



Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: 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: June 20, 2018

Subject: **Request for Rulemaking Hearing**  
Proposed Amendments to 6 CCR 1010-21, *Colorado Wholesale Food Regulations* with a request for a rulemaking hearing to be set for August 15, 2018

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The Division of Environmental Health and Sustainability ("division") is proposing revisions to 6 CCR 1010-21, *Colorado Wholesale Food Regulations*, and is requesting that the Board of Health schedule a rulemaking hearing to consider adoption of the proposed amendments at the August 15, 2018, Board of Health meeting.

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 a review of 6 CCR 1010-21, *Colorado Wholesale Food Regulations*. Based on this review, the department is recommending amendments to update and align the state regulation with recently revised federal regulations through incorporation by reference. 6 CCR 1010-21 was last amended by the Board of Health in August 1999. This request for rulemaking proposes to update the 1999 incorporation by reference by incorporating the applicable portions of the current 21 CFR 100-190 (April 1, 2017), and U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance [(2015 Revision), "NSSP Shellfish Ordinance"]*. 21 CFR 100-190 and the NSSP Shellfish Ordinance are developed, administered, and maintained by the U.S. Food and Drug Administration ("FDA") and provide regulations addressing Food for Human Consumption and the national shellfish sanitation standards.

The proposed revisions to the wholesale food regulation will ensure that all locations in Colorado where foods are manufactured, packed, processed, prepared, treated, packaged, transported, or held for distribution are done in accordance with the "Pure Food and Drug Law", Section 25-5-401 *et seq.*, C.R.S. and the "Shellfish Dealer Certification Act," Section 25-4-1801 *et seq.*, C.R.S.

Electronic copies of 21 CFR 100-190, the NSSP Shellfish Ordinance, the "Pure Food and Drug Law", and the "Shellfish Dealer Certification Act," are available for review on the division website and at the Colorado Legal Resources provided by LexisNexis:

- <https://www.colorado.gov/pacific/cdphe/wholesale-food-stakeholder-meetings>

- <https://advance.lexis.com/container?config=0345494EJAA5ZjE0MDIyYy1kNzZkLTRkNzk tYTkxMS04YmJhNjBINWUwYzYKAFBvZENhdGFsb2e4CaPI4cak6laXLCWyLBO9&crId=28abb ed8-56f4-44da-9671-a4ad25ba0ba4&prId=d441faf3-c6aa-4ddf-ab54-167f1bfc5e2f>

Also, federal regulation proposed for incorporated by reference and applicable law are posted and available for review using the following websites:

- 21 CFR Parts 100-190  
<https://ecfr.io/Title-21/>
- NSSP Shellfish Ordinance  
<https://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM505093.pdf>  
<https://advance.lexis.com/container?config=0345494EJAA5ZjE0MDIyYy1kNzZkLTRkNzk tYTkxMS04YmJhNjBINWUwYzYKAFBvZENhdGFsb2e4CaPI4cak6laXLCWyLBO9&crId=28abb ed8-56f4-44da-9671-a4ad25ba0ba4&prId=d441faf3-c6aa-4ddf-ab54-167f1bfc5e2f>

The proposed rule includes registration requirements for wholesale food manufacturers and certification requirements for wholesale food manufacturers who are also shellfish dealers. These registration and certification requirements have been included in the proposed regulation for clarity and ease of use and to reflect current statutory requirements contained in Sections 25-5-426 and 25-4-1801 *et seq.*, C.R.S.

Pursuant to Sections 25-1.5-102(1)(c), 25-4-1810, 25-5-406, and 25-5-420, C.R.S., the proposed regulation also establishes embargo and enforcement standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers. These standards comport with current statutory language and have been included in the proposed regulation for ease of reference.

The proposed incorporation by reference of the applicable portions of 21 CFR 100-190 and the NSSP Shellfish Ordinance into state regulation will maintain public health protections while: providing alignment with current and nationally accepted federal standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers; allowing Colorado's food manufacturers to participate in interstate commerce associated with wholesale food and shellfish; 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 Wholesale Food Regulations*.

The division appreciates the Board's consideration.

STATEMENT OF BASIS AND PURPOSE  
AND SPECIFIC STATUTORY AUTHORITY  
for Amendments to  
6 CCR 1010-21, *Colorado Wholesale Food Regulations*

Basis and Purpose.

Revisions to *Colorado Wholesale Food Regulations*, 6 CCR 1010-21 would incorporate by reference and adopt the current 21 CFR 100-111, 113-170, and 172-190 (April 1, 2017), and U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance [(2015 Revision, "NSSP Shellfish Ordinance")]*. 6 CCR 1010-21 was last amended by the Board of Health in 1999.

The current *Colorado Wholesale Food Regulation*, 6 CCR 1010-21, incorporates by reference 21 CFR 110.3-110.93, *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (1998, "GMP" or "part 110")*. Through the enactment of the federal Food Safety Modernization Act ("FSMA"), signed into law on January 4, 2011, and consequently the subsequent federal Preventative Controls for Human Food Final Rule, 21 CFR 110.3-110.93 has been replaced with 21 CFR 117.

21 CFR 117 establish the "base requirements" that all food manufacturers must follow in order ensure the safe production of food. The federal rules provide additional clarity of requirements based on the types of foods being manufactured (e.g., acidified foods bottled water, and juice) in the other parts of 21 CFR 100 through 190, beyond part 117. The department proposed to incorporate the entirety of 21 CFR 100-190, except parts 112 and 171. This ensures Colorado and facilities operating in Colorado are in alignment with current federal industry standards. A summary of the substantive updates in the federal regulations include:

- An allergen program with adequate protection to prevent cross-contamination is required through all phases of production.
- Appropriate training for specific food manufacturing jobs is now a requirement. Personnel responsible for identifying sanitation failures or food contamination must have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food.
- FDA eliminated guidance materials regarding the food safety of raw materials. Compliance with requirements for the safety of raw materials and ingredients may be achieved by purchasing raw materials and ingredients under a supplier's guarantee or certification.
- During processing activities such as washing, peeling, and grinding, requirements were added to prevent drips from contaminating products.

Part 112 and 171 have not be incorporated because:

- 21 CFR 112 - *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*: 21 CFR 112 is implemented by the Colorado Department of Agriculture (CDA) through a cooperative agreement with FDA. CDA has full responsibility, authority, and accountability for the implementation of 21 CFR 112; and

- 21 CFR 171 - *Food Additive Petitions*: 21 CFR 171 regulates wholesale food producers who create food additives (i.e., preservatives) and seek FDA approval. Though the Department is authorized, pursuant to Section 25-5-413, C.R.S., to promulgate rules related to food additives when public health or other considerations so require. The Department has not been presented with circumstances that demonstrate a need for rules that elaborate upon statute. The statute is in alignment with the federal framework; thus, not incorporating this part of the federal regulations does not adversely impact wholesale food manufacturers or interstate commerce.

Wholesale food manufacturers who are also shellfish dealers must also comply with the U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (2015 Revision, NSSP Shellfish Ordinance)*. This has been required since the Colorado Shellfish Dealer Certification Act was enacted in 1997. Inclusion of the shellfish dealer certification requirements provides clarity and ease of use for these facilities.

Due to the interstate nature of commerce for wholesale food from manufacturers and shellfish dealers, Colorado's businesses are currently subject to the federal wholesale food and shellfish dealer requirements proposed for incorporation. The proposed incorporation by reference of 21 CFR 100-190 (except for 112 and 171) and the NSSP Shellfish Ordinance continue public health protections while:

- providing alignment with current and nationally accepted federal standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers;
- assuring that Colorado wholesale food manufacturers are permitted to ship their products in interstate commerce; and
- maintaining the efficiency and effectiveness of the rulemaking process and Department services.

In select instances where incorporated terminology is defined in both federal regulation and Colorado statute, the term shall have the meaning contained in the "Pure Food and Drug Law," part 4, article 5, title 25, C.R.S. and the "Shellfish Dealer Certification Act," part 18, article 4, title 25, C.R.S. This ensures the incorporation by reference aligns with state statute.

Along with updating the incorporation by reference, 6 CCR 1010-21 is revised to include:

- registration requirements for wholesale food manufacturers in accordance with Section 25-5-426, C.R.S.;
- certification requirements for wholesale food manufacturers who are also shellfish dealers in accordance with Section 25-4-1805, C.R.S.;
- embargo and enforcement standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers pursuant to Sections 25-1.5-102(1)(c), 25-4-1810, 25-5-406, and 25-5-420, C.R.S.; and,

- hearing requirements for cease-and-desist orders in conformance with provisions of article 4 of title 24, C.R.S.

These areas were identified as areas where elaborating upon the statutory framework add needed clarity and improve ease of use and processing. Along with these substantive changes, technical edits and reformatting occurred to improve readability and alignment with other Department rules.

Specific Statutory Authority.

Statutes that require or authorize rulemaking: Sections 25-1.5-102(1)(c), 25-4-1810, 25-5-406, and 25-5-420, 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

<https://ecfr.io/Title-21/> , and

<https://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM505093.pdf>

\_\_\_\_\_ 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. This rule does not require a local government to provide a specific service or increase a specific activity for which the local government will not be reimbursed.

\_\_\_\_\_ No. This rulemaking reduces or eliminates a state mandate on local government.

\_\_\_\_\_ Yes. This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

- \_\_\_\_\_ Necessitated by federal law, state law, or a court order
- \_\_\_\_\_ Caused by the State's participation in an optional federal program
- \_\_\_\_\_ Imposed by the sole discretion of a Department
- \_\_\_\_\_ Other: \_\_\_\_\_

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? \_\_\_Yes \_\_\_No

If yes, please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

REGULATORY ANALYSIS  
for Amendments to  
6 CCR 1010-21, *Colorado Wholesale Food 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.

- A. Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:

There are approximately 2,200 department-regulated wholesale food manufacturing and storage facilities throughout the state. The department and the regulated community are all affected and will benefit from the proposed incorporation by reference of the applicable portions of 21 CFR 100-190 and the National Shellfish Sanitation Program Shellfish Ordinance (NSSP Shellfish Ordinance). Although minimal and administrative in nature, costs are largely born by the department.

- B. Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group:

The wholesale food stakeholder group consisted of approximately 220 participants that included wholesale food manufacturers and storage facilities, wholesale food manufacturers who are also shellfish dealers, representatives from food industry associations, wholesale food lobbyists, and the Colorado Department of Agriculture.

- C. Identify each group of individuals/Entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:

The incorporation by reference of applicable federal regulation will continue to ensure that the sale and distribution of manufactured food from approximately 2,200 wholesale food manufacturers to over 21,000 grocers, restaurants, and schools and institutions are manufactured, packed, processed, prepared, treated, packaged, transported, or held for distribution in accordance with the "Pure Food and Drug Law" and the "Shellfish Dealer Certification Act". The ultimate customer of wholesale food manufacturing, the consumers inside Colorado and worldwide, will benefit from the revision by ensuring that the sale and distribution of Colorado's manufactured food is consistent with established federal requirements and come from approved sources.

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.

For those that rely on the rule to maintain their own businesses, agencies or operations:

At this time, there are no known or foreseen increases in cost to Colorado wholesale food manufacturers or wholesale food manufacturers who are also shellfish dealers.

Describe the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

Due to the interstate nature of commerce for wholesale food from manufacturers and shellfish dealers, Colorado's businesses are already subject to the federal wholesale food and shellfish dealer requirements proposed for incorporation. The proposed incorporation by reference of 21 CFR 100-190 (except for 112 and 171) and the NSSP Shellfish Ordinance continues public health protections while:

- providing clarification for consistent interpretation through alignment with current and nationally accepted federal standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers;
- maintaining the efficiency and effectiveness of the rulemaking process and Department services.

Unfavorable non-economic outcomes:

No unfavorable non-economic outcomes are anticipated. Colorado businesses affected by this regulation are already subject to the federal wholesale food and shellfish dealer requirements proposed for incorporation and the proposed revisions provide clarification for consistent interpretation of these requirements and state law.

Anticipated financial impact:

| Anticipated Costs:  | Anticipated Benefits:   |
|---|---|
| <p>None anticipated. Colorado businesses affected by this regulation are already subject to requirements proposed for incorporation.</p> <p>Description of costs that may be incurred.</p> <p>None anticipated.</p> | <p>Rulemaking efficiency, both current and future, and clarification for consistent interpretation and application of federal requirements and state law.</p> |
| <p>Cost or cost range.</p> <p>\$ <u>None</u> or<br/>___ No data available.</p>  | <p>Savings or range of savings.</p> <p>\$ <u>None</u> or<br/>___ No data available.</p>   |
| <p>Dollar amounts that have not been captured and why: <u>NA</u></p>  | <p>Dollar amounts that have not been captured and why: <u>NA</u></p>  |



Local Government Impact:

Statement from HB/SB NA Fiscal Note:

B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

Those affected by or interested in the outcomes of this rule are the same as those that rely on the rule to maintain their own businesses, agencies or operations. Due to the interstate nature of commerce for wholesale food from manufacturers and shellfish dealers, Colorado's businesses are already subject to the federal wholesale food and shellfish dealer requirements proposed for incorporation. The proposed incorporation by reference of 21 CFR 100-190 (except for 112 and 171) and the NSSP Shellfish Ordinance continues public health protections while:

- providing clarification for consistent interpretation through alignment with current and nationally accepted federal standards for wholesale food manufacturers and wholesale food manufacturers who are also shellfish dealers;
- maintaining the efficiency and effectiveness of the rulemaking process and Department services.

Unfavorable non-economic outcomes:

Those affected by or interested in the outcomes of this rule are the same as those that rely on the rule to maintain their own businesses, agencies or operations. No unfavorable non-economic outcomes are anticipated. Colorado businesses affected by this regulation are already subject to the federal wholesale food and shellfish dealer requirements proposed for incorporation and the proposed revisions provide clarification for consistent interpretation of these requirements and state law.

Any anticipated financial costs monitored by these individuals/entities?

No new costs are anticipated.

Any anticipated financial benefits monitored by these individuals/entities?

The proposed incorporation by reference of applicable parts of 21 CFR 100-190 and the NSSP Shellfish Ordinance assures that Colorado wholesale food manufacturers are permitted to ship their products in interstate commerce.

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Financial costs to these individuals/entities:

No financial costs to these individuals is anticipated.

Financial benefits to or cost avoidance for these individuals/entities:

Consumers of wholesale food manufactured in Colorado benefit from the continuation of food safety practices this rule provides. The Centers for Disease Control and Prevention (CDC) estimates that each year roughly 48 million Americans (one in six) get sick, 128,000 are hospitalized, and 3,000 die of foodborne illnesses. Moreover, foodborne illnesses cost over \$50 billion each year. Reducing foodborne illness by just 10 percent would prevent 5 million Americans from getting sick each year. Preventing a single fatal case of *E. coli* O157 infection would save an estimated \$7 million dollars.

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:

| Type of Expenditure  | Year 1 | Year 2 |
|--|--------|--------|
| CDPHE personal services costs, operating costs and other expenditures are net neutral. No new funding was necessary. | \$ NA  | \$ NA  |
|  | \$     | \$     |
| Total  | NA     | NA     |

Anticipated CDPHE Revenues:

This rulemaking modifies fees:

| Entity Type | # of Entities | Current Fee | Proposed Fee | % increase or decrease |
|-------------|---------------|-------------|--------------|------------------------|
| NA          | NA            | NA          | NA           | NA                     |

The Department anticipates that it will need to modify fees to support the department's costs. The fees are not established by the Board of Health but are set administratively. The Department anticipates that the fee will be revised as follows:

| Entity Type | # of Entities | Current Fee | Proposed Fee | % increase or decrease |
|-------------|---------------|-------------|--------------|------------------------|
| NA          | NA            | NA          | NA           | NA                     |

| Type of Revenue | Year 1 | Year 2 |
|-----------------|--------|--------|
| NA              | \$ NA  | \$ NA  |
| NA              | \$ NA  | \$ NA  |
| Total           | NA     | NA     |

Anticipated personal services, operating costs or other expenditures by another state agency:

NA

Anticipated Revenues for another state agency:

NA

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<br>Goal 2, Increase Efficiency, Effectiveness and Elegance<br>Goal 3, Improve Employee Engagement<br>Goal 4, Promote health equity and environmental justice<br>Goal 5, Prepare and respond to emerging issues, and<br>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:

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 applicable portions of 21 CFR 100-190 and NSSP Shellfish Ordinance achieves alignment with federal wholesale food regulations, continues levels of wholesale food sanitation practices in place, and maintains the allowance for the interstate shipment of wholesale food products, including shellfish. No less costly or intrusive method for achieving the purpose of this rule was identified. Through the continued incorporation by reference of current federal regulations and the resulting efficiencies in the rulemaking process, significant costs savings to both the regulated community and the department are realized. The minimal short-term administrative costs are far out-weighted by the operational efficiencies and maintains 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 1999 base requirements of the federal wholesale food regulations and are necessary in achieving the safe production of food. Therefore, the adoption of updated federal regulation is considered the most effective and efficient approach to rulemaking while protecting public health and allowing Colorado businesses to continue sell their products in interstate commerce. Incorporation and implementation of these federal food regulations will ensure long-term consistency in the application of wholesale food regulatory 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.

The incorporation by reference of current federal wholesale food 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 1010-21, *Colorado Wholesale Food 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. The organizations and manufactures listed below vary widely in size, operation type and function. The role of the individual within the organization is often unknown. When known, it was provided. In some instances the Division does not have a representative name as the entity only provided an email address to receive communications about the stakeholder engagement; this is reflected with the term "email contact."

| <b>Organization</b>  | <b>Representative</b>      |
|--|----------------------------|
| 3rd Street Chai  | Rory Cooper                |
| 4 Noses Brewing CO, LLC  | Email Contact              |
| 5280 Chocolates, Inc.  | Sharon Adams               |
| A & K Ice, A & K Distributing                                  | Kevin Enders               |
| Albertsons Safeway, Inc.                                       | Karl Guderian              |
| Albertsons/Safeway   | Kelly Zielbauer            |
| All American Seasonings, Incorporated                          | Samuel Romero              |
| Alpenglow Mushrooms LLC  | Email Contact              |
| Alpine Summit Sales, Inc.                                      | Randy Brown                |
| Ambry Inc., Colorado Food Showroom                             | Email Contact              |
| Ameri-Asian Trading Development, Inc., Whole Fresh Foods, Inc. | John Zhao                  |
| Amusemints, LLC  | Kip Zsupnik                |
| Ardent Mills and Ardent Mills, LLC                             | Kurt Weber                 |
| Aspen Baking Company, Jeffrey Ventures, Inc.,                  | Jeffrey Nations            |
| Aspen Park Candies, Inc., Georgetown Valley Candy Company      | Email Contact              |
| Astec Ltd., Sprouts Extraordinaire                             | Email Contact              |
| Avery Brewing Company  | Bernardo Alatorre          |
| Baccary Brewing Company LLC., Station 26 Brewing Company       | Email Contact              |
| Baja Salsa   | Elvia Sandoval de Caldwell |
| Bay State Milling Company                                      | Poland Carmen              |
| Beet Box, Inc., Beet Box Bakery                                | Michael Craig              |
| Bhakti, Inc.   | Mark Osborne               |
| Big B's Juices, Two Brothers Organics                          | Jeff Schwartz              |
| Bimbo Bakeries USA, Inc.                                       | Michelle Bruns             |
| Bimbo Bakeries USA, Inc.                                       | Scott Knapp                |
| Blanca Potato, LLC   | Karen Lanning              |
| Bobo's Oat Bars, Simply Delicious, Inc.                        | Email Contact              |
| Boulder Brands USA Inc., Boulder Brands USA Inc.               | Kayla Chavez               |
| Breggos, Inc., Solis Distribution                              | Email Contact              |
| Burns and McCoy Sauce Company, Burns and McCoy                 | Jay Turner                 |
| Cafe Novo Coffee Roasters                                      | Email Contact              |
| Cappello's LLC   | Stacey Marcellus           |
| Care And Share Food Bank For Southern Colorado                 | Email Contact              |
| Care And Share, Inc.   | Scott Trenady              |
| CDPHE - DEHS   | Kelly Lancelot             |
| CDPHE - DEHS   | Jeff Lawrence              |
| CDPHE - DEHS   | Cary Ruble                 |
| CDPHE - DEHS   | Sean Scott                 |

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|---|--|
| CDPHE - DEHS  | Jon Strauss                            |
| CDPHE - DEHS  | Justie Trubee                          |
| CDPHE - DEHS  | Laura Van Wagenen                      |
| CDPHE-DEHS  | Brian Young                            |
| Celestial Seasonings, The Hain Celestial Group, Inc.              | Gary Korb                              |
| Central Distributing, Gaylord Codez                               | Email Contact                          |
| Chip Peddler, Durango Snack Werks, LLC                            | Neil Hannum                            |
| Chocolove   | Seth Nelson                            |
| Chocolove, Creative Natural Products                              | Email Contact                          |
| Cinnamonster Franchise Group, Inc., Cinnamonster                  | Rick Doeksen                           |
| Claremont Foods, LLC  | Brooks Carpenter                       |
| Colo-Pac Produce  | Joseph Garin                           |
| Colorado Brewers Guild  | Andres Gil Zaldana, Executive Director |
| Colorado Brewers Guild  | Laura Long, Lobbyist                   |
| Colorado Correctional Industries, Fish Processing And Aquaculture | Stacy Gordon                           |
| Colorado Department of Ag   | Wendy White                            |
| Colorado Distillers Guild   | Steve Gould, Government Affairs        |
| Colorado Distillers Guild   | Kara Miller, Lobbyist                  |
| Colorado Mills  | Email Contact                          |
| Colorado Popcorn Company  | Breanna Kelsch                         |
| Colorado Popcorn Company  | Tyler Kelsch                           |
| Colorado Popcorn Company  | Zachary Souffrant                      |
| Colorado Restaurant Association                                   | Nick Hoover, Mgr. of Gvt. Affairs      |
| Colorado Restaurant Association                                   | Sonia Riggs, President & CEO           |
| Colorado Retail Council   | Chris Howes                            |
| Condor Snack Company, UTZ Quality Foods Inc.                      | Dixon Don                              |
| Del Monte Fresh Produce N A, Inc.                                 | Dave Wallace                           |
| Desert Sun Coffee Roasters, Inc.                                  | Email Contact                          |
| Dillon Companies Inc./Kroger-Rasc, King Soopers Bakery            | John Philipson                         |
| Dillon Companies Inc./Kroger-Rasc, King Soopers Reclamation       | Ralph Powell                           |
| Don't Go Nuts, LLC  | Karen Anttila                          |
| Durango Coffee Company  | Caul Rand                              |
| Durango Soda Company, Inc., Zuberfizz                             | Dan Aggeler                            |
| Eddylne Brewing LLC   | Email Contact                          |
| Eldorado Artesian Springs/Eldorado Natural Spring Water           | Email Contact                          |
| Elixinol LLC  | Gabriel Ettenson                       |
| Enstrom Candies Inc.  | Doug Simons                            |
| Epicurean Honey Co  | Blane Colton                           |
| Esoteric Food Company LLC., Ozuké Pickled Things                  | Mara King                              |
| Farming Technology, Inc., Mountain King Potatoes                  | Stephen Trujillo                       |
| Food Bank Of The Rockies  | Tony Alexis                            |
| Food Bank Of The Rockies  | Sheral Stroup                          |
| Food Bank Of The Rockies, Western Slope Food Bank Of The Rockies  | Starlene Collins                       |
| Food Maven Corporation, Food Maven                                | P.J. Higgins                           |
| Fresh Pack Produce  | Angela Vigil                           |
| Freshies Food Corporation   | Email Contact                          |
| Freshpoint Denver, Inc.   | Email Contact                          |
| Frito-Lay Inc.  | Greg Velisek                           |
| Frontier Trout Ranch LLC, Frontier Trout Ranch                    | Kermit Krantz                          |
| Gaucho De Argentina LLC   | Email Contact                          |
| Giambrocco Food Services, Inc                                     | Email Contact                          |
| Golden Global Goods, Inc., Rocky Mountain Soda Company            | Drew Drew                              |
| Golden Organics Inc.  | Email Contact                          |
| Golden Roots, LLC   | Glenn McElfresh                        |
| Grandma's Rockin' Rolls, LLC                                      | Laura Neilson                          |
| Gruma Corporation, Mission Foods                                  | Ben Martinez                           |
| Gruma Corporation, Mission Foods                                  | Mike Rosales                           |
| Hammond's Candies Since 1920 II, LLC                              | Ralph Nafziger                         |
| Honey Bunchie LLC,  | Jennifer Payne                         |
| Honey Smoked Fish Co.   | Kevin Mason                            |

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|---|-----------------------------------|
| Hungenberg Produce Inc.   | Email Contact                     |
| Isatori, Inc.   | John Willis                       |
| Italco Food Products, Inc.                                      | Email Contact                     |
| Izzio Artisan Bakery  | Email Contact                     |
| J Vierling & Associates, LLC., Tailwind Nutrition               | Ryan Ovendorff                    |
| Jerry's Nut House, Inc.   | Email Contact                     |
| Kennosh, Inc.   | Ken Kennard                       |
| Kitchen Network   | Mercedes Covarrubias              |
| Kitchen Network Bottling  | Email Contact                     |
| La Tolteca Foods, Inc.  | Tom Carpenter                     |
| Loco Food Distribution, LLC.,                                   | Email Contact                     |
| Luberski Inc., Nest Fresh Eggs                                  | Greg Silkwood                     |
| Madhava Honey, Ltd., Madhava Natural Sweeteners                 | Larry Lane                        |
| Midland Bean Company Inc.                                       | Email Contact                     |
| Milberger Farms LLC   | Email Contact                     |
| Mile Hi Express, Inc.   | Cindy Cindy                       |
| Mile Hi Express, Inc.   | Brit Schabacker                   |
| Mile Hi Foods Inc.  | Email Contact                     |
| Mile High Specialty Foods Inc.                                  | Jeff Stuller                      |
| MM Local Foods LLC  | James Mills                       |
| Mother Lode Brewery, LLC., Tommyknocker Brewery & Pub           | Steve Indrehus                    |
| Motherlode Provisions, LLC                                      | Carolyn                           |
| Motherlove  | Nicole Murphee                    |
| Mountain Man Nut & Fruit Co.                                    | Brad Boness                       |
| Musso Farms   | Mussochile Mussochile             |
| Natural Food Works, LLC., Natural Foodworks Group, LLC          | Email Contact                     |
| Natural Grocers   | Alan Lewis                        |
| Nestle Waters North America Inc.                                | Teresa Holen                      |
| New Belgium Brewery - Warehouse                                 | Kelly Stewart                     |
| Nexgen Pharma Inc.  | Patricia Masters                  |
| Niagara Bottling, LLC   | Andy Peykoff II                   |
| Northeast Seafood Products, Inc.                                | Scott Packer                      |
| Oskar Blues Brewery LLC   | Email Contact                     |
| Page One Holdings, LP, Mountain Beverage Supply                 | Email Contact                     |
| Par's Natural Foods Inc.  | Email Contact                     |
| Peach Street Distillers   | Email Contact                     |
| Performance Food Group, Inc.                                    | Email Contact                     |
| Peteybird LLC   | Email Contact                     |
| Petrocco Farms, Inc.  | Kathleen Petrocco                 |
| Pj Food Service Inc.  | Gerhard Claassen                  |
| Probi USA, Inc., Nutraceutix                                    | Email Contact                     |
| Quixotic Farming LLC  | Email Contact                     |
| Raska Company, Raska Sauce                                      | Hanna Mulu                        |
| Ready Foods, Inc. 7 facilities                                  | Brandon Hoffman, QA Supervisor    |
| Reddy Ice Corporation   | Email Contact                     |
| Redlaw Sauce Company  | Justin Chinchin, Founder          |
| Rocky Mountain Chocolate Factory Inc.                           | Cindy Kennemer                    |
| Rocky Mountain Food Industry Association                        | Mary Lou Chapman, President & CEO |
| Rocky Mountain Salsa Company, LLC                               | Email Contact                     |
| Rocky Mountain Soda Company,                                    | Gannan Merrell                    |
| Rocky Mountain Spice Company Inc., Rocky Mountain Spice Company | Email Contact                     |
| Rocky Mountain Sprouts  | Young Seo                         |
| Royal Cup, Inc.   | Email Contact                     |
| Sakata Farms, Inc.  | Robert Sakata                     |
| San Luis Valley Brewing Company, LLC                            | Email Contact                     |
| San Luis Valley Hemp Company                                    | Monte Robertson                   |
| Seattle Fish Company  | Delphine Jadot                    |
| Seattle Fish Company  | Ken Boyer, Food Safety QA Manager |
| Seedstock Brewing Co., Seedstock Brewery                        | Ron Abbott                        |
| Shamrock Foods Company  | Kelly Green                       |

|  |                                    |
|--|------------------------------------|
| Shamrock Foods Company   | Carlleta Harty, Operations Manager |
| Silver State Foods, Inc.   | Email Contact                      |
| Simply Dara, Inc.  | David Haid                         |
| Ska Brewing Co   | Email Contact                      |
| Skyline Potato Company   | Ivan Wright                        |
| Skyview Cooling Company  | Mike Jones                         |
| Solar Roast Coffee, LLC  | Michael Harkde                     |
| Soloman Baking Company, Inc.   | Sam Soloman                        |
| Soloman Baking Company, Inc.   | JR Soloman                         |
| Solvay Chemicals, Inc.   | Email Contact                      |
| Springside Cheese Corporation  | Keith Hintz                        |
| Steamboat Meat & Seafood Company   | Bill Hamil                         |
| Steven Roberts Originals LLC., Steven Roberts Original Desserts                      | Brad Yeager                        |
| Sunfield Natural Foods, Fiona's Natural Foods  | Jarrett Eggers                     |
| Swire Coca Cola USA, Inc.  | Paul Logsdon                       |
| Swire Coca Cola USA, Inc.  | Kelly Rowley                       |
| Swire Pacific Holdings   | Dan Fritz                          |
| Swire Pacific Holdings   | Danny Johnson                      |
| Swire Pacific Holdings Inc.  | Mike Achatz                        |
| Swire Pacific Holdings Inc.  | Chris Cisneros                     |
| Swire Pacific Holdings Inc., Swire Coca Cola USA, Inc.                               | Christy Bennett                    |
| Swire Pacific Holdings Inc., Swire Coca Cola USA, Inc.                               | Plogsdon Plogsdon                  |
| Sysco USA I, Inc.  | Chuck Meyers                       |
| Talbott's Mountain Gold, LLP., Talbott Farms Inc.                                    | Email Contact                      |
| Target Distribution Center - T0554   | Rick Scholtes                      |
| Teakoe & Company, LLC., Teakoe & Company   | Email Contact                      |
| Teasdale Foods, Inc.   | Chad Woodrum                       |
| Teg Restaurant Group, Inc., East By Southwest  | Email Contact                      |
| The Amalgamated Sugar Company LLC  | Jeremy Nail                        |
| The Amalgamated Sugar Company LLC  | Joe Toste                          |
| The Boulder Hot Sauce Co LLC   | Email Contact                      |
| The Hain Celestial Group, Inc., Rudi's Organic Bakery                                | Suzie Murphy                       |
| The Hain Celestial Group, Inc., Westsoy Tofu   | David Vazquez                      |
| The Real Dill, LLC   | Email Contact                      |
| The Western Sugar Cooperative  | Mary Johnson                       |
| Thorin & Company, Ltd., Kaladi Coffee Roasters                                       | Andrew Melnik                      |
| Three Barrel Brewing Co  | John Bricker                       |
| Three Barrel Brewing Company, LLC  | William Krelitzer                  |
| Three Guys Farms, Inc.   | Email Contact                      |
| Tom Kinney Enterprises Inc., Magill's Ice Cream                                      | Tom Kinney                         |
| Tr Toppers, Inc.   | Tim Rode                           |
| Trinidad Benham Holding Company, Trinidad Bean & Elevator Co.                        | RJ Seader                          |
| Trinidad Benham Holding Company, Trinidad Benham Corp                                | Steve Schwartz                     |
| True World Foods Denver, LLC   | Mariko Cioffi                      |
| Vail Mountain Coffee & Tea Company, The Daily Grind Coffee Company, Inc.             | Craig Arsenean                     |
| Vern's Toffee House Inc.   | Stefanie O'Neill                   |
| Vitamin Cottage Natural Food Markets Inc., Natural Foodworks Group, LLC              | Sharon Wilson                      |
| VKGG, Inc.   | Email Contact                      |
| Wal Mart Stores Inc.   | Dan Speed                          |
| Watterson Foods, Inc., Roberto's Salsas And Sauces                                   | Doug Watterson                     |
| Whole Foods Market Inc.  | Ray Francisco                      |
| Whole Foods Market Rocky Mountain/SW LP, Whole Foods Market Rocky Mountain Bakehouse | Catherine Shiffrin                 |
| Wild Alaska Salmon LLC   | Matt Aboussie                      |
| Xylitol USA Inc.   | H Simmons                          |



On March 23, 2018 the division initiated stakeholder outreach communications and solicited contributions to proposed revisions. On April 6, 2018, the division held a stakeholder meeting to evaluate the proposed changes to the existing rule and receive additional feedback from stakeholders. Consensus on the proposed regulation, including the incorporation by reference of the applicable portion of 21 CFR 100-190 and the NSSP Shellfish Ordinance, was achieved. 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 and 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 10<sup>th</sup> 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 wholesale food regulations, the division began preparations for this rulemaking in 2015. On April 6, 2018, the division held a stakeholder meeting to evaluate the proposed changes to the existing rule. Stakeholders included representatives from wholesale food facilities, various food industry associations, wholesale food lobbyists, Colorado Department of Agriculture, and CDPHE. Since the current *Colorado Wholesale Food 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 the applicable portion of 21 CFR 100-190 and the NSSP Shellfish Ordinance, was achieved.

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

The incorporation by reference of the applicable portion of 21 CFR 100-190 and the NSSP Shellfish Ordinance will continue to safeguard public health and ensure that all locations in Colorado where foods are manufactured, packed, processed, prepared, treated, packaged, transported, or held for distribution are in accordance with the "Pure Food and Drug Law", Section 25-5-401 et seq., C.R.S. and the "Shellfish Dealer Certification Act," Section 25-4-1801 et seq., C.R.S., regardless of race, color, national origin, or income. The revised and proposed regulation will continue to assure uniformity and effectiveness in the implementation of wholesale food standards and promote the full health potential of all Coloradans.

Overall, after considering the benefits, risks and costs, the proposed rule:

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.   |
|   | Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.   |   | Ensures a competent public and environmental health workforce or health care workforce.   |
|   | Other: _____<br>_____   |   | Other: _____<br>_____   |

1 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2  
3 Division of Environmental Health and Sustainability

4  
5 COLORADO WHOLESALE FOOD AND SHELLFISH REGULATIONS

6  
7 6 CCR 1010-21

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

10  
11 21.1 Authority

12  
13 This regulation is adopted pursuant to Sections 25-4-1805, 25-5-420(1), and 25-5-426(1),  
14 Colorado Revised Statute (C.R.S.) and is consistent with the requirements of the State  
15 Administrative Procedure Act, Section 24-4-101, *et seq.*, C.R.S.

16  
17 21.2 Scope and Purpose

18  
19 A. This regulation shall be applied for the protection of public health by ensuring that the  
20 premises or places wherein manufactured foods are produced, manufactured, packed,  
21 processed, prepared, treated, packaged, transported, or held for distribution are in  
22 accordance with the "Pure Food and Drug Law", Section 25-5-401 *et seq.*, C.R.S. and  
23 the "Shellfish Dealer Certification Act," Section 25-4-1801 *et seq.*, C.R.S.

24  
25 B. This regulation shall govern the registration of wholesale food manufacturers. Along  
26 with the powers and duties delineated in Section 25-4-420 *et seq.*, C.R.S., Section 25-  
27 5-426(3), C.R.S., provides the department the power and duty:

- 28  
29 1. To grant or refuse to grant registration pursuant to section 25-5-426(4), C.R.S.  
30 and to grant or refuse to grant the annual renewal of a registration;  
31  
32 2. To deny, suspend, or revoke a registration;  
33  
34 3. To issue a certificate of free sale; and  
35  
36 4. To review any records of a wholesale food manufacturer or storage facility  
37 necessary to verify compliance with the provisions of section 25-5-426, C.R.S.  
38

39 C. This regulation does not apply to:

- 40  
41 1. Retail food establishments governed by the *Colorado Retail Food Establishment*  
42 *Regulations*, 6 CCR 1010-2, and  
43  
44 2. Facilities or conditions governed by the *Colorado Milk and Dairy Products*  
45 *Regulations*, 6 CCR 1010-4.  
46

47 D. Nothing in this rule shall be construed to limit the Department's statutory authority  
48 under the "Pure Food and Drug Law", Section 25-5-401 *et seq.*, C.R.S., the "Shellfish  
49 Dealer Certification Act," Section 25-4-1801 *et seq.*, C.R.S., or Section 25-1.5-102,  
50 C.R.S.  
51

52 **21.3 Applicability**

- 53
- 54 A. This rule establishes registration requirements for wholesale food manufacturers,  
55 Section 25-5-426, C.R.S., and certification requirements for wholesale food  
56 manufacturers who are also shellfish dealers, Section 25-4-1801 *et seq.*, C.R.S.  
57
- 58 B. This rule incorporates by reference the Code of Federal Regulations addressing Food  
59 for Human Consumption and the national shellfish sanitation standards.  
60
- 61 C. This rule establishes enforcement standards for wholesale food manufacturers  
62 pursuant to Sections 25-1.5-102(1)(c), 25-5-406 and 25-5-420, C.R.S., and enforcement  
63 standards for wholesale food manufacturers who are also shellfish dealers pursuant to  
64 Section 25-4-1810, C.R.S.  
65

66 **21.4 Definitions**

- 67
- 68 A. For the purpose of these rules and regulations, unless otherwise specified herein:  
69
- 70 1. Department means the Colorado Department of Public Health and Environment.  
71
  - 72 2. Dealer or Shellfish Dealer means a person to whom certification is issued for  
73 the activities of shell stock shipper, shucker-packer, repacker, reshipper,  
74 depuration processor, or wet storage.  
75
  - 76 3. Wholesale food manufacturer or Wholesale food manufacturing facilities means  
77 a facility that manufactures, produces, packs, processes, treats, packages,  
78 transports, or holds human food, including dietary supplements. These terms  
79 include storage facilities. These terms include shellfish dealers when the  
80 wholesale food manufacturer is also a shellfish dealer.  
81

82 **21.5 Wholesale Food Manufacturer and Shellfish Dealer Requirements**

- 83
- 84 A. Wholesale food manufacturing facilities in Colorado must be registered in accordance  
85 with Section 25-5-426(4), C.R.S.  
86
- 87 1. The owner of any wholesale food manufacturer must submit to the department  
88 an application each year for registration, along with applicable application and  
89 registration fees, using forms provided by the department.  
90
  - 91 2. The owner of any wholesale food manufacturer must also submit to the  
92 department complete and accurate information about the facility's operation  
93 and business size, using forms provided by the department.  
94
- 95 B. Wholesale food manufacturers who are also shellfish dealers in Colorado must also be  
96 certified in accordance with Section 25-4-1805, C.R.S.  
97
- 98 1. Any person desiring to do business as a shellfish dealer must apply for and  
99 obtain a valid certification issued by the department.  
100
  - 101 2. Shellfish dealers must report to the department, in the form and manner  
102 required by the department, any change in the information provided in the

dealer's application or in such reports previously submitted, within thirty days of such change.

## 21.6 Incorporation by Reference

- A. The department shall utilize material incorporated by reference as appropriate to assure that wholesale food manufacturers comply with the "Pure Food and Drug Law", and wholesale food manufacturers who are also shellfish dealers comply with the "Shellfish Dealer Certification Act."
1. 21 CFR 100-190 (April 1, 2017) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the reference material.
  2. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance (2015 Revision)* is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the reference material.

- B. Any provision included or incorporated herein by reference which conflicts with the Colorado Revised Statutes, including but not limited to Section 25-5-401 et seq., C.R.S., Section 25-4-1801 et seq., C.R.S., and Section 25-1.5-102, C.R.S., shall be null and void. These regulations do not incorporate by reference:

1. 21 CFR 112, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*.
2. 21 CFR 171, *Food Additive Petitions*.

- C. The incorporated material is available for public inspection during regular business hours at:

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

Pursuant to C.R.S. 24-4-103(12.5)(V)(b), the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

- D. The incorporated materials are available at:

<https://www.colorado.gov/pacific/cdphe/wholesale-food-stakeholder-meetings>

154 **21.7 Enforcement**  
155

- 156 A. 1. Wholesale food manufacturers that fail to submit a complete and accurate  
157 annual application for registration, or fail to remit fees in accordance with  
158 Section 25-5-426(4), C.R.S., are not considered an approved source for  
159 introduction of manufactured food into retail commerce.  
160
- 161 2. Wholesale food manufacturers who are also shellfish dealers that fail to submit  
162 a complete and accurate annual application for certification are not considered  
163 an approved source for introduction of shellfish into retail commerce.  
164
- 165 B. Adulterated or misbranded food, including food from unapproved sources, may be  
166 embargoed in accordance with Section 25-5-406, C.R.S.  
167
- 168 C. In accordance with Section 25-1.5-102(1)(c), C.R.S., the department may require  
169 wholesale food manufacturers, including wholesale food manufacturers who are also  
170 shellfish dealers, to recall adulterated or misbranded food in order to investigate and  
171 control the causes of epidemic and communicable diseases affecting public health.  
172
- 173 D. Pursuant to Sections 25-4-1810 and 25-5-420, C.R.S., if the department has reasonable  
174 cause to believe a violation of this regulation has occurred and immediate  
175 enforcement is necessary, it may issue a cease-and-desist order, which shall set forth  
176 the provisions alleged to have been violated, the facts constituting the violation, and  
177 the requirement that all violating actions immediately cease.  
178
- 179 1. At any time after service of the order to cease and desist by certified mail, the  
180 person for whom such order was served may request a hearing to determine  
181 whether such violation has occurred. Such hearing will be conducted in  
182 conformance with the provisions of article 4 of title 24, C.R.S. and shall be  
183 determined promptly.  
184
- 185 E. To the extent and manner authorized by law, the department may issue letters of  
186 admonition or may deny, suspend, refuse to renew, restrict, or revoke any wholesale  
187 food manufacturer registration or any shellfish dealer certification if the wholesale  
188 food manufacturer or wholesale food manufacturer who is also a shellfish dealer has:  
189
- 190 1. Refused or failed to comply with any provision of this regulation or any lawful  
191 order of the department;  
192
- 193 2. Had an equivalent certification or registration denied, revoked, or suspended  
194 by another authority, including but not limited to another state, or the U.S.  
195 Food and Drug Administration;  
196
- 197 3. Refused to provide the department with reasonable, complete, and accurate  
198 information when requested by the department; or  
199
- 200 4. Falsified any information submitted to the department.  
201
- 202 F. In addition to the requirements herein, when the department determines that a  
203 wholesale food manufacturer who is also a shellfish dealer's activity constitutes a  
204 major public health threat, the department shall cooperate with other authorities  
205 pursuant to Section 25-4-1805(5), C.R.S.

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Division of Environmental Health and Sustainability**

**COLORADO WHOLESALE FOOD REGULATIONS**

**6 CCR 1010-21**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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**CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING OR HOLDING HUMAN FOOD**

1. ~~Statutory Authority.~~ Authority to promulgate these regulations is found at §25-5-420(1), C.R.S.
2. ~~Applicability.~~ These regulations shall apply to all wholesale manufacturers, packers or holders of human food in Colorado.
3. ~~Incorporation of Federal Regulations by Reference.~~
  - a. These regulations incorporate by reference the requirements of 21 C.F.R. §§110.3-110.93 *Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food* (1998) and do not include later amendments or editions.
  - b. The material incorporated by reference is available for public inspection and copying during regular business hours by contacting:  
  
Division Director Consumer Protection Division Colorado Department of Public Health & Environment 4300 Cherry Creek Drive South Denver, CO 80246-1530
  - c. ~~Materials or regulations incorporated by reference are also available for examination at the State Publications Depository and Distribution Center and are available for interlibrary loans.~~

**STATEMENT OF BASIS AND PURPOSE FOR THE ADOPTION BY REFERENCE OF 21 CFR 110-CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING OR HOLDING HUMAN FOOD**

**ADOPTED BY STATE BOARD OF HEALTH AUGUST 18, 1999**

The criteria in this federal regulation has been used for a number of years as an official policy guideline to determine whether a food is adulterated within the meaning of §25-5-410, C.R.S. of the Colorado Pure Food and Drug Act (Act) in that the food has been manufactured under such conditions that it is unfit for food; or within the meaning of §25-5-410(d), C.R.S. in that the food has been prepared, packed or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. The regulation pertains to food manufacturing and storage facilities for which there are not more specific federal regulations and for facilities which are operating as wholesalers not subject to the Colorado Sanitation of Food Service Establishments Rules and Regulations, 6 CCR 1010-2. We are seeing the continuing evolution of new food products and food processing techniques that in some cases may be found in both wholesale and retail establishments. There is also an increasing number of wholesale facilities that are being inspected by local government health agencies. Ensuring that these establishments are being inspected and regulated in a statewide uniform manner using the most appropriate statutes and regulations has become more difficult. The use of 21 CFR 110 as a policy guideline no longer achieves the purpose for which it was being used and all state health agencies need the ability to utilize it as an official state regulation. Therefore, under the authority of § 25-5-420(1), C.R.S.

~~the Colorado Board of Health hereby adopts by reference 21 CFR 110.~~

~~The purpose of the adoption of 21 CFR 110 is to ensure a statewide uniform inspection program for wholesale operations involved in the manufacture and storage of human food.~~

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**Editor's Notes**

**History**

DRAFT