



To: Members of the State Board of Health

From: Justin Trubee, Manufactured Food Safety Program Manager,  
Division of Environmental Health and Sustainability  
Cary E. Ruble, Regulation Development Coordinator,  
Division of Environmental Health and Sustainability

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

Date: December 16, 2020

Subject: **Request for Rulemaking Hearing**  
Proposed Amendments to 6 CCR 1010-21, *Colorado Wholesale Food and Shellfish Regulations* with a request for a rulemaking hearing to be set for February 17, 2021

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The Division of Environmental Health and Sustainability ("division") is proposing revisions to 6 CCR 1010-21, *Colorado Wholesale Food and Shellfish Regulations* and is requesting that the Board of Health schedule a rulemaking hearing to consider adoption of the proposed amendments at the February 17, 2021, Board of Health meeting.

In compliance with the State Administrative Procedure Act, §24-4-103.3, C.R.S., the department is proposing amendments to 6 CCR 1010-21, *Colorado Wholesale Food and Shellfish Regulations*. These revisions are based on stakeholder input received during the Department of Agriculture's 2019 Colorado Hemp Advancement & Management Plan (CHAMP) initiative, and the division's stakeholder engagement process. The proposed revisions refine and clarify manufacturing and testing requirements for the production of industrial hemp products and unfinished industrial hemp products in the state of Colorado. 6 CCR 1010-21 was last amended by the Board of Health in August 2018.

This request for rulemaking proposes to maintain the requirements of 21 Code of Federal Regulations (C.F.R.) 100-111, 113-170, and 172-190 (April 1, 2017), as applicable to industrial hemp manufacturers and processors, and incorporate new requirements to define and clarify manufacturing and testing requirements for the production of industrial hemp products in Colorado.

Electronic copies of 21 C.F.R. 100-190 and Colorado's "*Pure Food and Drug Law*" are available for review on the division website and at the Colorado Legal Resources provided by LexisNexis:

- <https://cdphe.colorado.gov/industrial-hemp-in-food/industrial-hemp-news-and-announcements>
- <https://advance.lexis.com/container?config=0345494EJAA5ZjE0MDIyYy1kNzZkLTRkNzkTYTkxMS04YmJhNjBINWUwYzYKAFBvZENhdGFsb2e4CaPI4cak6laXLCWylBO9&crId=28abb-ed8-56f4-44da-9671-a4ad25ba0ba4&prId=d441faf3-c6aa-4ddf-ab54-167f1bfc5e2f>

Also, federal regulation currently incorporated by reference and applicable law is posted and available for review using the following website:

- 21 C.F.R. 100-190 - [https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab\\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)

The proposed amendments to 6 CCR 1010-21 do not apply to:

- Retail food establishments governed by the *Colorado Retail Food Establishment Regulations*, 6 CCR 1010-2;
- Facilities or conditions governed by the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4;
- Medical or retail marijuana regulated by the *Colorado Marijuana Rules* 1 CCR 212-3;
- Cultivation of industrial hemp governed by the *Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act*, 8 CCR 1203-23;
- Entities that are manufacturing intermediate or finished hemp products from the fibrous material of the plant that are not intended for human consumption;
- Entities that are manufacturing industrial hemp-derived smokable products, inhalable products, over-the-counter drugs or medical devices; and
- Testing performed in accordance with the *Hemp Testing Laboratory Certification*, 5 CCR 1005-5.

The proposed rule applies the definition of relevant terms, ingredient and approved-source standards, potency and purity testing standards and permissible levels of contaminants, and packaging and labeling, record-keeping, transportation, and waste management requirements, which provide clarity and ease of use and reflect current statutory requirements contained in Sections 25-1.5-102(1)(c), 25-5-406, 25-5-420, and 25-5-426, C.R.S.

The continued incorporation by reference of 21 C.F.R., 100-111, 113-170, and 172-190, in state regulation and application and enforcement of new industrial hemp requirements identified through the CHAMP initiative and the division's robust stakeholder engagement process will retain current public health protections while maintaining the efficiency and effectiveness of the rulemaking process. The division has engaged stakeholders and has achieved consensus with respect to the proposed amendments to the *Colorado Wholesale Food and Shellfish 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 and Shellfish Regulations*

Basis and Purpose.

Revisions to *Colorado Wholesale Food and Shellfish Regulations*, 6 CCR 1010-21 would include amendments to the existing wholesale food regulation based on broad stakeholder input received during the 2019 Colorado Hemp Advancement and Management Plan (CHAMP) initiative and the division's robust early stakeholder engagement process. The proposed revisions are necessary to refine and clarify manufacturing and testing requirements for the production of industrial hemp products and unfinished industrial hemp products in the State of Colorado. 6 CCR 1010-21 was last amended by the Board of Health in 2018.

The passage of the 2018 Agriculture Improvement Act, commonly called the Farm Bill, requires each state department of agriculture to submit a state management plan to the U.S. Department of Agriculture (USDA), outlining how various aspects of hemp cultivation and processing will be managed within their jurisdiction. In response, the Colorado Department of Agriculture (CDA) partnered with leading state, local, and tribal agencies, as well as industry stakeholders possessing expertise in the cultivation, testing, research, processing, finance, and economics to establish a statewide initiative known as the Colorado Hemp Advancement and Management Plan (CHAMP).

The proposed regulatory requirements do not infer conformance with federal laws and the allowance for manufacturing, sale, and distribution of industrial hemp products and unfinished industrial hemp product to other states or countries. U.S. Food and Drug Administration (FDA) does not recognize industrial hemp as an allowable food ingredient; therefore, the proposed regulation does not govern the allowance of interstate commerce. However, Colorado's industrial hemp manufacturers and processors are currently subject to the federal wholesale food requirements incorporated by reference. The incorporation by reference and application of 21 C.F.R. 100-190 (2017), except for 112 and 171, continues public health protections while:

- providing alignment with current and nationally accepted federal standards for wholesale food manufacturers who are also industrial hemp manufacturers and processors; and
- maintaining the efficiency and effectiveness of the rulemaking process and Department services.

Based on the outcomes from the CHAMP initiative and the division's early stakeholder engagement process, proposed revisions to 6 CCR 1010-21 include and clarify:

➤ ***Definition of relevant terms***

The majority of the proposed definitions were based on federal or state statute or existing regulation, revised during the division's early stakeholder engagement process, and represent stakeholder consensus. However, based on discussions during the stakeholder meeting held on July 28, 2020, two independent workgroups were formed to discuss additional revisions to the proposed definitions and testing requirements.

The definitions workgroup met on August 12, 2020, to focus on further refining the definitions of "*Broad spectrum*", "*Full spectrum*", "*Cannabinoid*", and "*Unfinished industrial hemp product*". Following evaluation and input, workgroup-proposed revisions to the definition of these relevant terms were incorporated into the proposed redline and presented for review to all stakeholders at the October 20, 2020 stakeholder meeting. Stakeholder consensus was achieved on the proposed definitions.

Subsequently, stakeholders requested further discussion and clarity regarding the definition of "*Industrial hemp*". Specifically, does the department have the authority to regulate specific cannabinoids in the same manner as delta-9 tetrahydrocannabinols (THC)? The definition of industrial hemp includes "*cannabinoids*" and is referenced in Section 25-5-426(2)(g.3), C.R.S., as having the same meaning as presented in 35-61-101(7), C.R.S., that states:

*"Industrial hemp" or "hemp" means the plant Cannabis sativa L. and any part of the plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of no more than three-tenths of one percent on a dry-weight basis."*

Furthermore, Section 25-5-426(2)(g.5)(III), C.R.S., provides a definition of "*Industrial hemp product*" that states, in part:

*"Contains any part of the industrial hemp plant, including naturally occurring cannabinoids..."*

Therefore, state statute and department authority currently only allows for the regulation and limitation of the concentration of THC, the primary psychoactive component of the cannabis and industrial hemp plants. As the science of industrial hemp continues to evolve, additional "*naturally occurring cannabinoids*" have been identified that can create or have a psychoactive component similar to that of THC. It is anticipated more psychoactive cannabinoids will be identified.

While debate continues nationally and at the state level on what the allowable limit should be for THC in an industrial hemp plant, it was clear in both the *Federal Farm Bill* and the *Colorado Industrial Hemp Act* that the allowance of industrial hemp as a crop was because of the utility of the crop and its naturally low non-psychoactive concentration of THC. Neither of these two laws considered the inclusion of hemp and hemp derivatives being allowed in food, supplements, or other products. Consequently, with Colorado allowing for the use of hemp and its derivatives in cosmetics, dietary supplements and foods, the allowable levels of these other "*naturally occurring cannabinoids*" that have psychoactive properties should be established. However, as the statutory requirements are currently constructed, the department does not have the authority to establish limits on these other naturally occurring psychoactive cannabinoids [e.g., delta-8 THC, Cannabinol (CBN), and Cannabigerol (CBG)].

➤ ***Processing and manufacturing requirements***

Title 21 of the Code of Federal Regulations (C.F.R.) 100-111, 113-170, and 172-190 (2017) provides the basis for the regulation of wholesale foods in the state of

Colorado. The proposed regulation would require all industrial hemp processors and manufacturers to comply with these federal regulations and the additional requirements included in the proposed regulation. The following additional industrial hemp manufacturing requirements were identified as more substantive, vetted through the stakeholder process, and included in the proposed regulation by consensus.

- Section 21.7(A) - "*Oils, concentrates or other substances that are above 5.0% total THC must undergo further refinement or processing by the original registered industrial hemp manufacturer.*"
- Section 21.7(E)(2) - "*All industrial hemp products or unfinished industrial hemp products shall be clearly identified to allow for appropriate traceability...*"

➤ **Testing requirements and effective date**

In order for a food, food additive, dietary supplement, or cosmetic to contain industrial hemp, the manufacturer shall demonstrate through analytical testing at a department certified laboratory that the product does not contain contaminant levels that exceed the action limits defined in the testing tables proposed in sections 21.7(F)(5)(a)(b)(c)(d) and (e) of the proposed regulation. The proposed analytical testing requirements will be implemented on the effective date of the regulation. The certified laboratory requirement will be delayed until July 1, 2021, to provide the necessary time for CDPHE to certify industrial hemp laboratories. Action limits for the identified and proposed contaminants were based on the following sources and vetted through the stakeholder process:

- Microbials - The American Herbal Product Association (AHPA), *Recommended Microbial Limits for "Finished" Botanical Products* and United States Pharmacopeia (USP), Chapter <2023>, *Microbiological Attributes of Nonsterile Nutritional and Dietary Supplements*, were the basis for the action limits proposed in table 21.7(F)(5)(a), *Microbials*;
- Mycotoxins - The Food and Drug Administration (FDA), *Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed*, and European Union (EU) regulation, Commission Regulation (EC) No 1881/2006, *Setting Maximum Levels for Certain Contaminants in Foodstuffs* were the basis for the action limits for Total Aflatoxins (FDA), Aflatoxin B1 (EU), and Ochratoxin A (EU), as defined in proposed table 21.7(F)(5)(b), *Mycotoxins*;
- Pesticides - The Government of Canada, Health Canada, *Mandatory Cannabis Testing for Pesticide Active Ingredients*, was the basis for the action limits defined in proposed table 21.7(F)(5)(c), *Pesticides*;
- Heavy Metals - USP, Chapter <2232>, *Elemental Contaminants in Dietary Supplements*, was the basis for the action limits defined in proposed table 21.7(F)(5)(d), *Heavy metals*; and
- Residual Solvents - USP, Chapter <467>, *Residual Solvents*, and the *Colorado Marijuana Rules*, 1 CCR 212-3, were the basis for the action limits defined in proposed table 21.7(F)(5)(e), *Residual solvents*.

Based on discussions during the stakeholder meeting held on July 28, 2020, the testing workgroup was formed and met on August 4, 2020, to further evaluate appropriate action limits for the identified microbials, mycotoxins, pesticides, heavy metals, and residual solvents. Following evaluation and input, workgroup-proposed revisions to the testing requirements were incorporated into the proposed redline and presented for review to all stakeholders at the October 20, 2020, stakeholder meeting.

Stakeholder consensus was achieved on the proposed testing requirements with noted objections. Some stakeholders were less supportive of the proposed residual solvent action limits. However, a more appropriate resource or proxy rather than the USP that would assist in establishing more defensible and protective action limits was not identified. Those stakeholders in opposition of utilizing the USP desired to establish limits based on the solvents being characterized as direct or indirect food ingredients. However, these limits would vary greatly depending on what food product was chosen as a reasonable proxy. Additionally, several other states have established residual solvent limits based on the USP and while Canada's limits are not based on the USP, their established limits are closely aligned to those established in the USP and within these regulations.

➤ ***Packaging and labeling, record keeping, recalls, transportation, and waste management requirements***

The basis of the regulation of wholesale foods in Colorado can be found at 21 C.F.R. 100-111, 113-170, and 172-190 (2017). The proposed packaging and labeling requirements in section 21.7(G)(1) of the proposed changes will be delayed until July 1, 2021, to allow industry to transition into compliance. The following additional industrial hemp requirements were identified as the more substantive additions, were vetted through the stakeholder process, and included in the proposed regulation by consensus:

- Section 21.7(G)(2)(d) requires all industrial hemp finished product labels to; *“(1) identify industrial hemp as an ingredient, (2) identify each isolated cannabinoid as an ingredient and the amount labeled in milligrams or when using a broad or full spectrum product, label the total amount in milligrams, and (3) identify in milligrams the total THC content per serving and total THC content per finished individual product packaging.”*;
- Section 21.7(H)(1) requires that the following records be maintained; *“(a) Certificates of analysis, (b) Batch production records; (c) Recalled product information, (d) Source of ingredients, and (e) Other records as required by the department (e.g., ingredient records, corrective action logs, mock recall documents, calibration records, as applicable).”*;
- Section 21.7(J)(1) requires that the *“Transfer of industrial hemp or unfinished industrial hemp product shall be conducted in accordance with the law.”*, and
- Section 21.7(K) requires that, *“1. Industrial hemp-derived THC shall be diluted to a concentration less than 0.3%, converted, or disposed of in accordance with the department’s Hazardous and Waste Management Division’s Marijuana and Marijuana-Related Waste Disposal Compliance Bulletin.”* and *“2. Facility*

*owner/operator is responsible to secure and limit access to industrial hemp-derived THC with a concentration greater than 0.3%."*

➤ ***Formatting and technical edits to improve readability***

These proposed amendments align non-substantive and formatting revisions with other division regulations and Secretary of State's requirements.

These proposed requirements were identified as areas where elaborating upon the statutory framework added needed clarity and improved ease of use and application. 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.

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Is this rulemaking due to a change in state statute?

Yes, the bill number is \_\_\_\_\_. Rules are \_\_\_ authorized \_\_\_ required.  
 No

Does this rulemaking include proposed rule language that incorporates materials by reference?

Yes      \_\_\_ URL <https://ecfr.io/Title-21/>  
 No

Does this rulemaking include proposed rule language to create or modify fines or fees?

Yes  
 No

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

No.

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

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: \_\_\_\_\_  
(i.e. requested by local governments and consensus was achieved)

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.

REGULATORY ANALYSIS  
for Amendments to  
6 CCR 1010-21, *Colorado Wholesale Food and Shellfish Regulations*

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

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/CLG/S/B
Industrial hemp and unfinished industrial hemp product manufacturers, processors, or storage facilities registered with the department.	~486	C
Industrial hemp transporters	~17	C
Medical and retail marijuana dispensaries	~700	S
Colorado Dept. of Public Health & Environment	~1,600	S
Marijuana Enforcement Division	~120	S
Colorado Department of Agriculture	~300	S
Colorado Bureau of Investigation	~300	S
Colorado State University	~1,900	S
Analytical Laboratories / LSD	~21	S
Retail food establishments	~23,000	S
Consulting/engineering firms	Unknown	S
Pharmaceutical companies	Unknown	S
Institutes, unions, associations, advocacy groups	Unknown	S
Legal firms	Unknown	S
Local county government	64	S
Financial institutions	Unknown	S
Tribal agencies	2	C/S
Industrial hemp consumers in Colorado	~1.5M	S/B
Industrial hemp consumers in US	~70M	S/B

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

- C = individuals/entities that implement or apply the rule.
- S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
- B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

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.

Registered industrial hemp manufacturers and storage facilities represent approximately 486 of the 2,529 department-regulated wholesale food manufacturing and storage facilities throughout the state of Colorado. The department and the regulated community are all affected and will benefit from the proposed amendments. Maintaining the requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017), as applicable to industrial hemp manufacturers and processors, and adoption of the proposed amendments ensures that industrial hemp products in the State of Colorado come from an approved sources, are tested for potency and purity, are packaged and labeled in accordance with 21 C.F.R. 101(A-G) (2017) and the department's labeling requirements, are subject to an established recall plan (if necessary), are transported and disposed properly, and that appropriate records are retained. Costs borne by the department are minimal and administrative in nature.

Industrial hemp manufacturers and processors will bear the costs associated with the proposed industrial hemp testing and labeling requirements. Although the proposed laboratory testing of industrial hemp products may represent an economic impact to our industry partners, these anticipated costs were discussed and vetted during the CHAMP initiative and the division's stakeholder processes. Industrial hemp manufacturers recognize that Colorado is one of the first states to apply the requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017), as applicable to industrial hemp manufacturers and processors. The surety of the proposed regulation, including the testing standards, provides stability and validity to this novel industry. Manufacturers of industrial hemp products and unfinished industrial hemp products understand that continued alignment with current industry standards and adoption of the proposed amendments are necessary to refine and clarify manufacturing, testing, and labeling requirements for the production of industrial hemp products in the State of Colorado. The department is proposing July 1, 2021, for compliance with laboratory certification requirements proposed in section 21.7(F)(1) and the labeling requirements proposed in section 21.7(G)(1) of the amended regulation.

The ultimate customer of industrial hemp manufacturing, the consumers inside Colorado and worldwide, will benefit from the proposed revisions by ensuring that the sale and distribution of Colorado's industrial hemp product remains consistent with established requirements and that food containing industrial hemp is honestly represented and safe.

Maintaining the requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017), as applicable to industrial hemp manufacturers and processors, and inclusion of the proposed manufacturing and testing requirements will continue to safeguard public health and ensure that food and supplements containing industrial hemp that is served in Colorado is unadulterated and honestly presented to all consumers. The proposed regulation revisions will continue to assure uniformity and effectiveness in the implementation of food safety standards and promote the full health potential of all Coloradans.

#### Economic outcomes

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

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

- C: Industrial hemp manufacturers will bear the costs associated with the proposed industrial hemp analytical testing requirements. Although the required laboratory testing may represent an economic impact to our industry partners, these anticipated costs were discussed and vetted during the CHAMP initiative and division's early stakeholder engagement process.

Also, industrial hemp manufacturers will bear some costs associated with the proposed industrial hemp labeling requirements. The department is proposing July 1, 2021, for compliance with the labeling requirements in section 21.7(G)(1). The delayed implementation of the labeling requirements allows manufacturers to exhaust current labeling inventory and complete the reprinting of labels.

- S: No anticipated financial costs or benefits to the department or any state regulatory agency were identified.
- B: No anticipated financial costs were identified, but the consumer will benefit from proposed amendments by ensuring that food or dietary supplements containing industrial hemp that is manufactured or processed in Colorado is unadulterated, safe, and honestly presented.

#### Non-economic outcomes

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

- C: Industrial hemp manufacturers recognize that Colorado is one of the first states to apply the requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017) to industrial hemp manufacturers and processors and that the surety of the proposed regulation provides stability and validity to this novel industry. Manufacturers of industrial hemp products and unfinished industrial hemp products in Colorado understand that maintaining alignment with current federal food safety standards and adoption of the proposed state-specific amendments provides the necessary clarity regarding the manufacturing and testing requirements for the production of industrial hemp products in the State of Colorado.
- S: The department will benefit from the proposed revisions by ensuring that the sale and distribution of Colorado's industrial hemp product is consistent with established federal food safety requirements, from approved sources, tested for potency and purity at a CDPHE certified laboratory, packaged and labeled in accordance with 21 C.F.R. 101(A-G) (2017) and the departments labeling requirements, subject to an established written recall plan (if necessary), transported and disposed in accordance with the law, and that appropriate records are retained.
- B: The ultimate customer of industrial hemp manufacturing and processing, the consumers inside Colorado and worldwide, will benefit from the proposed revisions by ensuring that the sale and distribution of Colorado's industrial hemp products is consistent with established federal food safety requirements, from approved sources, and are honestly represented and safe.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures: None

Anticipated CDPHE Revenues: None. Registration fees for industrial hemp manufacturers were established in statute in 2018 and revised in 2019 (25-5-426, C.R.S).

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

Anticipated Revenues for another state agency: None

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

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

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

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

1.	Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO <sub>2</sub> e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO <sub>2</sub> e per year by June 30, 2020 and to 113.144 million metric tons of CO <sub>2</sub> e by June 30, 2023.
	<input type="checkbox"/> Contributes to the blueprint for pollution reduction <input type="checkbox"/> Reduces carbon dioxide from transportation <input type="checkbox"/> Reduces methane emissions from oil and gas industry <input type="checkbox"/> Reduces carbon dioxide emissions from electricity sector
2.	Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.
	<input type="checkbox"/> Reduces volatile organic compounds (VOC) and oxides of nitrogen (NO <sub>x</sub> ) from the oil and gas industry. <input type="checkbox"/> Supports local agencies and COGCC in oil and gas regulations. <input type="checkbox"/> Reduces VOC and NO <sub>x</sub> emissions from non-oil and gas contributors
3.	Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.
	<input type="checkbox"/> Increases the consumption of healthy food and beverages through education,

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

<p>noted in the assessment.</p> <p>___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.</p>
<p>9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 30, 2020 and 90 of the existing applications by June 30, 2023.</p> <p>___ Implements the CDPHE Digital Transformation Plan.</p> <p>___ Optimizes processes prior to digitizing them.</p> <p>___ Improves data dissemination and interoperability methods and timeliness.</p>
<p>10. Reduce CDPHE's Scope 1 &amp; 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.</p> <p>___ Reduces emissions from employee commuting</p> <p>___ Reduces emissions from CDPHE operations</p>
<p>11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.</p> <p>___ Used a budget equity assessment</p>

X Advances CDPHE Division-level strategic priorities.

The DEHS *Strategic Plan Update*, dated February 15, 2019, identified the creation of a program and regulations that adequately regulates industrial hemp products.

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

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

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary, or are the most feasible manner to achieve compliance with statute.

Adoption of the proposed industrial hemp manufacturing and testing requirements and maintaining the incorporation by reference and application of 21 C.F.R. 100-111, 113-170, and 172-190 (2017), as applicable to industrial hemp manufacturers and processors, achieves alignment with existing federal wholesale food regulations and continues levels of wholesale food sanitation practices currently in place. No less costly or intrusive method for achieving the purpose of this rule was identified. The

department will update the incorporation by reference as needed to remain current.

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

No alternate rules or alternatives to the proposed rulemaking were considered. Current regulations incorporate by reference the 2017 base requirements of the federal wholesale food regulations and are necessary in achieving the safe production of food and dietary supplements. Colorado House Bill HB 18-1295 directed the department to consider industrial hemp and its derivatives as an allowable food and dietary supplement ingredient. Therefore, continued incorporation by reference of federal regulations as applicable to industrial hemp products and application of the proposed requirements clarifying approved sources, testing, packaged and labeling, record keeping, recalls, transportation, and waste management, is the most effective and efficient approach to rulemaking while protecting public health and allowing Colorado's industrial hemp businesses to continue sell their products. Retention of these federal food regulations and adoption of the proposed amendments will ensure long-term consistency in the application of industrial hemp 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 division began preparations for this rulemaking in 2019, as a co-sponsor and participant in CDA's CHAMP initiative. The proposed revisions to the existing regulation incorporate stakeholder input received during the 2019 CHAMP initiative, stakeholder input received during the division's early stakeholder engagement process (July through November 2020), and are necessary to refine and clarify manufacturing and testing requirements for the production of industrial hemp products in the State of Colorado

Maintaining the incorporation by reference of current federal wholesale food regulation 21 C.F.R. 100-111, 113-170, and 172-190 (2017) and application of the proposed requirements clarifying approved sources, testing, packaged and labeling, record keeping, recalls, transportation, and waste management, for the industrial hemp industry 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 and Shellfish 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:

<b>Organization</b>	<b>Representative Name and Title (if known)</b>
1287 Enterprises	Jimmy Haberer/CHAMP
13 Trees Coffee Co LLC	
271 Lake Davis Holding	
4 Corners Cannabis	
43 CBD	
5280 Chefs	
Aaron Horwich	
Abe Rahmanizadeh	
Acacia	
Aceso	
Active Botanical Company	
ADM Labs LLC	
Advanced Plant Processing	
Adventure CBD	
Agile CBD	
Ahava Care Labs	
Alan Call	
Alchemy Processing Laboratory, LLC	
All About Minutes Inc.	
Allay Consulting LLC	Kimberly A Stuck/CHAMP
Alliance Nutra	
Allo Blends, LLC	
Altitude Pioneer Industries LLC	
Alyssa Rosenblum	CHAMP
Ambarly Gardens, LLC	
American Original Hemp	
America's Finest CBD, LLC	
Amy Charkowski	CHAMP
Anandamide Alchemy LLC	
Antedotum	
Antonio Negroni	CHAMP
APAX USA, Inc.	
Arcanum Sports Performance	
Arendis, LLC	
Arkansas Valley Farms, LLC	
Aspen Grove Tea Co. LLC.	
Authentic Hemp Company	
Axtell Labs	Blake Boehmier
Ayani Botanicals, LLC	
Azuca	
Backyard Soda	
Bainstar	
Balanced Health Botanicals	Sommer Martinez/CHAMP

Balefire Botanicals	
Basecamp Co-Pack	
BE Labs/CBD Luxe	
Bees Knees CBDs	
Bellisimo Botanicals, LLC	
Benjamin Waters	
Bernie Perry	
Better Way CBD	
Bio Herbs And More	
BioLiveit Cannabinoids	
Bjorn's Colorado Honey	
Blister Pack Pro LLC	
Bloomble Inc.	
Blue Forest Farms	
Blue Sky Ventures LLC	
Bluebird Botanicals	Kevin Liebrock/CHAMP
Bluebird Botanicals	Kasey Irwin/CHAMP
Bluegrass State Holdings, LLC	
Bob Sculpt	CHAMP
BoCo Farms, LLC	Grant Orvis/CHAMP
Bonsai Wellness, LLC	
Botana	
Botanex Technologies Ltd	Industry
Botanix Equities, LLC	
Boulder Botanicals & Bioscience Laboratories, Inc.	Robert Dimarco/CHAMP
Boulder Hemp	
Boulder Raw	
Brian Donovan	
Brian Koontz	CHAMP
Brian Lukas	CHAMP
Brian Morrow	CHAMP
Bryan Burke Astral Organica	
Butterfly, LLC	
Cabaniss Group, LLC	
Cactus Valley Hemp Farm LLC	
Canna Brothers Distribution	
Cannabinoid Contract Manufacturing, LLC	
CannaGea	
Canopy Corporation	
Canopy Growth Corporation	Ken Woodlin/CHAMP
Care Division, LLC	
Caring Creatures LLC	
CBD CliniLabs, LLC	
CBD Global, LLC	
CBD Inc Group	
CBD Janes LLC	
CBD Universe, LLC	
CBD-Ease	
CBuzzD	
CDA	Duane Sinning
CDPHE-DEHS	Aaron Doussett
CDPHE-DEHS	Anjelica Thibault
CDPHE-DEHS	Bonnie Laws
CDPHE-DEHS	Cary Ruble/CHAMP
CDPHE-DEHS	David Kollar
CDPHE-DEHS	Jeff Lawrence/CHAMP
CDPHE-DEHS	Joe Lomeli/CHAMP
CDPHE-DEHS	Justin Trubee
CDPHE-DEHS	Kelly Lancelot
CDPHE-DEHS	Margaret Furlow

CDPHE-DEHS	Sean Scott
CDPHE-DEHS	Jon Strauss/CHAMP
Centered Snacks	
Cepheus Grown LLC	
Chae International	
Charlotte's Web, Inc.	Nathan Gerhardt/CHAMP
Chromo Labs LLC	
Citizens Laboratories LTD	
City of Aurora	Kim Kreimeyer/CHAMP
City of Colorado Springs	Mattie Gullixson/CHAMP
Cloud Co Farms LLC	
Clutch Hemp Co.	
CML	Laurel Witt/CHAMP
CML	Brandy Delange/CHAMP
Color Up Therapeutics	
Colorado Better Days Ltd	
Colorado BioDynamic	
Colorado Bureau of Investigation	Shawn West/CHAMP
Colorado Cannabinoids	
Colorado Chromatography	
Colorado Commodities Exporters LLC	
Colorado Cultivars USA	
Colorado Cultivars USA	
Colorado Dept Of Public Health and Environment	Kaitlin Urso/CHAMP
Colorado Farms, LLC	
Colorado Green Films Technology LLC	
Colorado Hemp Institute, LLC	
Colorado Hemp Solutions, LLC	
Colorado Medicine Woman	
Colorado Mountain Jam	
Colorado Processing Company, LLC	
Colorado Processing LLC	
Colorado State University	Kathleen Russell/CHAMP
Common Ground	
Cottonwood Sciences, LLC	
CoziCBD	
Crazy Mountain Brewing Company	
Cured Nutrition LLC	
Curnativ Labs	
CW Hemp	
Dan Arensmeier	
David USAGOV	
Deez Tea / Deez Coffee	
Denver Department of Public Health and Environment	Abby Davidson / CHAMP
Denver's Department of Excise and Licenses	Erica Rogers/CHAMP
Department of Agriculture	Wondirad Gebru/CHAMP
Diesel Haus Extracts	
Dion Oakes	
Director of Hemp Operations.	Preston Whitfield/CHAMP
Discover CBD/ Active CBD Oil	
Doka LLC	
Don Polly, LLC	
Down Range Productions, LLC	
Dr. Woodard's Colorado Cubes Ltd	
Dragonfly Botanicals	
Dram	
DTN, Inc	
e2 Enterprises, LLC	
Eagle Ridge Extractions	
Earth Pharmaceuticals LLC	

EB Transaction Sub 1, LLC	
Ecclesias Extracts	
EcoGen Laboratories, Eco-X Incorporated	
Eco-X Incorporated	
Ed Lehrburger	CHAMP
EdenFlo LLC	
Elena Bragg	
Elevated Elixirs	
Elevated Gains LLC	
Elevated Softgels, LLC	
Elevation Farms CO, LLC	
Elite Botanicals, LLC	
Elite Health Partners, LLC	
Elixinol	
Ellipse Analytics	Sean Callan/CHAMP
Empeiria Subscriptions	
Enerhealth Botanicals	
EP Greens	
Epic Relief LLC	
Erin Spies, Native Roots Dispensary	
ERL, LLC	
Evello Labs	
EVG Extracts, LLC	
Evolved Alchemy	
Extract Labs	
Eye of Ra Beverages, Inc	
Farmhouse Hemp	
Fat Pig Society	
First Crop, Inc.	Michael Bowman/CHAMP
Fishski Provisions LLC	
Flo Hemp Co	
Flora's Mercantile & Hemp Emporium	Chris Bedrosian/CHAMP
Flowerchild	
FM Labs LLC	
Folium Biosciences	
Fountain of Health Supplements, LLC	
FOURPOINTS BAR	
Frangiosa Farms	
Frank Registrato	
Frying Pan Hemp LLC	
Full Metal Canning	
Functional Remedies	Tim Gordon/CHAMP
Galaxy S9+	
General Processing LLC	
Gerald Campbell	
Glacier Pak LLC	
GOHCo Operations LLC	
Gold Care, LLC	
Good Love CBD	
Good Plant Hemp Inc	
Good Vibe CBD	
Good Vibe Tribe Inc	
Goodberry, LLC	
Grand Valley Gourmet, LLC	
Granny's High Altitude Super Hemp, LLC	
Green Cherry Organics	
Green Mart	
Green Oils	
Grover Family Farms	
GrowHempColorado	Veronica Carpio/CHAMP

Gunbarrel Organic Extractions	
H&H Labs LLC	
H&W Holdings LLC	
H.C. Labs, LLC	
H3L Labs, LLC	
Haleighs Hope Inc.	
Hammer Enterprises	Thuy Vu/CHAMP
Hapi Innovations, LLC	
Hass Farms, LLC	
Hau Processing	
Healing Power of Hemp	
HE-Colorado LLC	
Heilen Organics LLC	
Hemp by Tumbleweed	
Hemp Depot	
Hemp Foundry	
Hemp Health	
Hemp Way Foods	
Hemp Xtracts of Colorado	
Hemperor's Choice LLC	
Hempex	
Hempire Oils LLC	
Hempothecary	
HempStead Enterprises LLC	
Henep LLC	
Herbal Fracture	
Herbal Infusions	
Herbal Pharm Rx	
Herb-A-Lites	
High Altitude Wellness	
High Country ENT LLC	
High Country Kombucha, Inc. and Rocky Mountain Cultures	
High Elevation Laboratories LLC	
Hippie Dip Inc	
HM Health, LLC	
Hoban Law Group	Garrett Graff/CHAMP
HonestCeuticals LLC	
Honey Gold Processing, LLC	
Honeyspoon LLC	
HOPE Manufacturing, LLC	Jackson Tine/CHAMP
Hoplite Collective LLC	
Hunter Buffington	
Ideal Organics LLC	
IHP Refinery	Jessica McStravick/CHAMP
Indulge, LLC	
Incorrigible LLC	
Incredible Hemp Oil, Incredible CBD	
IncredMed Inc	
Infinite CBD	
Infinite Interactions LLC	
Infusionz LLC	
Injoy Integration	
James (Jamie), Baumgartner	James (Jamie), Baumgartner
Jeff Markley	CHAMP
Jen's CBD Shop, LLC	
Jessica Alizadeh	CHAMP
Josh Raderman	CHAMP
Joshua Jetton Sacred Body	Joshua Jetton
Joy Organics	
Just Hemp Co. LLC	

Justin Brothers	Justin@properrhino.com
Justin Singer	CHAMP
Kasey Irwin, Bluebird Botanicals	Kasey Irwin
Kara Lavaux	
Katie Wolf	
Kaylx LLC	
Kazmira LLC	Priyanka Sharma/CHAMP
Kelsie Biotech Inc	
Kelsey Hanley	
Kind Roots Botanicals LLC	Kind Roots
Kindred Extracts Inc	
King Pharma and 7Hands	Francis DellaVecchia/CHAMP
King Pharma, LLC	
Kipp Stroden	CHAMP
KM Relief	
KND Labs, LLC	
Laurel Will	
Laura Miller	
L7 AG, LLC	
L7 Labs	
Leafwell Botanicals, Inc.	Leafwell Botanicals
Leanna Organics	Leanna Organics
Lee Hemp	
Lichen Livin LLC	Lichen Livin
Little Flower Colorado Hemp Company	Little Flower
Loco Food Distribution	Loco Food
Lost Range	Lost Range
Loyal Leaf CBD, LLC	Loyal Leaf
Luke Johnson	
MAKA	
Malcomb Boyce	
Mariah Shaw	
Marijuana Enforcement Division	Brandon Jeffery
Marijuana Enforcement Division	Heather Krug
Marijuana Enforcement Division	Steve Clark/CHAMP
Marijuana Enforcement Division	Kim Kreimeyer/CHAMP
Mark Angerhofer	
Marquis Private Label	Marquis Private
Mary's Nutritionals	Mary's Nutritionals
Mary's Pet Shop, Whole Pet, Mary's Tails	Mary's Pet
Masri Ltd.	Masri Ltd.
Master Smith Enterprises	Master Smith
Mavatika Ltd	Mavatika Ltd
Maven Hemp	Maven Hempp
Maverick Natural Oils	Maverick Natural
Med USA CBD	Med USA CBBD
Melda's Essentials LLC	Melda's Essentials
Mesa Lavender Farms, LLC.	Mesa Lavender
Method CBD	Method CBDD
Metta Hemp Company	Metta Hemp
Metta Hemp Company LLC	Metta Hemp
MHL Broomfield Owner LLC	MHL Broomfield
Mile High Analytical LLC	Mile High
Mile High CBD	Mile High
Mile High Labs LLC	Mile High
Mile High WorkShop	Mile High
Mind Body & Soul Medicinals	Mind Body
Mineralife Nutraceuticals LLC	Mineralife Nutraceuticals
Miracles of Health	Miracles of Health
Missy J's	

MJ BioEssentials	MJ BioEssentials
Monarch Purple	Monarch Purple
Moon Mother Hemp Company	Moon Mother
Mota Munchies LLC	Mota Munchies
Motherlode Provisions, LLC	Motherlode Provisions
Mountain Flower Botanicals, LLC	Mountain Flower
Mountain Made LLC	Mountain Made
Mountain Palm	Mountain Palm
Mtn Distribution	Mtn Distribution
My Farmer CBD	My Farmer
Mycotechnology	Mycotechnool
MYKU Biosciences LLC	MYKU Biosciences
Nathan Gerhardt Charlotte's Web, Inc.	Nathan Gerhardt
Native Roots Dispensary	Erin Spies/CHAMP
Natural Foodworks Group, LLC	Natural Foodworks
Natural Grocers	Alan Lewis/CHAMP
Natural Leaf CBD	Natural Leaf
Natural Path Botanical, LLC	Natural Path
Nature's Full Spectrum Kitchen	Nature's Full
Nature's Love	Nature's Love
Nature's Root and Nature's Root Lab	Nature's Root
New Herb Health	New Herb Health
Next Frontier Biosciences	Steve Cape/CHAMP
NHC	
Niagara Bottling LLC	Niagara Bottling
Nikkal Farms, LLC	Nikkal Farms
Nimbus Wholesale	Nimbus Wholesale
NOCO Labs LLC	NOCO Labs
North Field Farmacy, LLC	North Field
NuLeaf Naturals	NuLeaf Naturals
Numb Nuts	
NuRange CBD Cold Brew	NuRange CBBB
Nymm CBD	
Oak Creek Hemp Company	Oak Creek
Oh-Hi Beverages Inc	Oh-Hi Beverages
Optiverde Systems, LLC	Optiverde Systems
Palisade Botanicals	Palisade Botanicals
Pamela Baxter	CHAMP
Panacea Life Sciences	Panacea Life
Paragon Processing LLC	Paragon Processing
Peak Labs & Development, LLC	Peak Labs
Peak Performance	Peak Performance
Perez Agricultural	Scott Perez/CHAMP
Phineas CBD	Phineas CBBB
Phoenix Extractions	Phoenix Extractions
Planetarie, LLC	Planetariee, LLC
Point3 Farma LLC	Point3 Farma
Positive Drop	Positive Drop
Potent Pantry LLC	Potent Pantry
Precision Plant Molecules	Precision Plant
Preston Whitfield	Preston Whitfield
Priyanka Sharma Kazmira LLC	Priyanka Sharma
Proper Rhino Packaging	Proper Rhino
Pueblo County	Chris Wiseman/CHAMP
Pulpo LLC	
Pure 5 Nutrients Colorado LLC	Pure 5 Nutrients
Pure Hemp Technology LLC/Pure Kind Botanicals	Pure Hemp
Pure Spectrum CBD	Pure Spectrum
Pure Water, llc	George Rhoades/CHAMP
Purple Monkey LTD	Purple Monkey

OSP Design, LLC	OSP Design
R & R Medicinals, LLC	R & R Medic
Rad Extraction	Rad Extraction
Raising Vibes LLC	Raising Vibes
Receptra Naturals LLC	Receptra Naturals
Redlaw Sauce Co	Redlaw Sauce
Reef Drink Company	Reef Drink
Resilience CBD	Resilience CBD
Resinosa LLC	Jeff Hays/CHAMP
Restorative Botanicals	Restorative Botanicals
Revitalize Inc	Revitalize Inc.
Revive Hemp	Revive Hemp
RFI Ingredients, RFI Extracts	RFI Ingredients
RH Company	RH Company
Rise Relief	Rise Relief
Robin Peterson	
Rockies Agricultural Processing LLC	Rockies Agricultural
Rocky Mountain Bob CBD, LLC	Rocky Mountain
Rocky Mountain Extraction Services, LLC	Rocky Mountain
Rocky Mountain Farmers Union	Nick Levendofsky/CHAMP
Rocky Mountain Soda Company, CO's Best Drinks, and Lifted Libations	Rocky Mountain
Rocky Mountain Supply Co	Rocky Mountain
Rose Bud Ice Cream LLC	Rose Bud LLC
S&C Lab Corp LLC	S&C Lab Corp
Sacred Body	Joshua Jetton/CHAMP
Saint Raphael of the Hills	Saint Raphael
Salad Ground Kitchens	Matthew Arnold/CHAMP
Salt Creek Hemp Co LLC	Salt Creek
San Luis Valley Hemp Company	San Luis Valley Hemp Co
Saving Grace Oils.Inc.	Saving Grace
Sawatch Hemp	Sawatch Hemp
Scott McWhorter	
Seattle Fish Company	Seattle Fish
Selah Organics Natural Healing and Wellness	Selah Organics
Serendipity Farms, LLC	Serendipity Farms
Shanao Chocolate Products LLC	Shanao Chocolate
Sheilah Ophaug	
Simply Hemp LLC	Simply Hemp
Simtech LLC	Simtech LLC
Ska Brewing Co	Ska Brewing
Sky and Wyatt Hemp Company	Sky and Wyatt
Snowball Distribution	Snowball Distribution
SoluScience, LLC	SoluScience, LLC
Southern Ute Indian Tribe	Eric Thayer/CHAMP
Southern Ute Indian Tribe	Roger Zalneraitis/CHAMP
Sovine Consulting	Cindy Sovine/CHAMP
Speedy Grow Inc.	Speedy Grow
St. Bernie's	St. Bernie's
SteepFuze	
Stefanie Gilbretj	
Steven Stinson	CHAMP
Steve's Goods	Steve's Goods
Still Point Coffee	Still Point
Stillwater	
Straight Hemp	Straight Hemp
Strasburg Pharms Cannaoil & Aethics	Strasburg Pharms
Strategic Healing Solutions	Strategic Healing
Stratos CBD	Stratos CBBDD
Strava Craft Coffee, Inc.	Strava Craft
Strongwater LLC	Strongwater LLC

STRW LLC	
Subtle Relief LLC	Subtle Relief
Sub-Zero Extracts	Sub-Zero Extracts
Summit Extraction Systems	Summit Extraction
Summit Manufacturing Corporation	Summit Manufacturing
Sundown Sparkling	Sundown Sparkling
Sungting Chen	
Sunrise Beverage	Sunrise Beverage
Supergood, LLC	Supergood,, LLC
Supreme Labs	Supreme Labs
Sylva Labs	Sylva Labs
Szm, LLC	
Tailwind Nutrition	Tailwind Nutrition
Tanner Willis	
Terra Gold Plus	Terra Gold
TGC Network	TGC Netwrk
Thar Extracts CO, LLC	Thar Extraacts
The CBD Honey Company	The CBD Honey
The CBDistillery	The CBDistillery
The Hemp Shoppe	The Hemp Shoppe
The Hibbert Group	The Hibbert
The Tea Spot, Inc.	The Tea Spot
Three Kings Kombucha, LLC	Three Kings
Thunder Mountain Chocolate LLC	Thunder Mountain
Tiffany Moseley	
Topline Management Inc.	Topline Management
Treehouse	
Trill Pills	Trill Pills
Trove, LLC	Trove, LLC
Tru Pura CBD	Tru Pura CCB
Truesdell Manufacturing and Consulting	Truesdell Manufacturing
Turtle House Holdings, LLC	Turtle House
UBIX Processing	UBIX Processing
Uleva Products, Inc.	Uleva Products
UnCanny Wellness	UnCanny Wellness
United Cannabis Corporation	United Cannabis
Upstart Kombucha	Upstart Kombucha
Valley CBDS LLC	Valley CBDDS
Vantage Hemp Co	Vantage Hemp
Vapor Distilled	Dana Shierstone/CHAMP
Vera Herbals LLC	Vera Herbals
Verdant Formulas	Verdant Formulas
Verks Unlimited, Ltd.	Verks Unlimited
VESL Oils	
Vidya LLC	
Violet's Miracle	Violet's Miracle
V-tek Botanicals LLC	V-tek Botanicals
WAAYB Labs, LLC	WAAYB Labs
Wana Wellness, LLC	Wana Wellness
Wasa Development Company LLC	Wasa Development
Weller	
Wellicy Inc	Wellicy Inc.
Welltiva Labs, LLC	Welltiva Labs
Western CBD	Western CBBB
White Buffalo Hemp Company	White Buffalo
WholeMade, Inc.	Jerell Klaver/CHAMP
Wild West Weed and Seed/ Dr Herb-al	Wild West
William Billings	
Windy Hill Hemp	Windy Hill
Wise Bar	

Wise Hemp LLC	Wise Hemp
WL324 LLC	
WOH Consulting	James Reil/CHAMP
World Class Health, LLC	World Class
Wow Organics LLC	Wow Organics
Yoh F	
Z3 Sciences	Z3 Sciences
Zakah Life	Zakah Liece
Zelios	
Zimgrove LLC	Zimgrove LLLC
zumXR	

The passage of the 2018 Agricultural Improvement Act, commonly called the Farm Bill, requires each state department of agriculture to submit a state management plan to the United States Department of Agriculture (USDA), outlining how various aspects of hemp cultivation and processing will be managed within their jurisdiction. In response, the Colorado Department of Agriculture (CDA) partnered with leading state, local, and tribal agencies, as well as industry experts in cultivation, testing, research, processing, finance and economics to establish a statewide initiative known as the Colorado Hemp Advancement and Management Plan (CHAMP).

The 2018 Farm Bill provided Colorado a unique opportunity to establish a comprehensive blueprint for how the state will not only manage, but also advance this emerging industry by examining the entire supply chain from cultivation to market, and the steps in between. The CHAMP was a broad stakeholder-based effort initiated in 2019, and represented a collaborative effort between CDA, the Governor's Office, Department of Public Health and Environment, Department of Revenue, Department of Regulatory Agencies, Office of Economic Development and International Trade, Department of Public Safety, Colorado Commission of Indian Affairs, Department of Higher Education, local governments, and industry experts. CHAMP stakeholder meetings addressing the industrial hemp supply chain were conducted from July through December 2019, and included stakeholder group discussions related to research and development and seed, cultivation, transportation, testing, processing, manufacturing, marketing, and banking and insurance. On June 18, 2020, Colorado submitted the *Colorado State Hemp Management Plan* and associated appendices to the USDA.

The proposed revisions to the existing wholesale food regulation incorporate pertinent stakeholder input received during the 2019 CHAMP initiative and the division's stakeholder process conducted from July through November 2020, and are necessary to refine and clarify manufacturing and testing requirements for the production of industrial hemp products in the State of Colorado.

On July 14, July 21, and July 28, and October 20, 2020, the division held four stakeholder meetings to evaluate the proposed changes to the existing wholesale food regulation and receive additional feedback from industrial hemp stakeholders.

Based on discussion during the stakeholder meeting held on July 28, 2020, stakeholders formed two independent workgroups to discuss additional revisions to the proposed definitions and testing requirements. The hemp testing workgroup met on August 4, 2020 and the definitions workgroup on August 12, 2020. Following agency evaluation and input, proposed revisions to definitions and testing requirements resulting from the workgroups were incorporated into the proposed redline and presented for review to all stakeholders at the October 20, 2020 stakeholder meeting.

Consensus was achieved on the proposed regulation, including definitions of relevant terms, industrial hemp manufacturing and testing requirements, and continued application of 21 C.F.R. 100-111, 113-170, and 172-190 (2017). All documents associated with stakeholder engagement were made available on the department's webpage:

<https://cdphe.colorado.gov/industrial-hemp-in-food/industrial-hemp-news-and-announcements>

#### 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 amended regulations and associated documents and resources could 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.

The division began preparations for this rulemaking in 2019, as co-sponsors and participants in CDA's CHAMP initiative. On July 14, July 21, and July 28, and October 20, 2020, the division held stakeholder meetings to evaluate the proposed changes to the existing rule that resulted from the CHAMP initiative. Stakeholders included industrial hemp and unfinished industrial hemp product manufacturers, processors, or storage facilities registered with the department, industrial hemp transporters, dispensaries, multiple state and local government agencies, educational institutes, analytical laboratories, retail food establishments, consulting firms, pharmaceutical companies, various institutes, unions, associations, and advocacy groups, legal firms, financial institutions, tribal agencies, and consumers of industrial hemp products.

Based on discussion during the stakeholder meeting held on July 28, 2020, stakeholders formed two independent workgroups to discuss and refine revisions to the proposed definitions and testing requirements. The hemp testing workgroup met on August 4, 2020 and the definitions workgroup on August 12, 2020. Following agency evaluation and input, proposed revisions to definitions and testing requirements resulting from the workgroups were incorporated into the proposed redline and presented for review to all stakeholders at the October 20, 2020 stakeholder meeting.

United States Pharmacopeia (USP), Chapter <467> and the *Colorado Marijuana Rules*, 1 CCR 212-3, provided the basis for the action limits defined in table 21.7(F)(5)(e), *Residual solvents, of the proposed rules*. Some stakeholders were less supportive of these proposed residual solvent action limits. However, an appropriate resource or proxy that would establish more defensible and protective action limits was not identified.

Those not in support of utilizing the USP desired to use levels for residual solvents utilized by FDA for indirect or direct food additives. While the approach seems reasonable, the application of this approach presented challenges and conflicts. First, the allowed levels of the solvent varies greatly depending on the food ingredient/product. Levels were based on normal daily intake and required the manufacturer to petition FDA with their proposed levels and their rationale. As we currently stand hemp products are not federally approved and the state does not have the resources or expertise to review the petition. Additionally, several other states have established hemp product regulation and utilize the USP. Canada’s cannabis regulations, while not referencing the USP, have limits that are aligned with those established in the USP. Finally, the long-standing requirements for commensurate marijuana products in the state utilize the USP as the action levels for residual solvent.

Consensus was achieved on the proposed regulation, including maintaining the requirements of 21 C.F.R. 100-190 (2017), as applicable to industrial hemp manufacturers, as well as including new definitions of relevant terms and industrial hemp manufacturing, testing and labeling requirements.

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

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.

	<p>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.</p>	<p>Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.</p>
	<p>Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.</p>	<p>Ensures a competent public and environmental health workforce or health care workforce.</p>
	<p>Other: _____ _____</p>	<p>Other: _____ _____</p>

# COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

## Division of Environmental Health and Sustainability

### COLORADO WHOLESALE FOOD, INDUSTRIAL HEMP, AND SHELLFISH REGULATIONS

#### 6 CCR 1010-21

Adopted by the Board of Health on August 15, 2018; effective, October 15, 2018.

#### 21.1 Authority

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

#### 21.2 Scope and Purpose

A. This regulation shall be applied for the protection of public health by ensuring that the premises or places wherein manufactured foods and industrial hemp products are produced, 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.

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

1. To grant or refuse to grant registration pursuant to ~~s~~Section 25-5-426(4), C.R.S. and to grant or refuse to grant the annual renewal of a registration;
2. To deny, suspend, or revoke a registration;
3. To issue a certificate of free sale; and
4. To review any records of a wholesale food manufacturer or storage facility necessary to verify compliance with the provisions of ~~s~~Section 25-5-426, C.R.S.

C. This regulation does not apply to:

1. Retail food establishments governed by the *Colorado Retail Food Establishment Regulations*, 6 CCR 1010-2-~~7~~and~~4~~;
2. Facilities or conditions governed by the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4-~~2~~;
3. Entities engaged in the business of possessing, cultivating, dispensing, transferring, transporting, or testing Medical Marijuana or Retail Marijuana governed by the *Colorado Marijuana Rules*, 1 CCR 212-3;

53 4. The cultivation of industrial hemp governed by the *Rules Pertaining to the*  
54 *Administration and Enforcement of the Industrial Hemp Regulatory Program*  
55 *Act, 8 CCR 1203-23;*

56  
57 5. Entities that are manufacturing intermediate or finished hemp products from  
58 the fibrous material of the plant that are not intended for human  
59 consumption. These products include, but are not limited to, cordage, paper,  
60 fuel, textiles, bedding, insulation, construction materials, compost materials,  
61 and industrial materials;

62  
63 6. Entities that are manufacturing industrial hemp-derived smokable products,  
64 inhalable products, over-the-counter drugs, drugs, or medical devices; and

65  
66 7. Testing performed by a certified laboratory in accordance with the *Hemp*  
67 *Testing Laboratory Certification, 5 CCR 1005-5.*

68  
69 D. Nothing in this rule shall be construed to limit the ~~d~~Department's statutory authority  
70 under the "Pure Food and Drug Law", Section 25-5-401 et seq., C.R.S., the "Shellfish  
71 Dealer Certification Act," Section 25-4-1801 et seq., C.R.S., or Section 25-1.5-102,  
72 C.R.S.

### 73 74 **21.3 Applicability**

75  
76 A. This rule establishes registration requirements for wholesale food and industrial hemp  
77 product manufacturers, Section 25-5-426, C.R.S., and certification requirements for  
78 wholesale food manufacturers who are also shellfish dealers, Section 25-4-1801 *et*  
79 *seq.*, C.R.S.

80  
81 1. This regulation establishes the allowance that industrial hemp manufacturers  
82 [as defined in 21.4(A)(16)] shall adhere to for the production of industrial hemp  
83 products and unfinished industrial hemp products in the State of Colorado.

84  
85 2. These regulatory requirements do not infer conformance with federal laws and  
86 the allowance for manufacturing, sale, and distribution of industrial hemp  
87 products and unfinished industrial hemp products to other states or countries.

88  
89 B. This rule incorporates by reference the Code of Federal Regulations addressing Food  
90 for Human Consumption and the national shellfish sanitation standards.

91  
92 C. This rule incorporates by reference 21 Code of Federal Regulations (C.F.R.) 100-111,  
93 113-170, and 172-190 (April 1, 2017), including requirements of the *Current Good*  
94 *Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for*  
95 *Human Food (cGMP) 21 C.F.R. 117, and other State or U.S. Department of Health and*  
96 *Human Services, Food & Drug Administration (FDA) guidance regarding food safety and*  
97 *Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or*  
98 *Holding Operations for Dietary Supplements.*

99  
100 D. This rule establishes enforcement standards for wholesale food manufacturers  
101 pursuant to Sections 25-1.5-102(1)(c), 25-5-406 and 25-5-420, C.R.S., and enforcement  
102 standards for wholesale food manufacturers who are also shellfish dealers pursuant to  
103 Section 25-4-1810, C.R.S.

104

105 21.4 Definitions

106

107 A. For the purpose of these rules and regulations, unless otherwise specified herein:

108

109 1. Approved Source means:

110

111 a. A product from a wholesale food manufacturer, industrial hemp  
112 manufacturer, or a storage facility registered with the department in  
113 accordance with Section 25-4-426, C.R.S, or

114

115 b. Generally Recognized As Safe (GRAS), or

116

117 c. Hemp seed, hemp seed co-products, or hemp-seed by-products, or

118

119 d. Industrial hemp or hemp products from a state that has an established  
120 and approved industrial hemp program, or

121

122 e. Industrial hemp or hemp products from a country that inspects or  
123 regulates hemp under a food safety program or equivalent criteria to  
124 ensure safety for human consumption.

125

126 2. Broad spectrum means industrial hemp products that contain multiple  
127 cannabinoids and no more than 0.01% total THC.

128

129 3. Cannabinoids means a class of lipophilic molecules that are naturally occurring  
130 in industrial hemp.

131

132 4. Certified laboratory means a public or private laboratory or testing facility  
133 certified by the department to perform testing on industrial hemp and  
134 industrial hemp products or a testing facility licensed by the Marijuana  
135 Enforcement Division.

136

137 5. Certificate of Analysis means an official document issued by a certified  
138 laboratory or testing facility that shows results of scientific tests performed on  
139 a product.

140

141 6. Cosmetics means articles intended to be rubbed, poured, sprinkled, or sprayed  
142 on, introduced into, or otherwise applied to the human body or any part  
143 thereof for cleansing, beautifying, promoting attractiveness, or altering the  
144 appearance or an article intended for use as a component of any such articles;  
145 except that such term does not include soap.

146

147 2-7. Dealer or Shellfish Dealer means a person to whom certification is issued for  
148 the activities of shell stock shipper, shucker-packer, repacker, reshipper,  
149 deuration processor, or wet storage.

150

151 8. Delta-9 tetrahydrocannabinols (THC) or delta-9 THC has the same meaning as  
152 "tetrahydrocannabinols" as set forth in Section 27-80-203 (24), C.R.S. Delta-9  
153 THC is the primary psychoactive component of cannabis. For the purposes of  
154 these regulations, the terms "Delta-9 THC" and "THC" are interchangeable.

155

156 3-9. Department means the Colorado Department of Public Health and Environment.

- 157 10. Dietary supplement means a product taken by mouth that contains a dietary  
158 ingredient or a new dietary ingredient intended to supplement the diet.  
159
- 160 11. Full spectrum means an industrial hemp product that contains all  
161 phytochemicals naturally found in the plant, trace cannabinoids, terpenes, and  
162 essential oils, with no more than 0.3% total THC.  
163
- 164 12. Generally Recognized As Safe (GRAS) means any substance that is intentionally  
165 added to food which is a food additive, that is subject to premarket review by  
166 FDA, unless the substance is generally recognized, among qualified experts, as  
167 having been adequately shown to be safe under the conditions of its intended  
168 use, or unless the use of the substance is otherwise excepted from the  
169 definitions of food additive.  
170
- 171 13. Herb means any plant with leaves, seeds, or flowers used as a flavoring, food,  
172 food additive, or dietary supplement ingredient.  
173
- 174 14. Industrial hemp or hemp means the plant Cannabis sativa L. and any part of the  
175 plant, including the seeds, all derivatives, extracts, cannabinoids, isomers,  
176 acids, salts, and salts of isomers, whether growing or not, with a Delta-9  
177 tetrahydrocannabinol concentration of no more than 0.3% on a dry-weight  
178 basis.  
179
- 180 15. Industrial hemp extract means an unfinished industrial hemp product or  
181 industrial hemp product produced through a solvent or non-solvent based  
182 industrial hemp manufacturing process, including but not limited to oils,  
183 distillates, resins, and isolates.  
184
- 185 16. Industrial hemp manufacturer means a facility that manufactures, produces,  
186 packs, processes (extracts), treats, packages, or holds/warehouses industrial  
187 hemp products and unfinished industrial hemp products.  
188
- 189 17. Industrial hemp product means finished products containing industrial hemp  
190 that is for human use or consumption and:  
191
- 192 a. Is a cosmetic as defined in 25-5-402(6) C.R.S.; or  
193
- 194 b. Is a dietary supplement as defined in 25-5-426(2)(b) C.R.S.; or  
195
- 196 c. Is a food as defined in 25-5-402(11) C.R.S.;  
197
- 198 d. Is a food additive as defined in 25-5-402(12) C.R.S.;  
199
- 200 e. Contains any part of the hemp plant, including naturally occurring  
201 cannabinoids, compounds, concentrates, extracts, isolates, resins, or  
202 derivatives;  
203
- 204 f. Contains a Delta-9 THC concentration of no more than 0.3%, and  
205
- 206 g. Is not a drug as defined in 25-5-402(9) C.R.S.  
207

- 208 18. Labeling means a display of written, printed, or graphic matter upon a food,  
209 food ingredient container, or package and includes product inserts, and other  
210 promotional materials including digital communications.
- 211
- 212 19. Law means applicable local, state, and federal statutes, regulations and  
213 ordinances.
- 214
- 215 20. Packaging means any type of container, wrapping, or other type of vessel  
216 intended to protect both food or supplements from damage, contamination,  
217 spoilage, pest attacks, and tampering, during transport, storage, and sale.
- 218
- 219 21. THC means tetrahydrocannabinol.
- 220
- 221 22. THCA means tetrahydrocannabinolic acid.
- 222
- 223 23. Total THC means the sum of the percentage by weight of THCA multiplied by  
224 0.877 plus the percentage by weight of THC [i.e., (% THCA x 0.877) + % THC].
- 225
- 226 24. Unfinished industrial hemp product means an oil, concentrate or other  
227 substance that has a total THC concentration above 0.3% and less than or equal  
228 to 5.0%, is not for consumer use or distribution, must be sold or transferred  
229 between registered industrial hemp manufacturers or certified laboratories,  
230 and will undergo further refinement or processing into an industrial hemp  
231 product.
- 232
- 233 4-25. Wholesale food manufacturer means a facility that manufactures, produces,  
234 packs, processes, treats, packages, transports, or holds human food, including  
235 dietary supplements. These terms include storage facilities. These terms  
236 include shellfish dealers when the wholesale food manufacturer is also a  
237 shellfish dealer.

## 21.5 Wholesale Food Manufacturer and Shellfish Dealer Requirements

- 239
- 240
- 241 A. Wholesale food manufacturing facilities in Colorado must be registered in accordance  
242 with Section 25-5-426(4), C.R.S.
- 243
- 244 1. The owner of any wholesale food manufacturer must submit to the department  
245 an application each year for registration, along with applicable application and  
246 registration fees, using forms provided by the department.
- 247
- 248 2. The owner of any wholesale food manufacturer must also submit to the  
249 department complete and accurate information about the facility's operation  
250 and business size, using forms provided by the department.
- 251
- 252 B. Wholesale food manufacturers who are also shellfish dealers in Colorado must also be  
253 certified in accordance with Section 25-4-1805, C.R.S.
- 254
- 255 1. Any person desiring to do business as a shellfish dealer must apply for and  
256 obtain a valid certification issued by the department.
- 257
- 258 2. Shellfish dealers must report to the department, in the form and manner  
259 required by the department, any change in the information provided in the

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

262

## 263 21.6 Incorporation by Reference

264

265 A. The department shall utilize material incorporated by reference as appropriate to  
266 assure that wholesale food manufacturers comply with the "Pure Food and Drug Law",  
267 and wholesale food manufacturers who are also shellfish dealers comply with the  
268 "Shellfish Dealer Certification Act."

269

270 1. 21 C.F.R. 100-190 (April 1, 2017) is hereby incorporated by reference into this  
271 rule. Such incorporation, however, excludes later amendments to or editions of  
272 the reference material.

273

274 2. U.S. Department of Health and Human Services, Public Health Service/Food  
275 and Drug Administration, *National Shellfish Sanitation Program Guide for the*  
276 *Control of Molluscan Shellfish Model Ordinance (2015 Revision)* is hereby  
277 incorporated by reference into this rule. Such incorporation, however, excludes  
278 later amendments to or editions of the reference material.

279

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

284

285 1. 21 C.F.R. 112, *Standards for the Growing, Harvesting, Packing, and Holding of*  
286 *Produce for Human Consumption.*

287

288 2. 21 C.F.R. 171, *Food Additive Petitions.*

289

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

292

293 Division of Environmental Health and Sustainability  
294 Colorado Department of Public Health and Environment  
295 4300 Cherry Creek Drive South  
296 Denver, Colorado 80246-1530

297

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

303

304 D. The incorporated materials are available at:

305

306 [https://www.ecfr.gov/cgi-bin/text-  
307 idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab  
308 \\_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)

309

310

311

## 21.7 Industrial Hemp Processing and Manufacturing Requirements

A. Oils, concentrates or other substances that are above 5.0% total THC must undergo further refinement or processing by the original registered industrial hemp manufacturer.

B. Prior to manufacturing, packaging, or distributing an industrial hemp product or an unfinished industrial hemp product, a business shall:

1. Be registered with the department;

2. Obtain any necessary local licenses, registrations, and approvals;

3. Ensure all types of industrial hemp products and unfinished industrial hemp products, packaging, and labeling meet the requirements established within this regulation; and

4. Have conspicuously posted all applicable documentation in accordance with the law.

C. Industrial hemp manufacturing facilities shall maintain physical and operational separation from any marijuana-related facility, including separate entrances and exits.

D. All standard operating procedures and scheduled processes performed in the facility are limited to those approved by the appropriate regulatory authority.

E. Ingredients

1. All ingredients must come from an approved source;

2. All industrial hemp products or unfinished industrial hemp products shall be clearly identified to allow for appropriate traceability. Identification includes:

a. Name of ingredient;

b. Identifying batch or lot number from original package;

c. Date the ingredient was manufactured;

d. Date the ingredient was received at the facility; and

e. Expiration, re-test, or use-by date.

3. Spoiled, unwholesome, adulterated, vermin-infested or insect-infested ingredients are not allowed into the facility and shall be:

a. Removed immediately from the premises and properly disposed; or

b. Placed in a quarantine area temporarily until proper disposal if:

(1) Not practicable to remove immediately; or

364 (2) Required to be collected by a local or state regulatory agency  
365 for examination or testing.

366 F. Testing

- 367
- 368
- 369 1. Effective July 1, 2021, analytical testing shall be performed by a certified  
370 laboratory in accordance with the department's State Public Health  
371 Laboratory, Disease Control and Public Health Response Division's, *Hemp*  
372 *Testing Laboratory Certification*, 5 CCR 1005-5.
- 373
- 374 2. In order for a food, food additive, dietary supplement, or cosmetic to contain  
375 industrial hemp, the manufacturer shall be able to demonstrate the following  
376 purity and potency:
- 377
- 378 a. Industrial hemp shall conform to the standard of identity established by  
379 the Colorado Department of Agriculture.
- 380
- 381 b. The use of parts of the industrial hemp plant, other than seed and its  
382 derivatives (e.g., hulled hemp seed, hemp seed protein powder, hemp  
383 seed oil) shall have laboratory test results indicating conforming levels  
384 of THC and total THC.
- 385
- 386 c. The manufacturer shall be able to document that the industrial hemp  
387 product does not contain more than 0.3% total THC.
- 388
- 389 3. Additional Testing Standards: The testing requirements contained in this  
390 regulation are the minimum required and approved testing standards. Industrial  
391 hemp manufacturers are responsible for ensuring testing requirements listed in  
392 subparagraphs 21.7(F)(5)(a-e) are met and maintaining certificates of analysis  
393 on any regulated industrial hemp products they produce or transfer to ensure  
394 safety on all lots or batches for human consumption.
- 395
- 396 4. All certificates of analysis provided as documentation of conformance with the  
397 established testing requirements shall be furnished from a certified industrial  
398 hemp testing laboratory or a licensed retail marijuana testing laboratory.
- 399
- 400 a. Any exceedance of the contaminant action limits presented in section  
401 21.7(F)(5)(a-e) shall be reported to the department by the industrial  
402 hemp manufacturer within 48 hours of receipt of the analytical testing  
403 results.
- 404
- 405 5. Permissible Levels of Contaminants: If an industrial hemp product is found to  
406 have a contaminant in levels exceeding those established as permissible under  
407 this regulation, then it shall be considered to have failed contaminant testing.  
408 Notwithstanding the permissible levels established in this regulation, the  
409 department reserves the right to determine, upon good cause and reasonable  
410 grounds that a particular product presents a risk to public health or safety and  
411 therefore shall be considered to have failed a contaminant test.
- 412
- 413
- 414
- 415

416  
417a. Microbials (Bacteria and Fungus)

<u>Substance</u>	<u>Action Limits</u> Per gram (g), unless otherwise indicated
<u>Salmonella spp.</u>	<u>Absent in 25 g</u>
<u>-Shiga-toxin producing Escherichia coli (STEC) - Bacteria</u>	<u>Absent in 25 g</u>
<u>Total coliforms</u>	<u>&lt; 10<sup>2</sup> cfu/g</u>
<u>Total aerobic plate count</u>	<u>&lt; 10<sup>4</sup> cfu/g</u>
<u>Total yeast and mold</u>	<u>&lt; 10<sup>3</sup> cfu/g</u>

418  
419  
420b. Mycotoxins

<u>Substance</u>	<u>Action Limits</u> Parts per billion (ppb)
<u>Aflatoxins (B1, B2, G1, and G2)</u>	<u>&lt; 20</u> <u>(total of B1 + B2 + G1 + G2)</u>
<u>Aflatoxin B1</u>	<u>&lt; 5</u>
<u>Ochratoxin</u>	<u>&lt; 5</u>

421  
422  
423  
424  
425  
426  
427c. Pesticides

The following pesticides are not allowed in finished hemp products or unfinished hemp products. The following table establishes the Limits of Quantification (LOQ) for laboratory verification.

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> Parts per million (ppm)	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Abamectin</u>	<u>0.1</u>	<u>0.25</u>
<u>Acephate</u>	<u>0.02</u>	<u>0.05</u>
<u>Acequinocyl</u>	<u>0.03</u>	<u>*</u> <u>-</u>
<u>Acetamiprid</u>	<u>0.1</u>	<u>0.05</u>
<u>Aldicarb</u>	<u>1</u>	<u>0.5</u>

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> Parts per million (ppm)	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Allethrin</u>	<u>0.2</u>	<u>0.1</u>
<u>Atrazine</u>	<u>0.025</u>	<u>*</u> <u>-</u>
<u>Azadirachtin</u>	<u>1</u>	<u>0.5</u>
<u>Azoxystrobin</u>	<u>0.02</u>	<u>0.01</u>
<u>Benzovindiflupyr</u>	<u>0.02</u>	<u>0.01</u>
<u>Bifenazate</u>	<u>0.02</u>	<u>0.01</u>
<u>Bifenthrin</u>	<u>1</u>	<u>*</u> <u>-</u>
<u>Boscalid</u>	<u>0.02</u>	<u>0.01</u>
<u>Buprofezin</u>	<u>0.02</u>	<u>*</u> <u>-</u>
<u>Carbaryl</u>	<u>0.05</u>	<u>0.025</u>
<u>Carbofuran</u>	<u>0.02</u>	<u>0.01</u>
<u>Chlorantraniliprole</u>	<u>0.02</u>	<u>*</u> <u>-</u>
<u>Chlorphenapyr</u>	<u>0.05</u>	<u>1.5</u>
<u>Chlorpyrifos</u>	<u>0.04</u>	<u>0.5</u>
<u>Clofentezine</u>	<u>0.02</u>	<u>0.01</u>
<u>Clothianidin</u>	<u>0.05</u>	<u>0.025</u>
<u>Coumaphos</u>	<u>0.02</u>	<u>0.01</u>
<u>Cyantraniliprole</u>	<u>0.02</u>	<u>0.01</u>
<u>Cyfluthrin</u>	<u>0.2</u>	<u>*</u> <u>-</u>
<u>Cypermethrin</u>	<u>0.3</u>	<u>*</u> <u>-</u>
<u>Cyprodinil</u>	<u>0.25</u>	<u>0.01</u>
<u>Daminozide</u>	<u>0.1</u>	<u>*</u> <u>-</u>
<u>Deltamethrin</u>	<u>0.5</u>	<u>*</u> <u>-</u>
<u>Diazinon</u>	<u>0.02</u>	<u>*</u> <u>-</u>

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> Parts per million (ppm)	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Dichlorvos</u>	<u>0.1</u>	<u>0.05</u>
<u>Dimethoate</u>	<u>0.02</u>	<u>0.01</u>
<u>Dimethomorph</u>	<u>0.05</u>	* -
<u>Dinotefuran</u>	<u>0.1</u>	<u>0.05</u>
<u>Diuron</u>	<u>0.125</u>	* -
<u>Dodemorph</u>	<u>0.05</u>	* -
<u>Endosulfan sulfate</u>	<u>0.05</u>	<u>2.5</u>
<u>Endosulfan-alpha</u>	<u>0.2</u>	<u>2.5</u>
<u>Endosulfan-beta</u>	<u>0.05</u>	<u>2.5</u>
<u>Ethoprophos</u>	<u>0.02</u>	<u>0.01</u>
<u>Etofenprox</u>	<u>0.05</u>	* -
<u>Etoazole</u>	<u>0.02</u>	* -
<u>Etridiazole</u>	<u>0.03</u>	<u>0.15</u>
<u>Fenhexamid</u>	<u>0.125</u>	* -
<u>Fenoxycarb</u>	<u>0.02</u>	<u>0.01</u>
<u>Fenpyroximate</u>	<u>0.02</u>	* -
<u>Fensulfothion</u>	<u>0.02</u>	<u>0.01</u>
<u>Fenthion</u>	<u>0.02</u>	<u>0.01</u>
<u>Fenvalerate</u>	<u>0.1</u>	* -
<u>Fipronil</u>	<u>0.06</u>	<u>0.01</u>
<u>Flonicamid</u>	<u>0.05</u>	<u>0.025</u>
<u>Fludioxonil</u>	<u>0.02</u>	<u>0.01</u>
<u>Fluopyram</u>	<u>0.02</u>	<u>0.01</u>
<u>Hexythiazox</u>	<u>0.01</u>	* -

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> <u>Parts per million (ppm)</u>	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Imazalil</u>	<u>0.05</u>	<u>0.01</u>
<u>Imidacloprid</u>	<u>0.02</u>	<u>0.01</u>
<u>Iprodione</u>	<u>1</u>	<u>0.50</u>
<u>Kinoprene</u>	<u>0.50</u>	<u>1.25</u>
<u>Kresoxim-methyl</u>	<u>0.02</u>	<u>0.15</u>
<u>(Lambda) Cyhalothrin</u>	<u>0.25</u>	<u>*</u> <u>-</u>
<u>Malathion</u>	<u>0.02</u>	<u>0.01</u>
<u>Metalaxyl</u>	<u>0.02</u>	<u>0.01</u>
<u>Methiocarb</u>	<u>0.02</u>	<u>0.01</u>
<u>Methomyl</u>	<u>0.05</u>	<u>0.025</u>
<u>Methoprene</u>	<u>2</u>	<u>*</u> <u>-</u>
<u>Mevinphos</u>	<u>0.05</u>	<u>0.025</u>
<u>MGK-264</u>	<u>0.05</u>	<u>*</u> <u>-</u>
<u>Myclobutanil</u>	<u>0.02</u>	<u>0.01</u>
<u>Naled</u>	<u>0.1</u>	<u>*</u> <u>-</u>
<u>Novaluron</u>	<u>0.05</u>	<u>0.025</u>
<u>Oxamyl</u>	<u>3.0</u>	<u>1.5</u>
<u>Paclobutrazol</u>	<u>0.02</u>	<u>0.01</u>
<u>Parathion-methyl</u>	<u>0.05</u>	<u>*</u> <u>-</u>
<u>Permethrin</u>	<u>0.5</u>	<u>*</u> <u>-</u>
<u>Phenothrin</u>	<u>0.05</u>	<u>*</u> <u>-</u>
<u>Phosmet</u>	<u>0.02</u>	<u>*</u> <u>-</u>
<u>Piperonyl butoxide</u>	<u>0.2</u>	<u>1.25</u>
<u>Pirimicarb</u>	<u>0.02</u>	<u>0.01</u>

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> Parts per million (ppm)	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Prallethrin</u>	<u>0.05</u>	* -
<u>Propiconazole</u>	<u>0.1</u>	* -
<u>Propoxur</u>	<u>0.02</u>	<u>0.01</u>
<u>Pyraclostrobin</u>	<u>0.02</u>	<u>0.01</u>
<u>Pyrethrins</u>	<u>0.05</u>	* -
<u>Pyridaben</u>	<u>0.05</u>	<u>0.02</u>
<u>Pyriproxyfen</u>	<u>0.010</u>	* -
<u>Quintozene</u>	<u>0.02</u>	* -
<u>Resmethrin</u>	<u>0.1</u>	<u>0.05</u>
<u>Spinetoram</u>	<u>0.02</u>	<u>0.01</u>
<u>Spinosad</u>	<u>0.1</u>	<u>0.01</u>
<u>Spirodiclofen</u>	<u>0.25</u>	* -
<u>Spiromesifen</u>	<u>3</u>	* -
<u>Spirotetramat</u>	<u>0.02</u>	<u>0.01</u>
<u>Spiroxamine</u>	<u>0.1</u>	* -
<u>Tebuconazole</u>	<u>0.05</u>	<u>0.01</u>
<u>Tebufenozide</u>	<u>0.02</u>	<u>0.01</u>
<u>Teflubenzuron</u>	<u>0.05</u>	<u>0.025</u>
<u>Tetrachlorvinphos</u>	<u>0.02</u>	<u>0.01</u>
<u>Tetramethrin</u>	<u>0.1</u>	* -
<u>Thiabendazole</u>	<u>0.020</u>	* -
<u>Thiacloprid</u>	<u>0.02</u>	<u>0.01</u>
<u>Thiamethoxam</u>	<u>0.02</u>	<u>0.01</u>
<u>Thiophanate-methyl</u>	<u>0.05</u>	* -

<u>Substance</u> <u>(pesticides)</u>	<u>Detection Limit</u> Parts per million (ppm)	
	<u>Product Type</u>	
	<u>Dried Hemp</u>	<u>Hemp Oil</u>
<u>Trifloxystrobin</u>	<u>0.02</u>	<u>0.01</u>

\* Note: LOQ not available or established.

d. Heavy Metals

<u>Substance</u> <u>(heavy metals)</u>	<u>Action Limits</u> <u>(extracts, foods, supplements)</u> Parts per million (ppm)
<u>Arsenic</u>	<u>&lt; 1.5</u>
<u>Cadmium</u>	<u>&lt; 0.5</u>
<u>Lead</u>	<u>&lt; 0.5</u>
<u>Mercury</u>	<u>&lt; 1.5</u>

e. Residual Solvents

<u>Substance</u>	<u>Action Limits</u> <u>(solvent based industrial hemp</u> <u>extracts)</u> Parts per million (ppm)
<u>Acetone</u>	<u>&lt; 1,000</u>
<u>Benzene*</u>	<u>&lt;2</u>
<u>Butanes</u>	<u>&lt; 1,000</u>
<u>Ethanol</u>	<u>&lt; 1,000</u>
<u>Ethyl Acetate</u>	<u>&lt; 1,000</u>
<u>Heptanes</u>	<u>&lt; 1,000</u>
<u>Hexane</u>	<u>&lt; 60</u>
<u>Isopropyl Alcohol</u>	<u>&lt; 1,000</u>
<u>Methanol</u>	<u>&lt; 600</u>
<u>Pentane</u>	<u>&lt; 1,000</u>

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<u>Substance</u> (residual solvents)	<u>Action Limits</u> (solvent based industrial hemp extracts)  Parts per million (ppm)
<u>Propane</u>	< 1,000
<u>Toluene*</u>	< 180
<u>Total Xylenes (m, p, o-xylenes)*</u>	< 430
<u>Any other solvent not permitted for use</u>	None detected

\* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use, limits have been listed here accordingly.

#### G. Packaging and Labeling Requirements

1. Effective July 1, 2021, packaging and labeling shall be performed in accordance with the department's labeling requirements for industrial hemp food products listed in sections 21.7(G)(2-6).
2. Industrial hemp product packaging shall be food-grade or GRAS and labeling shall be performed in accordance with 21 C.F.R. 101, subparts A-G and the department's labeling requirements for hemp food products, which includes:
  - a. Product Identity Statement (in bold type) which indicates the common or usual name of the food ingredient;
  - b. Manufacturing address or a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for" or "distributed by");
  - c. Net Weight Statement placed as a distinct item parallel to the base of the package in the bottom third of the principal display panel; and
  - d. List of ingredients, in descending order of predominance by weight:
    - (1) Identify industrial hemp as an ingredient;
    - (2) Identify each isolated cannabinoid as an ingredient and the amount labeled in milligrams or when using a broad or full spectrum product, label the total amount in milligrams; and
    - (3) Identify in milligrams the total THC content per serving and total THC content per individual finished product package.
3. Allergens shall be clearly identified and listed separately.

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- 473 4. A code or numbering system that identifies the date and location of  
474 manufacturing and packaging is required for tracking and assisting in recalls or  
475 trace forward/trace back efforts.
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- 477 5. Health Benefit Claims for hemp or hemp-derived ingredients must be  
478 substantiated and should follow Federal Trade Commission (FTC) and FDA  
479 guidance, including marketing materials and electronic communications.
- 480
- 481 6. The label of a cosmetic product shall bear a warning statement whenever  
482 necessary or appropriate to prevent a health hazard that may be associated  
483 with the product. This applies to unsubstantiated claims on products and as well  
484 as ingredients, aerosol products, deodorant products, foaming detergent bath  
485 products, coal tar hair dyes, sun-tanning and sunscreen products. Additional  
486 cosmetic labeling requirements are listed in 21 C.F.R. 701, subparts A-C.

#### 487 H. Record Keeping

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- 490 1. For all facilities, the following records shall be maintained, as required herein:
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- 492 a. Certificates of analysis;
- 493
- 494 b. Batch production records;
- 495
- 496 c. Recalled product information;
- 497
- 498 d. Source of ingredients; and
- 499
- 500 e. Other records as required by the department (e.g., ingredient records,  
501 corrective action logs, mock recall documents, calibration records, as  
502 applicable).
- 503
- 504 2. For all facilities, records shall:
- 505
- 506 a. Be kept as original records, true copies (such as photocopies, pictures,  
507 scanned copies, microfilm, microfiche, or other accurate reproductions  
508 of the original record(s), or electronic records;
- 509
- 510 b. Contain the actual values and observations obtained during monitoring  
511 and, as appropriate, during verification activities;
- 512
- 513 c. Be accurate, indelible, and legible;
- 514
- 515 d. Be created concurrently with performance of the activity documented;
- 516
- 517 e. Be as detailed as necessary to provide history of work performed; and  
518 include:
- 519
- 520 (1) Information adequate to identify the plant or facility (e.g., the  
521 name and, when necessary, location of the plant of facility);
- 522
- 523 (2) The date and time of the activity documented, when  
524 appropriate;

525 (3) The signature or initials of the person performing the activity;  
526 and

527  
528 (4) The identity of the product and the lot code, when appropriate.  
529

530 3. Record retention for cGMP facilities

531  
532 a. Records shall be retained at the plant or facility for at least 2 years  
533 after the date they were prepared.

534  
535 4. Record retention for dietary supplement facilities

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537 a. Records shall be kept for one year past the shelf life date, if the shelf  
538 life dating is used, or two years beyond the date of distribution of the  
539 last batch of dietary supplements associated with those records.

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541 I. Recalls

542  
543 1. Industrial hemp product processing and manufacturing facilities shall establish  
544 a written recall plan in accordance with 21 C.F.R. 117.139, *Recall Plan*, that  
545 includes procedures that describe the steps to be taken, and assign  
546 responsibility for taking those steps, to perform the following actions as  
547 appropriate to the facility:

548  
549 a. Directly notify the direct consignees of the food being recalled,  
550 including how to return or dispose of the affected product;

551  
552 b. Notify the public about any hazard presented by the product when  
553 appropriate to protect public health;

554  
555 c. Conduct effectiveness checks to verify that the recall is carried out; and

556  
557 d. Appropriately dispose of recalled product (e.g., through reprocessing or  
558 reworking as appropriate, or diverting to a use that does not present a  
559 safety concern, or destroying the product).

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561 J. Transportation

562  
563 1. Transfer of industrial hemp or unfinished industrial hemp product shall be  
564 conducted in accordance with the law.

565  
566 2. Industrial hemp, unfinished industrial hemp products, and industrial hemp  
567 products shall be transported in a manner where they will be protected from  
568 adulteration, allergen cross-contact, environmental contamination and any  
569 other hazards.

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571 K. Waste Management

572  
573 1. Industrial hemp-derived THC shall be diluted to a concentration less than 0.3%,  
574 converted, or disposed of in accordance with the department's Hazardous and  
575 Waste Management Division's *Marijuana and Marijuana-Related Waste Disposal*  
576 Compliance Bulletin.

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2. Facility owner/operator is responsible to secure and limit access to industrial hemp-derived THC with a concentration greater than 0.3%.

**21.721.8 Enforcement**

- A. 1. Wholesale food manufacturers that fail to submit a complete and accurate annual application for registration, or fail to remit fees in accordance with Section 25-5-426(4), C.R.S., are not considered an approved source for introduction of manufactured food into retail commerce.
2. Wholesale food manufacturers who are also shellfish dealers that fail to submit a complete and accurate annual application for certification are not considered an approved source for introduction of shellfish into retail commerce.
- B. Adulterated or misbranded food, including food from unapproved sources, may be embargoed in accordance with Section 25-5-406, C.R.S.
- C. In accordance with Section 25-1.5-102(1)(c), C.R.S., the department may require wholesale food manufacturers, including wholesale food manufacturers who are also shellfish dealers, to recall adulterated or misbranded food in order to investigate and control the causes of epidemic and communicable diseases affecting public health.
- D. Pursuant to Sections 25-4-1810 and 25-5-420, C.R.S., if the department has reasonable cause to believe a violation of this regulation has occurred and immediate enforcement is necessary, it may issue a cease-and-desist order, which shall set forth the provisions alleged to have been violated, the facts constituting the violation, and the requirement that all violating actions immediately cease.
1. At any time after service of the order to cease and desist by certified mail, the person for whom such order was served may request a hearing to determine whether such violation has occurred. Such hearing will be conducted in conformance with the provisions of article 4 of title 24, C.R.S. and shall be determined promptly.
- E. To the extent and manner authorized by law, the department may issue letters of admonition or may deny, suspend, refuse to renew, restrict, or revoke any wholesale food manufacturer registration or any shellfish dealer certification if the wholesale food manufacturer or wholesale food manufacturer who is also a shellfish dealer has:
1. Refused or failed to comply with any provision of this regulation or any lawful order of the department;
2. Had an equivalent certification or registration denied, revoked, or suspended by another authority, including but not limited to another state, or the U.S. Food and Drug Administration;
3. Refused to provide the department with reasonable, complete, and accurate information when requested by the department; or
4. Falsified any information submitted to the department.
- F. In addition to the requirements herein, when the department determines that a wholesale food manufacturer who is also a shellfish dealer's activity constitutes a

630 major public health threat, the department shall cooperate with other authorities  
631 pursuant to Section 25-4-1805(5), C.R.S