STATE OF COLORADO

John W. Hickenlooper, Governor Larry Wolk, MD, MSPH Executive Director and Chief Medical Officer

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Colorado Department of Public Health and Environment

Division of Environmental Health and Sustainability

| To: | Members of the State Board of Health |
|----------|---|
| From: | 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: | June 18, 2014 |
| Subject: | Request for Rulemaking Hearing Proposed Amendments to 6 CCR 1010-4, <i>Colorado Grade A Pasteurized Milk and</i> <i>Fluid Milk Products</i> , with a request for the rulemaking hearing to occur in August 2014 |

The Division of Environmental Health and Sustainability is proposing revisions throughout 6 CCR 1010-4 and is requesting that the Board of Health schedule a rulemaking hearing for adoption of the above-revised regulations at the August 20, 2014, Board of Health Meeting.

This request for rulemaking proposes to incorporate changes in the *Grade "A" Pasteurized Milk Ordinance 2013 Revision* (PMO); *Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments 2013 Revision* (Procedures); and, *Methods of Making Sanitation Ratings of Milk Shippers*, *2013 Revision* (Methods), since 6 CCR 1010-4 was last amended by the Board of Health in 2010. The PMO, Procedures, and Methods are developed by the Federal Food and Drug Administration (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 the state milk sanitation programs. The PMO, Procedures, and Methods also serve as the official documents setting forth the sanitation requirements that govern the interstate shipment of Grade A milk and milk products. An electronic copy of these documents is presented on the Division of Environmental Health and Sustainability website:

• <u>http://www.colorado.gov/cs/Satellite?c=Page&childpagename=CDPHE-</u> DEHS%2FCBONLayout&cid=1251586894689&pagename=CBONWrapper

The 2013 PMO, Procedures, and Methods will be posted and available for review in the future on the following FDA website:

• <u>http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/</u><u>Milk/default.htm</u>

Adoption of the updated 2013 PMO, Procedures, and Methods will ensure that Colorado's milk sanitation program is in conformance with the latest national standards, thereby permitting Colorado milk and milk products to move freely in interstate commerce. No controversial issues related to the adoption of these federal documents have been identified.

The Division of Environmental Health and Sustainability greatly appreciates your cooperation and assistance in this matter.

Copies of the Statement of Basis and Purpose, Regulatory Analysis and a summary of the Incorporation by Reference documents are enclosed for your review.

STATEMENT OF BASIS AND PURPOSE AND SPECIFIC STATUTORY AUTHORITY

for Amendments to 6 CCR 1010-4 Colorado Grade A Pasteurized Milk and Fluid Milk Products

Basis and Purpose.

The Rules and Regulations Pertaining to Colorado Grade A Pasteurized Milk and Fluid Milk Products would adopt the Grade "A" Pasteurized Milk Ordinance, 2013 Revision (PMO) recommendations of the U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration (FDA) including provisions, supplements, administrative procedures, methods, and appendices. This document is identified as the 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), 2013 Revision.

The revised 2014 *Rules and Regulations Pertaining to Colorado Grade A Pasteurized Milk and Fluid Milk Products* represent an updating of the 2010 *Rules and Regulations Pertaining to Colorado Grade A Pasteurized Milk and Fluid Milk Products*, recognizing technological advances, milk plant environment changes, drug residue controls for food producing animals, and changes in production and processing equipment. The regulations will bring Colorado into conformance with the requirements adopted by other states, thereby permitting freedom in the movement of milk and milk products across state lines, to federal reservations and agencies and to certain school districts, 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) 2013 Revision,* including supplements, administrative procedures, appendices, and coded Food and Drug Administration Interpretative Memoranda;
- B. Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, 2013 Revision (Procedures); and,
- C. Methods of Making Sanitation Ratings of Milk Shippers, 2013 Revision (Methods).

The incorporation by reference of these documents into the revised 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 programs.

Recent coded FDA interpretive memoranda since the publication of the 2013 PMO are considered to be a part of the 2013 PMO in accordance with the procedural agreements of the National Conference of Interstate Milk Shippers.

Previous revisions of the *Colorado Grade A Pasteurized Milk and Fluid Milk Products Regulations* have been in substantial compliance with the various editions of the PMO. PMO requirements change after each Interstate Milk Shippers Conference; therefore, Colorado must include these

changes in the revisions of the *Colorado Grade A Pasteurized Milk and Fluid Milk Products Regulations.*

The PMO, Procedures, and Methods serve as the official documents setting forth the sanitation requirements governing the interstate shipment of milk and milk products to and from other states, federal reservations and certain Colorado school systems. A failure to keep Colorado's milk regulations current and in conformance with other states requirements, could result in Colorado milk processors not being allowed to ship milk and milk products in interstate commerce or to federal institutions.

The adoption of these revisions to the *Rules and Regulations Pertaining to Colorado Grade A Pasteurized Milk and Fluid Milk Products* will provide effective public health protection through the regulation of the Colorado dairy industry and other out-of- state dairy companies shipping into Colorado.

Specific Statutory Authority.

These rules are promulgated pursuant to the following statutes: Section 25-1.5-104(1)(b)(I), C.R.S.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____Yes, the bill number is _____; rules are ___ authorized ___ required.

<u>X</u>No

Is this rulemaking due to a federal statutory or regulatory change?

<u>X</u> Yes

____ No

Does this rule incorporate materials by reference?

- <u>X</u> Yes
- ____ No

Does this rule create or modify fines or fees?

- ____ Yes
- <u>X</u> No

REGULATORY ANALYSIS

for Amendments to 6 CCR 1010-4 Colorado Grade A Pasteurized Milk and Fluid Milk Products

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

Milk producers, milk processors and consumers of milk and milk products.

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.

At this time, there will be no known increase in cost to the Colorado milk industry or to consumers.

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.

The Colorado Department of Public Health and Environment, Division of Environmental Health and Sustainability, expects minimal, if any, increase in the costs to this Department. There is no increase in the inspectional time anticipated. Distribution of information relative to the regulations may result in a slight increase in the cost to CDPHE. The Department currently provides interpretations, training, and educational materials to regulated facilities, so little impact is anticipated in continuing these services with the regulations.

Local health agencies will not be involved with the inspection and enforcement of these facilities and, therefore, there is no associated cost to these agencies.

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

These revised regulations will bring Colorado into conformance with the requirements adopted by other states, thereby permitting freedom in the movement of milk and milk products across state lines, to federal reservations and agencies and to certain school districts, in accordance with the terms of the PMO, Procedures, and Methods governing Interstate Milk Shippers. The regulations translate new knowledge, technology and methodologies into effective and practicable public health practices.

Inaction would result in Colorado's milk regulations not being in conformance with the requirements of the 2013 Grade "A" PMO, Procedures, or Methods. A failure to keep Colorado's milk regulations current and in conformance with other states requirements, could result in Colorado milk processors not being allowed to ship milk and milk products in interstate commerce or to federal institutions.

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

Adoption of the 2013 PMO, Procedures, and Methods has been determined to obtain uniformity between states, higher levels of milk sanitation practices, and the facilitation of interstate shipments of quality products. We cannot determine that a less costly method could be developed.

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

Alternative methods were not considered.

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.

Quantification of the data is not applicable.

STAKEHOLDER Comment

for Amendments to

6 CCR 1010-4

Colorado Grade A Pasteurized Milk and Fluid Milk Products

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

- U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration (FDA)
- National Conference On Interstate Milk Shippers (NCIMS)
- CDPHE staff
 - Jeff Lawrence, Division of Environmental Health and Sustainability, Director
 - Sean Scott, Division of Environmental Health and Sustainability, Deputy Director
 - Susan Parachini, Direct Implementation Programs Unit Manager
 - Paul Klug, Division of Environmental Health and Sustainability, Milk Program Coordinator
 - Cary Ruble, Regulation Development and Enforcement Coordinator

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

- CDPHE staff
 - o Jeff Lawrence, Division of Environmental Health and Sustainability, Director
 - Sean Scott, Division of Environmental Health and Sustainability, Deputy Director
 - o Susan Parachini, Direct Implementation Programs Unit Manager
 - Paul Klug, Division of Environmental Health and Sustainability, Milk Program Coordinator
 - o Ben Chouaf, Laboratory Services Division, Physical Scientitst
 - Jeff Groff, Laboratory Services Division, Certification Program Manager
 - o Skip Gossack, Laboratory Services Division, Environmental Microbiologist
 - Cary Ruble, Regulation Development and Enforcement Coordinator
- Milk Program Stakeholders
 - Chris Maes, AMCOR PET Packaging North America
 - Peggy Cofelt, Aurora Organic Dairy Farms
 - Juan Velez, Aurora Organic Dairy Farms
 - Ricky Boren, Boren Trucking
 - Steve Valente, Bottles Unlimited
 - Joel Lederman, Colorado Dairy Supply
 - Brett Corsentino, Corsetino Dairy
 - Caille Gash, Cozy Cown Dairy
 - Bob Bullus, Dairy Engineering
 - Tim Houck, Dairy Farmers of America
 - Wade Meek, Dairy Farmers of America (Transfer Station)
 - o Tony Rosso, Dairy Farmers of America, Inc. , Ft. Morgan Plant
 - Randy Sorenson, Dairy Specialists
 - Larry Huffman, Dillon Dairy
 - Dave Nichols, Graff Dairy

- Milk Program Stakeholders (continued)
 - o Jim Smith, Hi Plains Dairy
 - o Jim Heaston, Juniper Valley Farm
 - Robert Kemp, Kemps Transport, LLC
 - Ken Benesch, Ken Benesch Trucking
 - Edith Wilkin, Leprino Foods
 - Ron Cantwell, Leprino Foods Fort Morgan
 - Nick Opper, Leprino Foods Greeley
 - o Dan Boyd, Longmont Dairy Plant
 - o Mark Ownby, Meadow Gold Dairies Delta
 - Ralph Lee, Meadow Gold Dairies Englewood
 - Terry Rettele, Meadow Gold Dairies Greeley
 - Wes Bangma, Mile High Dairy
 - Rob Anderson, Mini-Moos Dairy
 - Rob Graves, Morning Fresh Dairy
 - o Adeniyi Odugbemi, Mountain View Foods
 - Dave Davis, Noosa Yoghurt
 - Tammie Niemoth, Rich Thompson Trucking, Inc.
 - o John Gibson, Rockin' W Cheese
 - Tom Wolf, Royal Creast Dairy
 - o Karl Guderian, Safeway Stores Inc. Milk Plant
 - Dan Schwartz, Schwartz and Sons Trucking
 - Amanda Moore, Sinton Dairy Foods Co. LLC
 - Cindy Haren, Western Dairy Association
 - Phil Redd, Western Dairy Transport
 - o Russ Pirnie. Pirnie Services
 - Keith Roehr, DVM, Colorado Department of Agriculture
 - Nick Streigel, Colorado Department of Agriculture

<u>On or before the date of publication of the notice in the Colorado Register, the Division</u> sent notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/ information from the division regarding the proposed rule-making? <u>X</u> Yes <u>No.</u> The Division provided notice on May 12, 2014.

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.

• There were no major factual or policy issues encountered during the drafting of the adopted rule.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

• No HEEJ impacts were identified during revision of the subject regulation. The revised and adopted regulation will continue to promote the full health potential of all Coloradans regardless of race, color, national origin or income.

SUMMARY OF CHANGES TO THE PMO, PROCEDURES, AND METHODS, 2013 REVISIONS for Amendments to 6 CCR 1010-4 Colorado Grade A Pasteurized Milk and Fluid Milk Products

The following Proposals were passed and addressed changes to the PMO, Procedures, and <u>Methods:</u>

- Revisions provide consistent and uniform language and sanitary and sampling requirements for hauled water for use in milk plants as is currently required for use on dairy farms.
- The PMO states that "Equipment manufactured in conformity with 3-A Sanitary Standards complies with the sanitary design and construction standards of this Ordinance". For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices should be used as guidance for milk plant and dairy farm regulators. This will provide greater uniformity in determining compliance of all equipment with PMO Items 9r and 11p. Also, 3-A Accepted Practices and the organizational references cited in the "NOTE" have been updated to the current stakeholder names.
- Addresses concerns cited in Appendix Q-Operation of Automatic Milking Installations for the Production of Grade "A" Raw Milk for Pasteurization, Ultra-pasteurization or Aseptic Processing and Packaging, Item 14r-Protection from Contamination of the PMO. It is related to the requirement of a fail-safe valve system providing protection equivalent to an interwired block-and-bleed valve arrangement, reference in Item 15p (B) of the PMO, to prevent cross contamination and adding the applicable requirements from Item 15p (B) into Item 14r for their use on Grade "A" dairy farms. It also provided editorial updates to Appendix Q of the PMO based on FDA's evaluation of Automatic Milking Installations (AMIs).
- Incorporates M-I-12-11 "Additional Information Related to the Storage of Drugs under Item 15r Of The Grade "A" Pasteurized Milk Ordinance (PMO)" into the Grade "A" PMO. M-I-12-11 specifically address the definition of lactating and dry cow specific to the grade "A" PMO.
- Allows for approved hand-drying devices as an acceptable alternative to individual sanitary towels at hand-washing facilities on dairy farms, identical to what is currently allowed for hand-washing facilities in milk processing plants.
- Provides consistent and uniform wording and sanitary requirements for re-circulated cooling water systems, including systems using a freezing point depressant, for use in milk plants and on dairy farms.
- Adds an option to Item 15p (A)-Protection from Contamination, Administrative Procedures 19 of the PMO to allow for other combinations of valve(s) that supply equivalent protection to the sanitary check valve protection currently required in the PMO.
- Revision does not add any new Tests to Appendix I, but provides consistency of language between all of the Tests where appropriate. It also eliminates unwarranted requirements and provides needed flexibility in identified Test procedures.

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- Provides updated and simplified criteria/requirements for the use of pressure relief valves within HTST pasteurization systems. The simplified criteria/requirements do not change what is currently required but only provide a more easily understandable statement of these criteria/requirements.
- Addresses changes to Figures 37, 39, 41 and 42 of the PMO to rectify errors identified in the existing HTST and HHST Pasteurization System Figures. This Proposal is limited to correcting those errors and does not create any additional requirements for continuous flow HTST or HHST pasteurization systems.
- Clarifies what information needs to be supplied to the state regulatory agency and FDA to review that a non-grade "A" dairy ingredient meets the criteria of use "for a functional or technical effect" in Definition Z of the PMO and set forth a time frame for that review.
- Clarifies the pasteurization time and temperature charts in the PMO in relation to the type of pasteurization equipment utilized.
- Remove the PMO Section 4. Item 6.a. requirement for the identity of the regulatory agency on containers of condensed and dry milk products.
- Provides consistency and uniform wording in the PMO and MMSR in relationship to determining the inspection frequency for bulk milk hauler/samplers, industry samplers and dairy plant samplers.
- With the passage of M-a-98 (Official *Grade "A" Pasteurized Milk Ordinance* (PMO) Regulatory Laboratory Tests For Grade "A" Milk And Milk Products And Grade "A" Dairy Farm And Milk Plant Water), appropriate references citing M-a-98 are proposed to be added to the PMO and the MMSR.
- Provides clarification and corrections to Section 6-The Examination of Milk and Milk Products related to drug residue testing and Appendix N-Drug Residue Testing and Farm Surveillance of the PMO. A clarification is also made to make it clear that raw milk received at a milk plant in a manner other than on bulk milk pickup tankers is required to be tested for Beta lactam drug residues prior to processing.
- Updates criterion for the Commissioner of FDA to utilize for determination that a potential problem exists with animal drug residues or other contaminants in the milk supply that would result in additional analysis for the contaminant by a method(s) determined by FDA to be effective in determining compliance with actionable levels or established tolerances.
- Changes the conversion of 40°F to be 4.5°C instead of 4.4°C in the PMO and on the 2400 series forms.
- Allows for beta lactam drug residue testing of sheep milk, which had previously been stored frozen using methods validated for sheep milk, provided the milk is sampled in accordance with an approved sampling and handling protocol.
- The FDA 2400 Series Evaluation Forms being used as Conference documents should reflect the cooperative nature of the program. The forms are jointly worked on by the FDA/LPET and the NCIMS Laboratory Committee. A proposed name change would include NCIMS.

• Contains modifications to the PMO, Methods, Procedures and Bylaws documents that address the regulation and rating of milk plants producing Grade "A" low-acid retort processed after packaging milk and/or milk products. It will incorporate the Aseptic Program Committee's findings and determination for milk plants that produce Grade "A" low- acid retort processed after packaging milk and/or milk products into the NCIMS documents.

Also requests a two (2) year extension of the NCIMS Aseptic Pilot Program to specifically address Grade "A" acidified and fermented high-acid milk and/or milk products. The additional two (2) years will be utilized to evaluate the effectiveness of regulating and rating milk plants producing Grade "A" acidified and/or fermented high-acid milk an/or milk products.

Additionally addresses the regulation of Grade "A" low-acid retort processed after packaging milk and/or milk products manufactured in accordance with the Low Acid Canned Foods (LACF) regulations contained in 21 CFR 108, 110, and 113 while regulating the areas of the milk plant that are outside the low-acid retort processed after packaging system (RPPS) in accordance with the PMO. It provides for a separate IMS listing for Grade "A" milk plants producing Grade "A" low-acid retort processed after packaging milk and/or milk products.

• Contains modifications to the PMO, MMSR, Procedures, and the EML documents that the International Certification Pilot Program Committee (ICPPC) deemed necessary for the regulatory oversight, rating and IMS listing of milk shippers and milk laboratories located outside the geographic boundaries of the National Conference on Interstate Milk Shipments (NCIMS) Member States.

Also incorporates the findings of the ICPPC into the NCIMS documents and transform the International Certification Pilot Program (ICPP) into the International Certification Program (ICP) making it a permanent part of the NCIMS Grade "A" Milk Safety Program.

Additionally will utilize Third Party Certifiers (TPCs) who will act as regulatory, rating, and laboratory evaluation agencies in the regulation of foreign milk companies (MCs) and their associated farms, haulers, receiving stations, transfer stations, laboratories etc. FDA will conduct check ratings, laboratory evaluations and program evaluations in accordance with "Methods" and "Procedures".

The ICPPC has concluded that TPCs have the capability to operate as the regulatory, rating, and laboratory evaluation agencies as required to comply with the PMO and related NCIMS documents.

<u>The following Proposals were passed and addressed changes to the Procedures Governing</u> <u>the Cooperative State-Public Health Service/Food and Drug Administration Program of the</u> <u>National Conference on Interstate Milk Shipments (Procedures):</u>

• Identified as a new procedure: Provides language/guidance addressing the withdrawal of certification of a single-service containers and closures (SSCC) for milk and milk products manufacturer from the IMS List similar to what is already provided for Producer Dairies and Milk Plants, Receiving Stations and/or Transfer Station in *Procedures*.

It requests the NCIMS Chair to assign to the SSCC Committee and the Methods Committee to jointly develop IMS listing and withdrawal of IMS listing criteria for SSCC manufacturers. Consultants that currently have SSCC listings on the IMS List shall participate on these Committees.

Furthermore, it also requests the NCIMS Chair to assign to the SSCC Committee to develop qualifications, authorization, certification/recertification procedures, etc. for consultants that currently or wish to certify SSCC manufacturers located outside the geographical boundaries of NCIMS Member States. Consultants that currently have SSCC listings on the IMS List shall participate on this Committee.

| CO | LORADO DEPARTMENT OF PUBLIC HEALTH AND_ENVIRONMENT |
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| | Division of Environmental Health and Sustainability |
| | <u>6 CCR 1010-4</u> |
| | COLORADO GRADE A PASTEURIZED MILK AND FLUID MILK PRODUCTS |
| | 6 CCR 1010-4 |
| <u>1. 4.1</u> | <u>Statutory</u> Authority: |
| This r | egulation is adopted pursuant to the authority in Section 25-1.5-104(1)(b)(I), C.R.S. and is_ |
| consi | stent with the requirements of the State Administrative Procedures Act, Section 24-4-101, et seq., |
| <u>C.R.S.</u> | § 25-1.5-104(1)(b)(I), Colorado Revised Statutes. |
| 1.2 | Scope and Purpose |
| | |
| ۹. | This regulation establishes provisions governing dairy sanitation, the processing, packaging, |
| | transportation and sale of Grade "A" milk and milk products, and represents the state and |
| | federal standard for Grade "A" milk sanitation. |
| | This regulation does not apply to milk and dairy products as defined under the Colorado |
| - | Manufactured Milk & Dairy Products Regulations, 6 CCR 1010-3. |
| | |
| | Section 4.7 of this regulation incorporates by reference the Grade "A" Pasteurized Milk |
| | Ordinance 2013 Revision, including supplements, provisions, administrative procedures and |
| | <u>appendices (PMO), Procedures Governing the Cooperative State-Public Health Service/Food and</u> Drug Administration Program of the National Conference on Interstate Milk Shipments 2013 |
| | Revision (Procedures), and Methods of Making Sanitation Ratings of Milk Shippers 2013 Revision |
| | (Methods), in effect as of this date. |
| <u>4.3</u> | Adoption of United States Public Health Service Ordinance: Applicability |
| \ ppli | cability of the Grade "A" Pasteurized Milk Ordinance and the prohibition of the sale of raw milk. |
| | |
| ۹. | Pursuant to the provisions of Section 25-1.5-104(1)(b)(I), C.R.S., this regulation shall apply to |
| | dairy plants, dairy farms, processing plants, receiving stations and other facilities or |
| | establishments handling, transporting or selling any Grade "A" milk and milk products for human consumption |
| | human consumption. |
| | The provisions and supplements of the U.S. Department of Health and Human Services, Public |
| | Health Service/Food and Drug Administration, Grade "A" Pasteurized Milk Ordinance (PMO), |
| | 2009 Revision, including the Grade "A" Condensed and Dry Milk Products and Condensed and |
| | Dry Whey – Supplement I to the Grade "A" Pasteurized Milk Ordinance, including supplements, |
| | administrative procedures and appendices in effect as of this date, <u>The PMO</u> shall apply to |
| | regulate dairy sanitation and the labeling and grading of milk pursuant to the provisions of <u>Section 25-1.5-104(1)(b)(I), C.R.S., in so far that they are it is not inconsistent consistent</u> with |
| | <u>Section</u> 25-1.5-104(1)(0)(1), <u>C.R.S.</u> In so far that they are it is not inconsistent consistent with Colorado statutes and regulations, except that: a. In the PMO as indicated, "State of Colorado" |
| | shall be inserted in all footnotes numbered (2). |
| | |

| 51 | 2.4.4 | |
|----------|-------------------------|--|
| 52 52 | 3.<u>4</u>.4 | _Definitions ; |
| 53 | ٨ | For the purpose of these rules and regulations: |
| 54 | <u>A.</u> | For the purpose of these rules and regulations: |
| 55 56 | | 1 |
| | | 1. a. <u>Regulatory Agency</u> -, as defined in the PMO, shall mean the Colorado Department of |
| 57 | | Public Health and Environment and its authorized representative. |
| 58 | | 2 b Jurisdiction as used in the DMO shall mean the State of Colorado |
| 59 60 | | b-Jurisdiction, as used in the PMO, shall mean the State of Colorado. |
| 60 61 | | 3. <u>-</u> Ordinance, as used in the PMO, shall mean the rules and regulations of the State of |
| 62 | | <u>S. Colorado.</u> |
| 63 | | |
| 65 64 | | 3.4. Cottage cheese, dry curd cottage cheese, and low fat cottage cheese, as defined in the |
| 65 | | Code of Federal Regulations, Title 21, Sections 133.128 and 133.129, manufactured or |
| 65 66 | | sold in the State of Colorado, shall meet the applicable requirements of the PMO. |
| 67 | | sold in the state of colorado, shall meet the applicable requirements of the PMO. |
| 68 | 4. 4.5 | License Requirements; |
| 69 | <u></u> | |
| 70 | Any ne | rson desiring to operate a dairy farm, milk plant or receiving station or to sample or test milk or |
| 71 | | for the purpose of payment in this state, before undertaking such operation, shall make |
| 72 | | ition to and, if approved, be licensed by the Department in accordance with Section 25-5.5-107, |
| 73 | | The application shall be made on forms prepared or furnished by the Department, and shall set |
| 74 | | uch information as the Department may require, including the name and address of the applicant. |
| 75 | | the exception of dairy farm licenses, all other licenses shall be issued for a year or any part of a |
| 76 | | om July 1 through June 30 issued of the following year. |
| 77 | , | |
| 78 | 5. 4.6 | Denial and Suspension of Licenses: |
| 79 | | _ · |
| 80 | All den | ials, suspensions or revocations of licenses shall be conducted in accordance with the provisions |
| 81 | of sect | ions-Sections 24-4-104 and 24-4-105, Colorado Revised StatutesC.R.S. |
| 82 | | |
| 83 | <mark>6.</mark> 4.7 | Incorporation by Reference: |
| 84 | | |
| 85 | <u>A.</u> | Throughout these regulations, standards and requirements by outside organizations have been |
| 86 | | adopted and incorporated by reference. The material incorporated by reference cited herein |
| 87 | | includes only those versions that were in effect as of 2013, and not later amendments to the |
| 88 | | incorporated materials. These rules incorporate by reference: |
| 89 | | |
| 90 | | <u>a. These rules incorporate by reference the-</u>U.S. Department of Health and Human |
| 91 | | Services, Public Health Service/Food and Drug Administration <u>,</u> Grade "A" Pasteurized |
| 92 | | Milk Ordinanc <u>e e) 2009 (Includes provisions fromRevision, including</u> the Grade "A" |
| 93 | | Condensed and Dry Milk Products and Condensed and Dry Whey – Supplement I to the |
| 94 | | Grade "A" Pasteurized Milk Ordinance<u>PMO 2013 Revision</u> (PMO) , including |
| 95 | | supplements, administrative procedures, appendices, and coded Food and Drug |
| 96 | | Administration Interpretative Memoranda. These rules do not include later |
| 97 | | amendments to or editions of the incorporated material.; |
| 98 | | |
| 99 | | 2. U.S. Department of Health and Human Services, Public Health Service/Food and Drug |

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| 100 101 102 103 104 | | 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 2013 Revision (Procedures); and, |
|---|------------------------|---|
| 104 105 106 107 108 | | 3. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, <i>Methods of Making Sanitation Ratings of Milk Shippers 2013 Revision</i> (Methods). |
| 109 110 111 112 113 114 115 | A.<u>B.</u> | 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 |
| 116 | | Division of Environmental Health and Sustainability |
| 117 118 | | Colorado Department of Public Health and Environment 4300 Cherry Creek Drive South |
| 119 120 121 122 | B.<u>C.</u> | Denver, Colorado 80246-1530 Materials incorporated by reference have been submitted to the State Publications Depository and Distribution Center and may be examined at any state publications depository library. |

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