Doris Zubal

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 the program last attended the conference in April and May 2019. 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 2019 version of the PMO, Methods, and Procedures is provided.

On August 14, 2020, following the publication of FDA's revised 2019 PMO, Methods, and Procedures, the division initiated Colorado's stakeholder outreach communications regarding the proposed revisions. Based on subsequent conversations with stakeholders and the receipt of written support, consensus on the revised and proposed regulation was achieved, including the incorporation by reference of FDA's 2019 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 April and May 2019. 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 2019 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 2019 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, 2019 REVISION

The following Proposals were passed or passed as amended by state delegates at the 2019 NCIMS and addressed changes to the PMO, Procedures, Methods, and Forms:

- 106 Provides clarification on the emptying and cleaning of storage tanks as identified by item 12p within the PMO.
- 108 Adds language to Item 16p(B)2.f.(2)ii. and Appendix H that will allow use of the partial homogenization for producing the milk and/or milk products.
- 109 Allows milk pasteurization plants to list either their name and location or their milk plant code on their milk pasteurization charts.
- 111 The PMO should allow for an exception to the pH of yogurt needing to be 4.8 or

less at filling for cup set yogurt. Cup set yogurt should have the requirements of reaching a pH of 4.6 within 24 hours and cooled to 45° F or less within seventy-two (72) hours.

- 112 Allows for the transportation of yogurt in a sealed container from one plant to another for addition of flavoring and packaging as is allowed for cottage cheese. This proposal was assigned to a standing committee with input from affected stakeholders to review the NCIMS role in regulating the repackaging of cultured milk and/or milk products.
- 113 Adds a “flow control system” as an alternative to a “flow control valve” in Appendix D and Appendix H for controlling performance in UV light systems used to treat water. Remove reference to “design flow”.
- 114 Amended to be assigned to an NCIMS standing committee to address the issues identified in this proposal and proposals 115 and 116 involving UV disinfection and other technologies to product disinfected and or/ pasteurized equivalent water as prescribed in Section VII, Appendix D and Appendix H.
- 117 Outlines clarifications and editorial changes made to Item 16p and Appendix H of the PMO.
- 118 The technical engineering review committee determined that AMI technology shouldn't be regulated any differently than other dairy farm technology.
- 120 Adds language that will limit PMO Appendix I Tests 9.2.1 and 9.2.3 (of Test 9.2) to plate type and double tube/triple tube type HHST and HTST pasteurization systems, to clarify that test 9.2.1 and 9.2.3. do not apply to spiral tubular regenerators such as those in Spyrotherm and Unitherm HHST pasteurization systems.
- 122 Clarifies that to comply with the bacteria standard noted in Item 12p and Appendix J, a sample set shall not have two (2) or more out of four (4) samples exceeding the bacterial standard.
- 203 Eliminates the requirement for the need for the “Name of the supervising Regulatory Agency at the point of shipment.”
- 205 The 2017 Procedures Manual requires Sampling Surveillance Personnel to be recertified once every three years. This proposal allows for recertification period to include the remaining days of the month similar to what is allowed in the “Industry Plant Sampler” and “Dairy Plant Sampler” definitions found in the 2017 PMO.
- 206 Clarifies primacy of the FDA/NCIMS 2400 forms over *SMEDP* and *OMA* in the PMO.
- 207 Ensures the milk tests listed under Section 6 of the PMO are kept current by referring to the latest version of M-A-98.
- 208 Eliminates the requirement that vitamin volume control records, cleaning

charts/records, pasteurization charts, temperature records/charts for refrigerated rooms and pH recording charts be reviewed, dated, signed or initialed by or under the oversight of a Preventive Control Qualified Individual (PCQI) at facilities that are exempt from some or all of 21 CFR part 117 preventive controls regulations.

- 210 Allows for the use of the Piper DynaStream, an automated truck-mounted metering and sampling system, for the acquisition of representative samples of milk as described in the PMO.
- 211 Includes new procedures for the sampling required by aseptic in-line sampling systems, petcocks and in-line sample points.
- 212 FDA Form 2399a will need to be revised to reflect changes to Appendix B of the 2017 PMO.
- 215 Adds clarity to Appendix N for Farm Trace back and Reinstatement of Producers found to be positive and shipments discontinued for the period until found to be no longer positive for drug residues.
- 216 Eliminates the Appendix N reference to M-I-06-5 for the disposal of adulterated milk and updates the referenced FDA Compliance Policy Guide to the current CPG.
- 223 Grants LPET the option to extend certification from 3 to 6 years for LEOs in good standing. Allow on-site surveys to be done up to 60 days early yet maintain the previous date for determining the new biennial or triennial expiration dates.
- 228 Colitag, a Presence/Absence Chromogenic Substrate (ONPG-MUG), included as an approved test method for Coliforms in Potable Water.
- 229 Colitag, an MPN Chromogenic Substrate (ONPG-MUG), included as an approved test method for Coliforms in Potable Water.
- 230 Includes two additional controls to the disintegration procedure, and remove a control that should not be listed.
- 234 Changes FORM FDA/NCIMS 2400 Cultural Procedures - General Requirements to remove the requirement that Temperature Monitoring Systems described in section 3e that meet prerequisites of section 3c are compared weekly to an accurate thermometer.
- 238 Removes equipment listed in the FDA/NCIMS 2400 forms that is no longer approved for use.
- 239 Updates Charm FAP and Paslite Phosphatase 2400 forms with next generation novalUM II X instrumentation.
- 240 Approves the Charm beta-lactam 30 second test (BL30SEC) and incorporate into the SL/SL3 2400 form.

- 241 Updates Peel Plate 2400 form with room temperature stability and prepared cultured dairy plates.
- 301 Reconciles APPENDIX K. HACCP PROGRAM language with the APPENDIX T. PREVENTIVE CONTROLS FOR HUMAN FOOD REQUIREMENTS FOR GRADE "A" MILK AND MILK PRODUCTS language.
- 303 Clarifies the issuance process for Memorandums of Information (M-I) to be reviewed by the NCIMS document review committee.
- 304 Allows States and TPCs the option of having their State Program Evaluations (SPEs) conducted once every five (5) years instead of every three (3) years dependent on if The State or TPC had two (2) consecutive triennial written Regulatory/Rating Agency Program Evaluations conducted and completed within the established 3-year time frames, and both of these SPEs are classified as being "in compliance" with the requirements of the Grade "A" PMO and the NCIMS Procedures document.
- 305 Eliminates the requirement that shipping states and TPCs must immediately notify all known receiving States when there is a significant change in the number of dairy farms within certified interstate milk shippers supply (BTU).
- 306 Clearly defines attendance at the FDA Regional Milk Seminar for Laboratory Evaluation Officers.
- 307 The Appendix N Modification Committee will become a standing committee.
- 308 The utilization of the training from the PHS/FDA Milk Specialists on Appendix T coupled with the abbreviated training course approved by the HACCP Implementation Committee constitutes sufficient and adequate training for original certification of the SRO. The abbreviated training course approved by the HACCP Implementation Committee meets the training requirements for recertification of the SRO.
- JC-1 Calls for FDA to recognize and utilize the NCIMS PMO Appendix T process as meeting the requirements of the FSMA in the review of a milk processing facility producing both Grade A and Non-Grade A Dairy Products. It was amended to be assigned to a committee to work cooperatively with the FDA to develop a pilot program which finds efficiencies in inspection activities for facilities which manufacture both Grade "A" and non-Grade "A" products.
- JC-2 Contains modifications to the PMO, Methods, Procedures and Bylaws documents that address the regulation and rating of milk plants producing Grade "A" fermented high acid shelf stable milk and/or milk products.

1 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2
3 Division of Environmental Health and Sustainability

4
5 COLORADO MILK AND DAIRY PRODUCTS REGULATIONS

6
7 6 CCR 1010-4

8 *[Editors Notes follow the text of the rules at the end of this CCR Document]*

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10
11
12 Adopted by the Board of Health on ~~March 20, 2019~~; effective, ~~May 15, 2020~~

13
14 4.1 Authority

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

20
21 4.2 Scope and Purpose

22
23 A. This regulation shall govern:

- 24
25 1. Dairy sanitation, the processing, packaging, transportation and sale of Grade
26 “A” milk and milk products, and represents the state and federal standard for
27 Grade “A” milk sanitation;
28
29 2. Sanitary production of milk for manufacturing purposes including its
30 transportation, grading, use, processing, and the packaging, labeling and
31 storage of dairy products made there from;
32
33 3. Licensure and inspection of dairy farms and dairy plants for the production and
34 sale of milk or dairy products for manufacturing purposes;
35
36 4. Retention of appropriate documentation and records by plants licensed
37 hereunder;
38
39 5. Licensure of qualified milk or dairy product samplers and testers.

40
41 B. Section 4.7 of this regulation incorporates by reference the *Grade “A” Pasteurized*
42 *Milk Ordinance 20172019 Revision*, including supplements, provisions, administrative
43 procedures and appendices (PMO), *Procedures Governing the Cooperative State-Public*
44 *Health Service/Food and Drug Administration Program of the National Conference on*
45 *Interstate Milk Shipments 20172019 Revision* (Procedures), and *Methods of Making*
46 *Sanitation Ratings of Milk Shippers and the Certifications/Listings of Single-Service*
47 *Containers and/or Closures for Milk and/or Milk Products Manufacturers 20172019*
48 *Revision* (Methods) in effect as of this date.
49
50
51

52 **4.3 Applicability**
53

- 54 A. Pursuant to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., this regulation shall
55 apply to dairy plants, dairy farms, processing plants, receiving stations and other
56 facilities or establishments handling, transporting or selling any Grade “A” milk and
57 dairy products for human consumption.
58
- 59 B. The PMO shall apply to dairy sanitation and the labeling and grading of milk pursuant
60 to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., in so far as it is consistent with
61 Colorado statutes and regulations, except that: In the PMO as indicated, “State of
62 Colorado” shall be inserted in all footnotes numbered (2).
63
- 64 C. The PMO shall apply to the production of raw milk and cream for manufacturing
65 purposes, butter, raw aged cheeses, pasteurized cheese and cheese products, frozen
66 desserts, ice cream, pasteurized ice cream, dry whole milk, nonfat dry milk, dry
67 buttermilk, dry whey, evaporated milk (whole or skim), condensed whole milk
68 (excluding sweetened condensed milk), condensed skim milk, cottage cheese, dry curd
69 cottage cheese, low fat cottage cheese, and other such products for human
70 consumption, as may be otherwise designated. These products may be produced from
71 cow, goat, sheep, camel or other milk producing animals.
72
- 73 D. The PMO shall apply to the production, transportation, processing, handling,
74 sampling, examination, labeling, and sale of milk and dairy products; the
75 inspection of dairy farms, milk tank trucks, milk plants, receiving stations, transfer
76 stations, milk tank truck cleaning facilities, and bulk milk hauler/samplers.
77
- 78 E. The PMO shall apply to the issuing and revocation of licenses to milk and dairy
79 producers, dairy farms, bulk milk hauler/samplers, milk tank trucks, milk
80 transportation companies, milk plants, receiving stations, transfer stations, milk
81 tank truck cleaning facilities, haulers, and distributors; and the fixing of penalties.
82
- 83 F. The department shall utilize the PMO or other department approved methods as
84 appropriate to assure that non-Grade “A” manufactured milk and dairy products are in
85 compliance with Section 25-5.5-101, *et seq.*, C.R.S.
86

87 **4.4 Definitions**
88

- 89 A. For the purpose of these rules and regulations:
90
- 91 1. Jurisdiction (as used in the PMO) means the State of Colorado.
92
 - 93 2. Ordinance (as used in the PMO) means the regulations of the State of Colorado.
94
 - 95 3. Regulatory Agency means the Colorado Department of Public Health and
96 Environment and its authorized representative.
97
 - 98 4. Sale means the transfer of manufactured milk and dairy products from one
99 individual, partnership, or corporation to another individual, partnership, or
100 corporation in exchange for cash or any other contractual obligation to pay for
101 the product.
102

4.5 License Requirements

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

4.6 Denial and Suspension of Licenses

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

4.7 Incorporation by Reference

A. Throughout these regulations, standards and requirements of outside organizations have been adopted and incorporated by reference. The material incorporated by reference cited herein includes only those versions that were in effect as of 20172019, and not later amendments to the incorporated materials. These rules incorporate by reference:

1. 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 20172019 Revision)*, including supplements, administrative procedures, appendices, and coded Food and Drug Administration Interpretative Memoranda (PMO);
2. 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 20172019 Revision* (Procedures); and,
3. 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 20172019 Revision* (Methods).

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

Division Director
Division of Environmental Health and Sustainability
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

154 C. The incorporated materials are available at:

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