

**COLORADO**Department of Public
Health & Environment

To: Members of the State Board of Health

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

Date: November 15, 2023

Subject: **Request for Rulemaking Hearing**
Proposed Creation of 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations* for the rulemaking hearing to occur in November 2023

The Division of Environmental Health and Sustainability (“division”) is proposing the creation of 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations* and is requesting that the Board of Health adopt the proposed regulations at the November 15, 2023, Board of Health meeting.

In compliance with the State Administrative Procedure Act, §24-4-103.3, C.R.S., the Colorado Department of Public Health and Environment (“department”) is proposing creation of 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*. The creation of this regulation is proposed in coordination with amendments to 6 CCR 1010-21, *Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations* which remove all requirements associated with hemp products in Colorado from that regulation.

Senate bill SB22-205 established a task force to study intoxicating hemp products and to make recommendations for legislative and rule changes. (The task force report can be found [here](#) along with the department’s and Marijuana Enforcement Division’s [report supplement](#).) Senate bill SB23-271 codified the work of the task force and activated significant changes and additions to the requirements placed on regulated hemp products in Colorado. This rulemaking addresses the changes codified in SB23-271 by establishing requirements for regulated hemp products in a new regulation, 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*.

This 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 hemp product and safe harbor hemp product manufacturers and storage facilities, incorporates additional requirements to define and clarify manufacturing and testing requirements for the production of hemp products in Colorado, and establishes new requirements for safe harbor hemp products. Safe harbor hemp products are allowed to be manufactured, produced, packaged, processed, prepared, treated, transported, or held for export from Colorado but are not permitted to be sold or distributed 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://advance.lexis.com/container?config=0345494EJAA5ZjE0MDIyYy1kNzZkLTRkNzk tYTkxMS04YmJhNjBlNWUwYzYKAFBvZENhdGFsb2e4CaPI4cak6laXLCWyLBO9&crd=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

The proposed rule applies the definition of relevant terms, ingredient and approved-source standards, potency and purity testing standards, permissible levels of contaminants, packaging and labeling, record-keeping, transportation, waste management requirements and enforcement provisions, 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 25-5-427 *et seq*, 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 hemp product and safe harbor hemp product requirements identified through the SB22-205 task force, SB23-271, and the division's stakeholder engagement process will retain current public health protections while maintaining the efficiency and effectiveness of the rulemaking process.

The division appreciates the Board's consideration.

Following the Request for Rulemaking Hearing held on September 20, 2023, and based on feedback received from stakeholders, substantive amendments were made to the proposed regulation and highlighted for ease of reference.

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Creation of**

6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*

Basis and Purpose.

Creation of the *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*, 6 CCR 1010-24 include regulatory requirements based on broad stakeholder input received from the task force created by SB22-205, requirements codified by SB23-271, and the division's stakeholder engagement process. Regulation of hemp products has evolved to the point that a dedicated, stand-alone regulation is required for those products, which are quite different than those typically regulated under the wholesale food manufacturing and shellfish regulations that are currently applied. A new rule, specific to hemp-derived products, provides clarity and ease of implementation for both the hemp and wholesale food industries.

Simultaneous with the proposed creation of 6 CCR 1010-24, the *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*, regulation 6 CCR 1010-21, *Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations* is being revised to remove all requirements for hemp products in Colorado from that regulation and continue the regulation's specific applicability to wholesale food manufacturers, storage facilities, and shellfish operations.

The regulatory requirements in 6 CCR 1010-24, the *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*, do not infer conformance with federal laws and the allowance for manufacturing, sale, and distribution of hemp products and safe harbor hemp products to other states or countries. U.S. Food and Drug Administration ("FDA") does not recognize hemp as an allowable food ingredient; therefore, the proposed regulation does not govern the allowance of interstate commerce. However, Colorado's hemp product manufacturers and storage facilities have been 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, maintains public health protections while:

- Providing alignment with current and nationally accepted federal standards for the production of cosmetics, dietary supplements and foods for Colorado hemp product manufacturers and storage facilities; and
- Maintaining the efficiency and effectiveness of the rulemaking process and Department services.

Based on the outcomes from the SB22-205 Task Force, [SB23-271 - "Intoxicating Hemp"](#) and the division's stakeholder process, this proposed regulation was developed and includes:

- Updated and new definitions which establish hemp product tetrahydrocannabinol ("THC") thresholds;
- Safe harbor hemp product registration requirements;
- Updated manufacturing/production requirements;
- Modified testing requirements and a new potency testing requirement;
- Updates, additions, and clarifications to packaging and labeling requirements;
- Specific additional production requirements for safe harbor hemp products; and
- New enforcement provisions.

➤ **Several terms were added and others updated to close loop holes and eliminate regulatory ambiguity**

- *Approved Source*. Added clarifying language to allow for hemp products and/or ingredients from other states to be considered approved if certain conditions are met.
- *Full spectrum*. Added clarifying language to align with statute and remove the provision of percentage (%) of THC, and established THC limits in milligrams (mg) along with minimum CBD to THC ratios.
- *Hemp product*. This definition was updated to mirror the statutory definition that SB23-271 changed. The key change establishes a maximum amount of THC, in milligrams, per serving and establishes a minimum ratio of CBD to THC versus just a percentage limit of THC. The significance of these changes are discussed in more detail below in the section on THC limits.
- *Intoxicating and non-intoxicating cannabinoid*. These are new definitions in the regulation and mirror the statutory definitions adopted in SB23-271. These definitions clarify that hemp products to be sold in Colorado cannot contain intoxicating levels of cannabinoids, and identify which cannabinoids are considered non-intoxicating and therefore allowed in hemp products.
- *Safe harbor hemp product*. This is a new definition to the regulation and mirrors what is contained in statute. The statute allows for these products and directs the department to develop regulations around the manufacturing, testing, and labeling of these products. While there was significant debate within the task force and at the legislature on the legal and public health policy issues associated with the safe harbor provision, based on the clear legislative direction to allow for and regulate these products, these proposed rules implement the requirements of the law.
- *Semi-synthetic and synthetic cannabinoid*. These are new definitions to the regulation and mirror what is in statute. The statute and regulation prohibit the conversion, creation, bio-synthesis or bio-conversion of material into a synthetic cannabinoid and the use of that cannabinoid into hemp or safe harbor hemp products.
- *Serving*. A new definition in the regulation and mirrors what is in statute and is intended to ensure hemp products serving size aligns with traditional foods or supplements to prevent a distortion of how much THC can be in a product that is normally consumed in one or two servings.
- *Tincture*. A new definition in the regulation and mirrors what is in statute and draws a distinction between these products and other liquids, beverages or edible products.

➤ **Limits on the amount of THC in hemp products**

THC limits for hemp products were established within the definition of full spectrum, hemp products, non-intoxicating hemp products and the offenses section of the regulation. Significant discussions were held during the SB22-205 task force meetings and at the legislature when developing SB23-271 regarding how to ensure hemp products would not be intoxicating to the consumer. While the hemp market in Colorado, and nationally, has expanded significantly over the years, hemp products initially developed, manufactured and marketed were cannabidiol (“CBD”) isolate or full spectrum hemp products.¹

¹ Full spectrum hemp extract is a concentration of all components of the hemp plant, including cannabinoids, terpenes, plant sterols, fatty acids, flavonoids, and essential oils, vitamins, and other nutrients

It has been well established and long accepted that CBD is not considered an intoxicating cannabinoid; and since the allowed THC amount in the cultivated hemp plant was not to exceed 0.3% THC, the prevailing thought was that any full spectrum product would naturally be non-intoxicating due to the very low level of THC in the plant. However, associating low-level amounts of THC in the plant (0.3%) to a finished food or other consumer product does not correlate in a manner that ensures a hemp product contains very low THC amounts. In fact, when applying the percent THC allowance to a finished hemp product, products with THC levels well above that of allowed marijuana products could result. Below are two examples to illustrate that point:

1. Typical size chocolate bar

- Each ounce of a product equates to 28.3 grams
- Bar size is 1.55 ounces or 44 grams
- $44 \text{ grams} \times 0.003$ (max allowable THC of 0.3%) = 0.132 grams THC
- 0.132 grams of THC = 132 mg allowable THC in one 1.55 oz. chocolate bar

If the chocolate bar consisted of 10 distinct homogeneous pieces/servings, each piece/serving would have 13.2 mg of THC. Colorado marijuana regulations require no more than 10 mg of THC per serving and that the container or entire product not exceed 100 mg. The hemp product chocolate bar in this example would exceed both serving size and total package THC limits established for marijuana products.

2. A 12 oz. hemp-infused beverage

- One fluid ounce equates to 29.57 grams
- 12 ounce beverage = 355 grams
- $355 \text{ grams} \times 0.003$ (max THC of 0.3%) = 1.065 grams THC
- 1.065 grams THC = 1,065 mg allowable THC in one 12 oz. hemp-infused beverage.

A typical 12 oz. beverage is considered one serving. If this hemp beverage was compared to a similar product within the marijuana-regulated industry, it would contain over 10 times the allowed THC per container, thus representing a significant risk to the consumer.

To correct the unintended consequences described above, the law and these regulations establish a maximum limit on the amount of THC per serving, along with a minimum ratio of CBD to THC in the product. The establishment of these limits in law and the proposed regulations were based on a number of factors.

- Hemp plants and their full or broad spectrum² extracts have a number of naturally occurring elements and cannabinoids that work synergistically with each other to provide a number of purported benefits. This interplay of naturally occurring cannabinoids is referred to as the entourage effect.

² Broad-spectrum hemp products contain a range of naturally occurring compounds from the cannabis plant, but with tetrahydrocannabinol (THC) removed from the product.

- The goal of allowing for the production of hemp products was to allow for these benefits to be realized by consumers, while not creating products that illicit intoxication.
- Recent studies have indicated that for products with higher concentrations of CBD and lower levels of THC, the CBD mitigates the intoxicating effects of the THC.

Based on these factors, a limit of 1.75 mg THC/serving and a minimum ratio of CBD to THC of 15 to one (15:1) was established. In order for a hemp product to be sold in Colorado, this regulation would require laboratory test results from a certified CDPHE laboratory indicating the product contains no more than 1.75 mg of THC and contains a ratio of CBD to THC of at least 15:1. Additionally, any product that contains more than 1.25 mg of THC, with a ratio of CBD to THC of less than 20:1 cannot be sold to someone under the age of 21.

➤ **Registration requirements for Safe Harbor hemp product**

SB23-271 created the allowance for products not allowed for sale or distribution in Colorado to be produced here and shipped to other states that had not specifically prohibited the products in their state laws/statutes. Provisions have been placed around the registration requirements for these operations within these proposed regulations. Specifically, in order to register in Colorado, safe harbor manufacturers or storage facilities must demonstrate compliance with the federal current good manufacturing practices for food or dietary supplements by submitting to the department an annual inspection from a department-approved third-party auditor starting in July 2024, and by July 1 of each year thereafter. In addition, these operations will have to submit:

- An attestation form, which formally certifies that:
 - 1) The safe harbor manufacturer or storage facility does not export a safe harbor hemp product to a state where the safe harbor hemp product is prohibited by state law.
 - 2) The safe harbor manufacturer or storage facility does not manufacture, produce, or distribute a synthetic cannabinoid.
 - 3) The safe harbor hemp product is manufactured, produced, tested, labeled, stored, and distributed in accordance with all applicable rules.
 - 4) The safe harbor manufacturer or storage facility is:
 - a. Not a registered hemp manufacturer or storage facility or a registered wholesale food manufacturer or storage facility; or
 - b. If the safe harbor manufacturer or storage facility is a registered wholesale food or hemp manufacturer or storage facility, each safe harbor hemp product is:
 - i. Physically separated from hemp or food products during the manufacturing, production, storage, and distribution of the safe harbor hemp product; or
 - ii. Manufactured, produced, stored, and distributed in accordance with procedures approved by the department that ensure no cross contamination between safe harbor hemp products and hemp products or food.

While the law prohibits these products for sale and/or distribution in Colorado, the legislature, by allowing for the manufacturing to take place in Colorado, was trying to strike a balance by recognizing:

- Significant investment many businesses have made in the production of products that the initial federal Farm Bill and Colorado laws did not consider;
- Economic impacts to the state, employers and employees if these business were no longer considered legal in Colorado; and
- Other states have not made the distinctions that Colorado has between non-intoxicating and intoxicating hemp products; therefore, Colorado manufacturers should be able to compete and take advantage of the allowances available within other states.

➤ ***Manufacturing requirements***

The proposed regulations maintain the requirements established in the 2021 industrial hemp regulations to comply with Title 21 of the Code of Federal Regulations (C.F.R.) 100-111, 113-170, and 172-190 (2017) as the basis for the regulation of cosmetic, dietary supplement and food manufacturers in Colorado. Additional requirements included in the proposed regulation were developed for safe harbor hemp product manufactures and are listed in section 24.8 of the regulation. These requirements are specific to the ability to co-locate the manufacturing of safe harbor hemp products with hemp products, and were developed to prevent cross-contamination between the product types.

➤ ***Testing requirements***

The proposed regulations maintain the current testing requirements with updated action limits established in the original hemp regulations adopted in 2021, which includes testing of finished products and/or ingredients for the presence of microbials, mycotoxins, heavy metals, pesticides, and residual solvents. A few updates were made and include:

- Removing certain solvents to be tested for as they were removed from the approved solvent list;
- Changing the action limits on some solvents to align with requirements from other agencies and to reduce risk wherever possible; and
- Requiring to test products for potency, specifically THC, CBD, and any other cannabinoids identified/claimed/labeled to be in the finished product;

Additionally, the establishment of limits of quantification (LOQ) for the pesticide testing was removed from this proposed regulation. The approval of the analytical methods and thus the LOQ are established/approved in accordance with the *Hemp Testing Laboratory Certification* rules previously adopted by this Board, found at 5 CCR 1005-5; thus, inclusion in these regulations was redundant and created confusion.

Finally, consideration was given to establishing a serving size limit for the non-intoxicating cannabinoids allowed by the law. This concept was not included in the proposed regulations for a number of reasons:

- CBD and THC ratios/limits were expressly debated and considered during the development of the law, but product or serving size limits for non-intoxicating

cannabinoids were not discussed.

- Limited data exists as to what limits should be established and differ based on the cannabinoid in question; thus, attempting to establish a serving size limit would have been unavoidably arbitrary at this time.
- Consumers are informed based on the labeling that these products have not been evaluated for safety and efficacy, and establishing limits potentially infers a known safe serving size.

➤ **Packaging and labeling requirements**

The current regulation requires product packaging to conform to the federal labeling requirements for dietary supplements or food. In these proposed regulations, clarity was provided on how to apply those requirements to hemp and safe harbor hemp products. Clarification included minimum type or font size, location or disclosures of where certain information was required to be placed, and how to label and disclose THC or other cannabinoids in the product. These rules also add the requirement that the labels and packaging cannot be designed to appeal to children.

Additionally, the label of each hemp and safe harbor hemp product that contain intoxicating cannabinoids or potentially intoxicating cannabinoids is required to include a consumer notice statement that discloses the presence of intoxicating or potentially intoxicating cannabinoids, and includes at least the following notices:

- The potential for these products to cause a positive drug test result;
- The potential for these products to create impairment;
- Indication that these products have not been evaluated for safety or efficacy; and
- Recommending those that are pregnant, may become pregnant, or are breastfeeding to consult with their physician about the use of these products.

Also, the label of hemp and safe harbor hemp products that contain CBD is required to include a notice statement that informs the consumer of the presence of the CBD, and include at least the following notices:

- Recommending those that are pregnant, may become pregnant, or are breastfeeding to consult with their physician about the use of these products; and
- May cause health problems including liver injury, damage to male reproductive health, and sedative effects that may impair your ability to drive a motor vehicle or operate machinery.

Among other requirements, hemp product packaging under this proposed regulation would be required to:

- Identify, in milligrams, the total THC content per serving and total THC content per individual finished product package;
- Identify the ratio of CBD to THC per individual finished product package; and
- Identify the number of servings per individual finished product package.

In addition to the requirements listed above, safe harbor hemp products would be required to indicate on the label “that the product is approved for sale outside of Colorado.”

Lengthy discussions were held with stakeholders regarding the labeling requirements and vastly differing opinions were expressed. While we believe the proposed regulations represent consensus among the stakeholders, the division anticipates testimony both for and opposed to the rules at the rulemaking hearing.

The proposed requirements within this regulation represent the division’s best efforts to:

- Correlate the federal dietary supplement and food-labeling requirements to these products’ stakeholders;
- Meet the intention of state law with regard to consumer notice requirements;
- Ensure an honest representation of the product; and
- Ultimately, be protective of public health.

The substantive areas of dissenting views are included below, followed by the division’s rationale for maintaining inclusion in the proposed regulations for consideration by the Board of Health.

- Concerns with the volume of information being required and how it can fit on a label/package:
 - *Division Rationale: The amount of information being required is dictated by the product and the need to inform consumers. Package size can be increased along with the use of labeling foldouts to accommodate the required information.*
- The requirement to provide the consumer notice regarding health impacts for products containing CBD:
 - *Division Rationale: This requirement is based on current information being disseminated by FDA.*
- A desire to include more prescriptive language in the notices:
 - *Division Rationale: We believes prescriptive language is not necessary and limits the ability to communicate effectively with consumers.*
- Concerns from safe harbor stakeholders on the requirement to label products not for sale or distribution in Colorado.
 - *Division Rationale: During stakeholder meetings, safe harbor hemp product manufacturers expressed concern about being held responsible for their products once shipped out of state and those products being “redistributed” back to Colorado. These stakeholders indicated an inability to control what downstream distributors do with their products and that holding them responsible for another’s actions would be inappropriate. Based on these concerns, the labeling requirement was established to make the prohibition clear to distributors and simplify surveillance and enforcement of the statutory requirement. Based on feedback at our final stakeholder meeting on September 15, 2023, and as was discussed at the request hearing before this*

Board on September 20, 2023, the proposed language was modified to state “...these products are approved for sale outside of Colorado.”

This labeling requirement aligns with the offenses established in law (mirrored in this proposed regulation) which states:

“The distribution of a safe harbor product in Colorado or to a State that prohibits the product is prohibited.”

➤ ***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.

Specific Statutory Authority.

Statutes that require or authorize rulemaking: Sections 25-5-420(1), and 25-5-427 *et seq*, Colorado Revised Statute (C.R.S.)

Is this rulemaking due to a change in state statute?

Yes, the bill number is SB23-271. 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 Creation of

6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product 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
Hemp product manufacturers, processors, transporters, or storage facilities registered with the department.	~400	C
Wholesale food manufacturers or storage facilities registered with the department.	~2100	S
Medical and retail marijuana dispensaries	~700	S
Colorado Dept. of Public Health & Environment	~1,750	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 / CDPHE Laboratory	~21	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
Hemp product consumers in Colorado	~1.5M	S/B
Hemp product 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.
- CLG** = local governments that must implement the rule in order to remain in compliance with the law.
- 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.**

The department and the regulated community are all affected and will benefit from the regulation. Maintaining the incorporation by reference of the federal requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017), as applicable to regulated hemp facilities, and adoption of the requirements codified by SB23-271 ensures that these products in Colorado come from approved sources, are tested for potency and purity, are packaged and labeled properly to be informative to consumers, are subject to an established recall plan (if necessary), and are transported and disposed of properly. The rules further require the retention of necessary records.

Costs borne by the department are minimal and administrative in nature.

Hemp product and safe harbor hemp product manufacturers and storage facilities will bear the costs associated with the proposed testing and labeling requirements. While the proposed laboratory testing of these products may represent an economic impact to industry partners, these anticipated costs were discussed and vetted during the SB22-205 task force meetings, committee meetings and legislative deliberations as part of the passage of SB23-271, which included stakeholder outreach by the division through its stakeholder process. Additionally, the vast majority of testing requirements have been in place since 2021.

Regulated hemp facilities 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 hemp and safe harbor hemp product manufacturers and storage facilities. The surety of the proposed regulation, including the testing and labeling standards, provides stability and validity to this novel, growing and competitive industry. Manufacturers of regulated hemp products understand that continued alignment with current industry standards and adoption of the proposed requirements are necessary to refine and clarify manufacturing, testing, and labeling requirements for the production of hemp products and safe harbor hemp products in Colorado.

Maintaining the requirements of 21 C.F.R. 100-111, 113-170, and 172-190 (2017) as applicable to hemp and safe harbor hemp product manufacturers and storage facilities, and inclusion of the proposed manufacturing, testing and labeling requirements, will continue to safeguard public health and ensure that products containing hemp that are sold and distributed are unadulterated and honestly presented to all consumers. The proposed regulation will continue to assure uniformity and effectiveness in the implementation of appropriate safety standards and promote informed decision-making for 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: Hemp product manufacturers and safe harbor hemp product manufacturers will bear the costs associated with the proposed analytical testing and product labeling requirements. Although the required laboratory testing may represent an economic impact to our industry partners, these anticipated costs were discussed and vetted during the SB22-205 task force meetings, legislative deliberations, and throughout the division's early stakeholder engagement process, and are a continuation of already established requirements. In order to minimize the impacts of changes to the labeling requirements, those provisions will not be effective until June 1, 2024, which allows time for the development of new labels as well as minimizes lost costs on labels already in stock.
- CLG: No anticipated financial costs or benefits were identified.
- 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 these proposed amendments that ensure that food, dietary supplements, or cosmetics containing hemp that are manufactured or processed in Colorado are unadulterated, safe, and contain label information that allows the consumer to make an informed decision prior to purchase and/or consumption.

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: Regulated hemp facilities 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 hemp product manufacturers and processors and that the surety of the proposed regulation provides stability and validity to this novel industry. Manufacturers of hemp products in Colorado understand that maintaining alignment with current federal manufacturing standards and adoption of the proposed state-specific requirements provides clarity regarding the manufacturing, testing and labeling requirements for the production of hemp and safe harbor hemp products in Colorado.
- CLG: No anticipated impact.
- S: The department will benefit from the proposed revisions by ensuring that the sale and distribution of Colorado's hemp products are consistent with established federal manufacturing requirements, which include:
- ingredients must come from approved sources and are tested for potency and purity at a CDPHE certified laboratory,
 - creation of product packaging and labeling requirements in accordance with both 21 C.F.R. 101(A-G) (2017) and additional state requirements,
 - products are subject to an established written recall plan (if necessary),
 - products are transported and disposed in accordance with the law, and
 - manufacturers retain necessary records.

- B: Colorado customers who consume hemp products will benefit from the proposed revisions that ensure that the sale and distribution of Colorado's hemp products are consistent with established federal food and dietary supplement safety requirements, include additional requirements to ensure product safety that are unique to this industry, and provide sufficient package labeling information for the consumer to make an informed decision about what they are purchasing.

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:**
\$1.57M

Anticipated CDPHE Revenues: \$405,876 from the wholesale food manufacturing and storage protection fund for rule implementation and enforcement, and \$1,168,485 from the general fund for administration, support and legal services. Registration fees for hemp product and safe harbor hemp product manufacturers were amended in statute via SB23-271 at Section 25-5-427, 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):

- | |
|--|
| <p>1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO₂e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO₂e per year by June 30, 2020 and to 113.144 million metric tons of CO₂e by June 30, 2023.</p> <p><input type="checkbox"/> Contributes to the blueprint for pollution reduction
 <input type="checkbox"/> Reduces carbon dioxide from transportation
 <input type="checkbox"/> Reduces methane emissions from oil and gas industry
 <input type="checkbox"/> Reduces carbon dioxide emissions from electricity sector</p> |
| <p>2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023.</p> |

<ul style="list-style-type: none"> ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
<p>3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023.</p> <ul style="list-style-type: none"> ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ 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. 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> <ul style="list-style-type: none"> ___ Ensures access to breastfeeding-friendly environments.
<p>5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023.</p> <ul style="list-style-type: none"> ___ 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. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
<p>6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023.</p> <ul style="list-style-type: none"> ___ Creates a roadmap to address suicide in Colorado. ___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate. ___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries. ___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.
<p>7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020.</p> <ul style="list-style-type: none"> ___ Conducts a gap assessment. ___ Updates existing plans to address identified gaps. ___ Develops and conducts various exercises to close gaps.

<p>8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023.</p> <p><input type="checkbox"/> Uses an assessment tool to measure competency for CDPHE’s response to an outbreak or environmental incident.</p> <p><input type="checkbox"/> Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment.</p> <p><input type="checkbox"/> 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><input type="checkbox"/> Implements the CDPHE Digital Transformation Plan.</p> <p><input type="checkbox"/> Optimizes processes prior to digitizing them.</p> <p><input type="checkbox"/> Improves data dissemination and interoperability methods and timeliness.</p>
<p>10. Reduce CDPHE’s Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023.</p> <p><input type="checkbox"/> Reduces emissions from employee commuting</p> <p><input type="checkbox"/> Reduces emissions from CDPHE operations</p>
<p>11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023.</p> <p><input type="checkbox"/> Used a budget equity assessment</p>

X Advances CDPHE Division-level strategic priorities.

The division Workplan, within CDPHE’s Strategic Plan, identifies “Easily accessible and digestible information” as Priority #3. Separation of the hemp product regulations from the wholesale food manufacturer, storage facility and shellfish dealer regulations supports this priority.

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 hemp product 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 hemp product manufacturers and processors achieves alignment with existing federal wholesale food and dietary supplement regulations and continues levels of manufacturing 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 rulemaking were considered. SB23-271 codified significant changes and additions to the requirements placed on hemp products in Colorado which have been historically regulated under 6 CCR 1010-21, *Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations*. Regulation of hemp products has evolved to the point that a dedicated, stand-alone regulation is required for those products; thus, the creation of requirements for hemp products are proposed within this new rule set. The regulations continue to incorporate by reference the 2017 base requirements of the federal wholesale food and dietary supplement regulations and are necessary in achieving and ensuring the safe production of these products.

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 regulation creation incorporates stakeholder input from the SB22-205 task force, SB23-271 statutory amendments, and the division's stakeholder engagement process, and are necessary to refine and clarify manufacturing and testing requirements for the production of hemp products in Colorado.

Maintaining the incorporation by reference of current federal wholesale food and dietary supplement regulations 21 C.F.R. 100-111, 113-170, and 172-190 (2017) and application of the proposed requirements clarifying approved sources, testing, packaging and labeling, record keeping, recalls, transportation, and waste management, for the hemp industry will be a benefit to the department, the regulated community, and the public, both in the short- and long-term.

STAKEHOLDER ENGAGEMENT for Creation of

6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product 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:

Over 400 hemp registrants, trade associations, members from the SB22-205 Task Force not included within other stakeholder groups, staff from various CDPHE divisions, staff from the Marijuana Enforcement Division, the Attorney General's Office, the Governor's Office, Colorado Department of Agriculture, Colorado Bureau of Investigations, Colorado State University, law firms engaged in hemp activities, hemp certified laboratories, local fire and police departments and other local government groups. In all over 600 stakeholders were provided noticed and invited to participate in the rule development process.

The stakeholder engagement process was initiated in July 2023, with the first meeting held on July 28, 2023 and subsequent meetings on August 11, August 25, and September 15, 2023. These stakeholder meetings were the culmination of separate but related processes and functions.

First, in 2022, SB22-205 - *Intoxicating Hemp and Tetrahydrocannabinol Products* was passed. The law created a task force to study intoxicating hemp products and make legislative and rule recommendations. The task force consisted of 20 members including representatives of state government, experts in marijuana and industrial hemp regulation, persons licensed in the marijuana and medical marijuana fields, persons working with industrial hemp, testing laboratories, and a representative of a county or district public health agency. The task force submitted a report to the general assembly on January 1, 2023. This report was founded on several core long-standing legal and policy principles that are fundamental to protecting public health and safety.

- The 2018 Farm Bill exempted hemp from the Controlled Substances Act (CSA) but expressly preserved the Food and Drug Administration's (FDA) authority to regulate hemp and products containing hemp ingredients under the Food, Drug, and Cosmetics Act (FDCA), as well as other product safety laws and regulations.
- FDA, the federal agency charged with implementing the FDCA and other safety laws, has not executed its responsibilities to regulate consumable products containing hemp ingredients since the passage of the 2018 Farm Bill. FDA also has not expanded their authority with respect to existing product safety regulations to encompass hemp products (except where products make egregious drug claims).
- In part due to the FDA's inaction, Colorado law authorized hemp businesses to develop and innovate novel cannabinoids as consumer products. States around the country are attempting to address regulation of these products to ensure consumer safety while continuing to encourage development and innovation within an emerging industry.
- The absence of FDA oversight and enforcement created an active market for THC-

based intoxicating hemp products that may not be compliant with federal product safety standards nor subject to state marijuana regulations. These products often have higher levels of THC than are permitted in marijuana stores, produced using chemical synthesis, and many operations do not meet fundamental safety-based manufacturing, processing, and retail standards.

- State action should be grounded in core federal product safety standards for the relevant consumer goods. Those regulations are founded on fundamental components of product safety to ensure products are safe for their intended use and not adulterated.

Based on this report and the task force request for action, the Colorado General Assembly during the last legislative session passed SB23-271 - "*Intoxicating Hemp Products*," which provided the department with broad and comprehensive rule-making authority. Based on the bill passage and the direction to promulgate rules, the division initiated our stakeholder process.

Stakeholder Group Notification

The stakeholder group was provided notice of the request for 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 10th of the month following the Request for Rulemaking).

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

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

Lengthy discussions were held with stakeholders regarding the labeling requirements and vastly differing opinions were expressed. While we believe the regulations represent consensus of the stakeholders, the division anticipates testimony both for and opposed to the rules at the rulemaking hearing.

The proposed requirements within this regulation represent the division's best efforts to:

- Correlate the federal dietary supplement and food-labeling requirement to these products stakeholders;
- Meet the intention of the law with regard to consumer notice requirements;
- Ensure honest representation of the product through labeling requirements; and
- Ultimately, be protective of public health.

The substantive areas of dissenting views are included below followed by the division's rationale for maintaining inclusion in the proposed regulations for consideration by the Board of Health:

- Concerns with the volume of information being required and how it can fit on a label/package:
 - *Division Rationale: The amount of information being required is dictated by the product and the need to inform consumers. Package size can be increased along with the use of labeling foldouts to accommodate the required information.*
- The requirement to provide the consumer notice regarding health impacts for products containing CBD:
 - *Division Rationale: This requirement is based on current information being disseminated by FDA.*
- A desire for more prescriptive language in the notices:
 - *Division Rationale: The division believes prescriptive language is not necessary and limits the ability to communicate effectively with consumers.*
- Concerns from safe harbor stakeholders on the requirement to label products not for sale or distribution in Colorado.
 - *Division Rationale: During stakeholder meetings, safe harbor hemp product manufacturers expressed concern about being held responsible for their products once shipped out of state and those products being "redistributed" back to Colorado. These stakeholders indicated an inability to control what downstream distributors do with their products and that holding them responsible for another's actions would be inappropriate. Based on these concerns, the labeling requirement was established to make the prohibition clear to distributors and simplify surveillance and enforcement of the statutory requirement. Based on feedback at the final stakeholder meeting on September 15, 2023, and as was discussed at the request hearing before this Board on September 20, 2023, language was modified to state "...these products are approved for sale outside of Colorado."*

This labeling requirement aligns with the offenses established in law (mirrored in this proposed regulation) which states:

"The distribution of a safe harbor product in Colorado or to a State that prohibits the product is prohibited."

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

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.	X	Reduces occupational hazards; improves an individual’s ability to secure or maintain employment; or, increases stability in an employer’s workforce.
X	Improves access to food and healthy food options.	X	Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child’s ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
	Other: _____ _____		Other: _____ _____

1 COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

2
3 Division of Environmental Health and Sustainability

4
5 COLORADO HEMP PRODUCT AND SAFE HARBOR HEMP PRODUCT REGULATIONS

6
7 6 CCR 1010-24

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

10
11 **24.1 Authority**

12
13 This regulation is adopted pursuant to Sections 25-5-420(1) and 25-5-427, Colorado Revised
14 Statute (C.R.S.) and is consistent with the requirements of the State Administrative Procedure
15 Act, Section 24-4-101, et seq., C.R.S.

16
17 **24.2 Scope and Purpose**

18
19 A. This regulation shall be applied for the protection of public health by ensuring that the
20 premises or places wherein hemp products and safe harbor hemp products are
21 produced, manufactured, packed, processed, prepared, treated, packaged,
22 transported, or held for distribution are in accordance with the “Pure Food and Drug
23 Law”, Section 25-5-401 et seq., C.R.S.

24
25 B. This regulation shall govern the registration of hemp product manufacturers or storage
26 facilities and safe harbor hemp product manufacturers or storage facilities. In
27 accordance with the powers and duties delineated in Sections 25-5-420 and 25-5-427,
28 C.R.S., the department has the following powers and duties:

- 29
30 1. To grant or refuse to grant registration and to grant or refuse to grant the
31 annual renewal of a registration;
32
33 2. To deny, suspend, or revoke a registration;
34
35 3. To issue a cease-and-desist order or clean-up order to address violations; and
36
37 4. To review any records of a hemp product manufacturers or storage facilities
38 and safe harbor hemp product manufacturers or storage facilities necessary to
39 verify compliance.

40
41 C. This regulation does not apply to:

- 42
43 1. Wholesale food manufacturers and the premises or places wherein
44 manufactured foods are produced, manufactured, packed, processed,
45 prepared, treated, packaged transported, or held for distribution governed by
46 the Colorado Wholesale Food and Shellfish Regulations, 6 CCR 1010-21.
47
48 2. Retail food establishments governed by the Colorado Retail Food Establishment
49 Regulations, 6 CCR 1010-2;
50
51 3. Facilities or conditions governed by the Colorado Milk and Dairy Products
52 Regulations, 6 CCR 1010-4;

- 1
2 4. Entities engaged in the business of possessing, cultivating, dispensing,
3 transferring, transporting, or testing Medical Marijuana or Retail Marijuana
4 governed by the *Colorado Marijuana Rules*, 1 CCR 212-3;
5
6 5. The cultivation of hemp governed by the *Rules Pertaining to the*
7 *Administration and Enforcement of the Industrial Hemp Regulatory Program*
8 *Act*, 8 CCR 1203-23;
9
10 6. Entities that are manufacturing intermediate or finished hemp products from
11 the fibrous material of the plant that are not intended for human consumption.
12 These products include, but are not limited to, cordage, paper, fuel, textiles,
13 bedding, insulation, construction materials, compost materials, hemp crete and
14 industrial materials; and
15
16 7. Testing performed by a certified laboratory in accordance with the *Hemp*
17 *Testing Laboratory Certification*, 5 CCR 1005-5.
18
19 D. Nothing in this rule shall be construed to limit the department’s statutory authority
20 under the “Pure Food and Drug Law” at Section 25-5-401 *et seq.*, C.R.S., the “Shellfish
21 Dealer Certification Act” at Section 25-4-1801 *et seq.*, C.R.S., disease investigation,
22 reporting and control pursuant to Sections 25-1.5-101 and 25-1.5-102, C.R.S., or
23 enforcement of “Sanitary Regulations” pursuant to Section 25-4-101 *et seq.*, C.R.S.
24

25 **24.3 Applicability**

- 26
27 A. This rule establishes registration requirements for hemp manufacturers or storage
28 facilities and safe harbor manufacturers or storage facilities in accordance with
29 Section 25-5-427, C.R.S.
30
31 1. These regulatory requirements do not infer conformance with federal laws, nor
32 do they determine the allowability of the sale and distribution of hemp
33 products and safe harbor hemp products to other states or countries.
34
35 B. Pursuant to Section 24.6, this rule incorporates by reference 21 Code of Federal
36 Regulations (CFR) 100-111, 113-170, and 172-190 (April 1, 2017).
37
38 C. This rule establishes enforcement standards for hemp product manufacturers or
39 storage facilities and safe harbor hemp product manufacturers or storage facilities
40 pursuant to Sections 25-1.5-102(1)(c), 25-5-406, 25-5-420, and 25-5-427(8)(a)-(d),
41 C.R.S.
42

43 **24.4 Definitions**

- 44
45 A. For the purpose of these rules and regulations, unless otherwise specified herein:
46
47 1. Approved Source means:
48
49 a. Cultivated hemp from a state that has an approved United States
50 Department of Agriculture hemp program; or
51
52 b. A product from a wholesale food manufacturer, hemp product

1 manufacturer or storage facility registered with the department in
2 accordance with Section 25-5-426 or 427, C.R.S; or

3
4 c. A substance that is Generally Recognized As Safe (GRAS); or

5
6 d. Hemp products or ingredients from a state that inspects or regulates
7 hemp products under a food safety program or equivalent criteria to
8 ensure safety for human consumption; or

9
10 e. If the state does not inspect or regulate hemp products or ingredients,
11 the out-of-state hemp source can demonstrate equivalency by:

12
13 (1) Maintaining an annual 21 CFR 111 or 117 certification conducted
14 by a certified cGMP (21 CFR 117) or Dietary Supplement (21 CFR
15 111) auditor; and

16
17 (2) Providing evidence of this certification to the Colorado
18 registered hemp facility; and

19
20 (3) Providing documentation to the purchaser, or by the purchaser
21 providing documentation that all supplied hemp products or
22 ingredients have passed testing requirements for potency,
23 microbials, mycotoxins, pesticides, heavy metals, and residual
24 solvents in accordance with this regulation.

25
26 2. Broad spectrum means hemp products that contain multiple cannabinoids and
27 no more than 0.05 milligrams per gram of total THC and no more than 6.0
28 milligrams of total THC per container.

29
30 3. Certified laboratory means a public or private laboratory or testing facility
31 certified by the department to perform testing on hemp and hemp products in
32 accordance with *Hemp Testing Laboratory Certification*, 5 CCR 1005-5.

33
34 4. Certificate of Analysis means an official document issued by a certified
35 laboratory that shows the results of scientific tests performed on a product.

36
37 5. Cosmetics means articles intended to be rubbed, poured, sprinkled, or sprayed
38 on, introduced into, or otherwise applied to the human body or any part
39 thereof for cleansing, beautifying, promoting attractiveness, or altering the
40 appearance or an article intended for use as a component of any such articles;
41 except that such term does not include soap.

42
43 6. Department means the Colorado Department of Public Health and Environment.

44
45 7. Dietary supplement means a product taken by mouth that contains a dietary
46 ingredient or a new dietary ingredient intended to supplement the diet.

47
48 8. Full spectrum means a hemp product that contains all phytochemicals naturally
49 found in the plant, trace cannabinoids, terpenes, and essential oils, with no
50 more than 1.75 milligrams of THC per serving and contains a ratio of
51 cannabidiol to THC of greater than or equal to fifteen to one.
52

- 1 9. Generally Recognized As Safe (GRAS) means any substance that is intentionally
2 added to food which is a food additive, that is subject to premarket review by
3 the U.S. Food and Drug Administration (FDA), unless the substance is generally
4 recognized, among qualified experts, as having been adequately shown to be
5 safe under the conditions of its intended use, or unless the use of the
6 substance is otherwise excepted from the definitions of food additive.
- 7
- 8 10. Hemp has the meaning set forth in Section 35-61-101 (7) C.R.S.
- 9
- 10 11. Hemp manufacturer or storage facility means a facility where hemp products
11 are manufactured or stored.
- 12
- 13 12. Hemp product means a finished product that contains hemp and that:
- 14
- 15 a. Is a cosmetic, a dietary supplement, a food, a food additive, or an herb;
16
- 17 b. Is intended for human use or consumption;
18
- 19 c. Contains any part of the hemp plant, including naturally occurring
20 cannabinoids, compounds, concentrates, extracts, isolates, or resins;
21
- 22 d. Is produced from hemp;
23
- 24 e. Contains no more than 1.75 milligrams of tetrahydrocannabinol (THC)
25 per serving; and
26
- 27 f. Contains a ratio of cannabidiol (CBD) to THC of greater than or equal to
28 15 to one (15:1).
29
- 30 13. Herb means any plant with leaves, seeds, or flowers used as a flavoring, food,
31 food additive, or dietary supplement ingredient.
32
- 33 14. Intoxicating cannabinoid means any of the following in an amount that exceeds
34 the amount established by rule or, if no rule establishes the amount, in any
35 amount:
36
- 37 a. Delta-10 THC and its isomers;
38
- 39 b. Delta-9 THC and its isomers;
40
- 41 c. Delta-8 THC and its isomers;
42
- 43 d. Delta-7 THC and its isomers;
44
- 45 e. Delta-6a, 10a THC and its isomers;
46
- 47 f. Exo-tetrahydrocannabinol;
48
- 49 g. Metabolites of THC, including 11-hydroxy-THC, 3-hydroxy-THC, or 7-
50 hydroxy-THC;
51

- 1 h. Hydrogenated forms of THC, including hexahydrocannabinol,
2 hexahydrocannabiphorol, and hexahydrocannabihexol;
3
4 i. Synthetic forms of THC, including dronabinol;
5
6 j. Ester forms of THC, including delta-8 THC-O-acetate, delta-9 THC-O-
7 acetate, and hexahydrocannabinol-O-acetate;
8
9 k. Tetrahydrocannabivarin, including delta-8 tetrahydrocannabivarin but
10 excluding delta-9 tetrahydrocannabivarin (THCV);
11
12 l. Analogues or tetrahydrocannabinols with alkyl chain of four or more
13 carbon atoms, including tetrahydrocannabiphorols,
14 tetrahydrocannabioctyls, tetrahydrocannabihexols, or
15 tetrahydrocannabutols; and
16
17 m. Any combination of the compounds, including hexahydrocannabiphorol-
18 o-ester.
19
20 15. Labeling means a display of written, printed, or graphic matter upon a food,
21 cosmetic, dietary supplement, ingredient container, or package and includes
22 product inserts, and other promotional materials including digital
23 communications.
24
25 16. Law means applicable local, state, and federal statutes, regulations and
26 ordinances.
27
28 17. Manufacturing or processing, manufacturing, manufacture, process, or
29 processing has the meaning set for in Section 25-5-426(2)(h) C.R.S.
30
31 18. Non-intoxicating cannabinoid means:
32
33 a. Full spectrum hemp extract that contains no more than 1.75 milligrams
34 of THC per serving and contains a ratio of cannabidiol (CBD) to THC of
35 greater than 15 to one (15:1);
36
37 b. Broad spectrum hemp extract;
38
39 c. Cannabidiol (CBD);
40
41 d. Delta-9 tetrahydrocannabivarin tetrahydrocannabivarin (THCV);
42
43 e. Cannabichromene (CBC);
44
45 f. Cannabicitran (CBT);
46
47 g. Cannabicyclol (CBL);
48
49 h. Cannabielsoin (CBE);
50
51 i. Cannabigerol (CBG);
52

1 j. Cannabidivarin (CBDV); and

2
3 k. Cannabinol (CBN);

4
5 19. Packaging means any type of container, wrapping, or other type of vessel
6 intended to protect both food, cosmetics or dietary supplements from damage,
7 contamination, spoilage, pest attacks, and tampering, during transport,
8 storage, and sale.

9
10 20. Physical separation means segregation of the operations of a regulated hemp
11 facility:

12
13 a. Including the physical separation of hemp products and safe harbor
14 hemp products during manufacture, production, storage, and
15 distribution; and

16
17 b. The use of separate equipment for the manufacture or production of
18 hemp products and safe harbor hemp products.

19
20 21. Potentially intoxicating cannabinoid has the meaning set forth in Section 44-10-
21 103(48.5), C.R.S.

22
23 22. Process Validation means the collection and evaluation of data, from the
24 process design stage throughout production, which establishes scientific
25 evidence that a process is capable of consistently delivering quality products.

26
27 23. Registrant means a person registered under Section 25-5-427(5), C.R.S.

28
29 24. Regulated hemp facility means:

30
31 a. A hemp manufacturer or storage facility; or

32
33 b. A safe harbor manufacturer or storage facility.

34
35 25. Safe harbor hemp product means a hemp-derived compound or cannabinoid,
36 whether a finished product or in the process of being produced, that is
37 permitted to be manufactured for distribution, produced for distribution,
38 packaged for distribution, processed for distribution, prepared for distribution,
39 treated for distribution, transported for distribution, or held for distribution in
40 Colorado for export from Colorado but that is not permitted to be sold or
41 distributed in Colorado.

42
43 26. Safe harbor hemp manufacturer or storage facility or safe harbor hemp facility
44 means a facility that manufactures for distribution, produces for distribution,
45 packages for distribution, processes for distribution, prepares for distribution,
46 treats for distribution, transports for distribution, or holds for distribution a
47 safe harbor hemp product.

48
49 27. Semi-synthetic cannabinoid means a substance that is created by a chemical
50 reaction that converts one cannabinoid extracted from a cannabis plant
51 directly into a different cannabinoid.

52

- 1 a. Semi-synthetic cannabinoid includes cannabinoids, such as cannabitol
2 (CBN) that was produced by the conversion of cannabidiol (CBD).
3
4 b. Semi-synthetic cannabinoid does not include cannabinoids produced via
5 decarboxylation of naturally occurring acidic forms of cannabinoids,
6 such as tetrahydrocannabinolic acid, into the corresponding neutral
7 cannabinoid, such as THC, through the use of heat or light, without the
8 use of chemical reagents or catalysts, and that results in no other
9 chemical change.
10
11 28. Serving means the size or portion customarily consumed per eating occasion,
12 expressed in a common household measure as establish in Table 2 of 21 CFR
13 101.12.
14
15 29. State licensing authority has the meaning set forth in Section 44-10-103(69),
16 C.R.S.
17
18 30. Synthetic cannabinoid means a cannabinoid-like compound that was produced
19 by using chemical synthesis, chemical modification, or chemical conversion,
20 including by using in-vitro biosynthesis or other bioconversion of such a
21 method.
22
23 a. Synthetic cannabinoid does not include:
24
25 (1) A compound produced through the decarboxylation of naturally
26 occurring cannabinoids from their acidic forms; or
27
28 (2) A semi-synthetic cannabinoid.
29
30 31. Tetrahydrocannabinol (THC) means the substance contained in the plant
31 cannabis species, in the resinous extracts of the cannabis species, or a
32 carboxylic acid of, derivative of, salt of, isomer of, or salt or acid of an isomer
33 of these substances.
34
35 a. Tetrahydrocannabinol (THC) includes:
36
37 (1) Delta-10 THC and its isomers;
38
39 (2) Delta-9 THC and its isomers;
40
41 (3) Delta-8 THC and its isomers;
42
43 (4) Delta-7 THC and its isomers;
44
45 (5) Delta-6a, 10a THC and its isomers; and
46
47 (6) Exo-Tetrahydrocannabinol;
48
49 b. Tetrahydrocannabinol or THC may also contain:
50
51 (1) Products or metabolites of any of the compounds listed in 31(a).
52

1 32. Tincture means a liquid hemp product that is packaged in a container of four
2 fluid ounces or less, that is not a beverage or intended for drinking, and that
3 consists of a solution:

4
5 a. Containing at least 25% non-denatured alcohol or a base of glycerin or
6 plant-based oil;

7
8 b. Containing hemp, hemp concentrate, or hemp extract; and

9
10 c. Intended for human use.

11
12 33. Total THC means the sum of the percentage by weight of the THCA's multiplied
13 by 0.877 plus the percentage by weight of THC [i.e., (% THCA x 0.877) + %
14 THC].

15
16 34. Unfinished hemp product means an oil, extract, concentrate or other substance
17 that has a total THC concentration above 0.3%, is not for consumer use or retail
18 distribution, and will undergo further refinement or processing into a hemp
19 product or safe harbor hemp product.

20 21 **24.5 Registration Requirements**

22
23 A. Regulated hemp facilities in Colorado must be registered in accordance with Section
24 25-5-427(5), C.R.S.

25
26 1. The owner of any regulated hemp facility must submit to the department an
27 application each year for registration, along with applicable application and
28 registration fees, using forms provided by the department.

29
30 2. The owner of any regulated hemp facility must also submit to the department
31 complete and accurate information about the facility's operation and business
32 size, using forms provided by the department.

33
34 B. In addition to the requirements in Section 24.5(A) of this rule, safe harbor hemp
35 product manufacturers or storage facilities must demonstrate compliance with the
36 federal current good manufacturing practices for food or dietary supplements before
37 registering or within 12 months after the previous registration by submitting to the
38 department:

39
40 1. Evidence of obtaining an inspection from a department-approved third-party
41 auditor by July 1, 2024, and by July 1 of each year thereafter.

42
43 2. An attestation form, as provided by the department, by July 1 of each year
44 that includes, but may not be limited to, the following:

45
46 a. The safe harbor hemp product manufacturer or storage facility does not
47 export a safe harbor hemp product to a state where the safe harbor
48 hemp product is prohibited by state law; and

49
50 b. The safe harbor hemp product manufacturer or storage facility does not
51 manufacture, produce, or distribute a synthetic cannabinoid; and

52

- 1 c. The safe harbor hemp product is manufactured, produced, tested,
2 labeled, stored, and distributed in accordance with all applicable rules;
3 and
4
5 d. The safe harbor hemp product manufacturer or storage facility is:
6
7 (1) Not a registered hemp manufacturer or storage facility or a
8 registered wholesale food manufacturer or storage facility; or
9
10 (2) If the safe harbor hemp product manufacturer or storage facility
11 is a registered wholesale food or hemp manufacturer or storage
12 facility, each safe harbor hemp product is:
13
14 (A) Physically separated from hemp or food products during
15 the manufacturing, production, storage, and distribution
16 of the safe harbor hemp product; or
17
18 (B) Manufactured, produced, stored, and distributed in
19 accordance with procedures approved by the department
20 that ensure no cross contamination between safe harbor
21 hemp products and hemp products or food.
22

23 **24.6 Incorporation by Reference**

- 24
25 A. The department shall utilize material incorporated by reference as appropriate to
26 assure that regulated hemp facilities comply with the “Pure Food and Drug Law”.
27
28 1. 21 CFR 100-190 (April 1, 2017) is hereby incorporated by reference into this
29 rule. Such incorporation, however, excludes later amendments to or editions of
30 the reference material.
31
32 B. Any provision included or incorporated herein by reference which conflicts with the
33 Colorado Revised Statutes, including but not limited to Section 25-5-401 *et seq.*,
34 C.R.S., and Section 25-1.5-102, C.R.S., shall be null and void. These regulations do not
35 incorporate by reference:
36
37 1. 21 CFR 112, *Standards for the Growing, Harvesting, Packing, and Holding of*
38 *Produce for Human Consumption.*
39
40 2. 21 CFR 171, *Food Additive Petitions.*
41
42 C. The incorporated material is available for public inspection during regular business
43 hours at:
44
45 Division of Environmental Health and Sustainability
46 Colorado Department of Public Health and Environment
47 4300 Cherry Creek Drive South
48 Denver, Colorado 80246-1530
49
50 Pursuant to Section 24-4-103(12.5)(b), C.R.S., the agency shall provide certified copies
51 of the material incorporated at cost upon request or shall provide the requestor with
52 information on how to obtain a certified copy of the material incorporated by

1 reference from the agency of the United States, this state, another state, or the
2 organization or association originally issuing the code, standard, guideline or rule.

3
4 D. The incorporated materials are available at:

5
6 [https://www.ecfr.gov/cgi-bin/text-](https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)
7 [idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab](https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)
8 [_02.tpl](https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl)
9

10 24.7 Regulated Hemp Facility Manufacturing Requirements

11
12 A. Prior to manufacturing, packaging, or distributing a regulated hemp facility must:

- 13
14 1. Be registered with the department;
- 15
16 2. Obtain any other necessary state or local licenses, permits, registrations or
17 approvals.
- 18
19 3. Comply with state law, local ordinances, these governing regulations and all
20 other applicable state and local regulations; and
- 21
22 4. Have conspicuously posted all applicable documentation in accordance with the
23 law.

24
25 B. Ingredients

- 26
27 1. All ingredients must come from approved sources;
- 28
29 2. All ingredients shall be clearly identified to allow for appropriate traceability.
30 Identification includes:
 - 31
32 a. Name of ingredient;
 - 33
34 b. Identifying batch or lot number from original package;
 - 35
36 c. Date the ingredient was manufactured;
 - 37
38 d. Date the ingredient was received at the facility; and
 - 39
40 e. Expiration, re-test, or use-by date.
- 41
42 3. Spoiled, unwholesome, adulterated, vermin- or insect-infested
43 ingredients are not allowed into the facility and shall be:
 - 44
45 a. Removed immediately from the premises and properly disposed; or
 - 46
47 b. Placed in a quarantine area temporarily until proper disposal if:
 - 48
49 (1) Not practicable to remove immediately; or
 - 50
51 (2) Required to be collected by a local or state regulatory agency
52 for examination or testing.

1 C. Approved Solvents

- 2
3 1. The use of solvents for manufacturing within a regulated hemp facility is
4 limited to those listed in the following table:

5

<u>Acetic acid</u>	<u>Acetone</u>
<u>Anisole</u>	<u>1-Butanol</u>
<u>2-Butanol</u>	<u>Butyl acetate</u>
<u>Carbon dioxide</u>	<u>tert-Butylmethyl ether</u>
<u>Ethanol</u>	<u>Ethyl acetate</u>
<u>Ethyl ether</u>	<u>Ethyl formate</u>
<u>Formic acid</u>	<u>Heptane</u>
<u>Isobutyl acetate</u>	<u>Isopropyl acetate</u>
<u>Methanol</u>	<u>3-Methyl-1-butanol</u>
<u>Methylene chloride</u>	<u>Methyl acetate</u>
<u>2-Methyl-1-propanol</u>	<u>Methylethyl ketone</u>
<u>Pentane</u>	<u>1-Pentanol</u>
<u>Propane</u>	<u>1-Propanol</u>
<u>2-Propanol (isopropyl alcohol)</u>	<u>Propyl acetate</u>
<u>Triethylamine</u>	

6
7 Note: The use and storage of solvents used in regulated hemp facilities must be
8 in compliance with all applicable local, state, and federal regulations
9 including, but not limited to rules promulgated by the Colorado Air Quality
10 Control Commission, Colorado Board of Health, Colorado Solid and Hazardous
11 Waste Commission, and Colorado Water Quality Control Commission.

12
13 D. Testing

- 14
15 1. Analytical testing shall be performed by a certified laboratory in accordance
16 with the department's *Hemp Testing Laboratory Certification* rules, located at
17 5 CCR 1005-5.
- 18
19 2. Any exceedance of the potency or contaminant action limits presented in this
20 Section 24.7(D) shall be reported to the department by the regulated hemp
21 facility within 48 hours of receipt of the confirmed analytical testing results.
- 22
23 a. If a regulated hemp facility product is found to contain a contaminant
24 at levels exceeding those permissible under this regulation, then it shall
25 be considered to have failed contaminant testing.
- 26
27 b. Notwithstanding the permissible levels established in this regulation,
28 the department reserves the right to determine, upon good cause and
29 reasonable grounds that a particular hemp product or safe harbor hemp
30 product may present a risk to public health or safety, and may request

additional laboratory testing to demonstrate a product does not present a risk to public health or safety.

3. All certificates of analysis provided as documentation of conformance with the established testing requirements shall be furnished from a certified hemp testing laboratory.

4. Regulated hemp facilities are responsible for ensuring the testing requirements listed in subparagraphs 24.7(D)(5) and (6) of this rule are met, and must maintain certificates of analysis on any regulated hemp products they produce or transfer to ensure safety on all lots or batches. The testing requirements contained in this regulation are the minimum required and approved testing standards.

5. THC and Other Cannabinoid Content

a. All regulated hemp facility products must have testing results for any cannabinoid that is a known component and for any ingredient for which there is a label claim. Any unidentified peak present at more than 1.0% of the total peak area in a regulated hemp facility product will be investigated and, if determined to be an unlabeled cannabinoid, will be considered to have failed THC and other cannabinoid testing.

b. Hemp products must have laboratory test results indicating the product is:

(1) A broad spectrum hemp product or ingredient; or

(2) A full spectrum product that contains no more than 1.75 milligrams of total THC and contains a ratio of cannabidiol (CBD) to THC of greater than 15 to one (15:1).; ~~or~~

~~(3) A non-intoxicating cannabinoid product that contains no more than 25 milligrams per non-intoxicating cannabinoid as defined in 24.4(18)(d) through (k) of this rule, per serving.~~

c. Safe harbor hemp products must have test results indicating cannabinoid levels, including listing THC and other intoxicating or potentially intoxicating cannabinoid levels.

6. Contaminant Testing Requirements and Limits

a. Microbials (Bacteria and Fungus)

<u>Substance</u>	<u>Action Limits</u> Per gram (g), unless otherwise indicated
Salmonella spp.	Absent in 25 g
Shiga-toxin producing Escherichia coli (STEC) - Bacteria	Absent in 25 g

<u>Total coliforms</u>	<u>< 10² cfu/g</u>
<u>Total aerobic plate count</u>	<u>< 10⁴ cfu/g</u>
<u>Total yeast and mold</u>	<u>< 10³ cfu/g</u>

b. Mycotoxins

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

c. Pesticides

The following pesticides are not allowed in regulated hemp facility products and should not be detected during laboratory testing at the limits of quantification (LOQ) established or approved in accordance with the department's State Public Health Laboratory, Disease Control and Public Health Response Division's, *Hemp Testing Laboratory Certification*, 5 CCR 1005-5.

<u>Abamectin</u>	<u>Acephate</u>	<u>Acequinocyl</u>
<u>Acetamiprid</u>	<u>Aldicarb</u>	<u>Allethrin</u>
<u>Atrazine</u>	<u>Azadirachtin</u>	<u>Azoxystrobin</u>
<u>Benzovindiflupyr</u>	<u>Bifenazate</u>	<u>Bifenthrin</u>
<u>Boscalid</u>	<u>Buprofezin</u>	<u>Carbaryl</u>
<u>Carbofuran</u>	<u>Chlorantraniliprole</u>	<u>Chlorphenapyr</u>
<u>Chlorpyrifos</u>	<u>Clofentezine</u>	<u>Clothianidin</u>
<u>Coumaphos</u>	<u>Cyantraniliprole</u>	<u>Cyfluthrin</u>
<u>Cypermethrin</u>	<u>Cyprodinil</u>	<u>Daminozide</u>
<u>Deltamethrin</u>	<u>Diazinon</u>	<u>Dichlorvos</u>
<u>Dimethoate</u>	<u>Dimethomorph</u>	<u>Dinotefuran</u>
<u>Diuron</u>	<u>Dodemorph</u>	<u>Endosulfan sulfate</u>
<u>Endosulfan-alpha</u>	<u>Endosulfan-beta</u>	<u>Ethoprophos</u>
<u>Etofenprox</u>	<u>Etoxazole</u>	<u>Etridiazole</u>
<u>Fenhexamid</u>	<u>Fenoxycarb</u>	<u>Fenpyroximate</u>
<u>Fensulfothion</u>	<u>Fenthion</u>	<u>Fenvalerate</u>
<u>Fipronil</u>	<u>Fonicamid</u>	<u>Fludioxonil</u>
<u>Fluopyram</u>	<u>Hexythiazox</u>	<u>Imazalil</u>

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<u>Imidacloprid</u>	<u>Iprodione</u>	<u>Kinoprene</u>
<u>Kresoxim-methyl</u>	<u>(Lambda) Cyhalothrin</u>	<u>Malathion</u>
<u>Metalaxyl</u>	<u>Methiocarb</u>	<u>Methomyl</u>
<u>Methoprene</u>	<u>Mevinphos</u>	<u>MGK-264</u>
<u>Myclobutanil</u>	<u>Naled</u>	<u>Novaluron</u>
<u>Oxamyl</u>	<u>Paclobutrazol</u>	<u>Parathion-methyl</u>
<u>Permethrin</u>	<u>Phenothrin</u>	<u>Phosmet</u>
<u>Piperonyl butoxide</u>	<u>Pirimicarb</u>	<u>Prallethrin</u>
<u>Propiconazole</u>	<u>Propoxur</u>	<u>Pyraclostrobin</u>
<u>Pyrethrins</u>	<u>Pyridaben</u>	<u>Pyriproxyfen</u>
<u>Quintozene</u>	<u>Resmethrin</u>	<u>Spinetoram</u>
<u>Spinosad</u>	<u>Spirodiclofen</u>	<u>Spiromesifen</u>
<u>Spirotetramat</u>	<u>Spiroxamine</u>	<u>Tebuconazole</u>
<u>Tebufenozide</u>	<u>Teflubenzuron</u>	<u>Tetrachlorvinphos</u>
<u>Tetramethrin</u>	<u>Thiabendazole</u>	<u>Thiacloprid</u>
<u>Thiamethoxam</u>	<u>Thiophanate-methyl</u>	<u>Trifloxystrobin</u>

1
2
3

d. Heavy Metals

<u>Substance</u>	<u>Action Limits</u> Parts per million (ppm)
<u>Arsenic</u>	<u>< 1.5</u>
<u>Cadmium</u>	<u>< 0.5</u>
<u>Lead</u>	<u>< 0.5</u>
<u>Mercury</u>	<u>< 1.5</u>

4
5
6

e. Residual Solvents

<u>Substance</u>	<u>Action Limits</u> Parts per million (ppm)
<u>Acetic acid</u>	<u>< 1000</u>
<u>Acetone</u>	<u>< 1000</u>
<u>Anisole</u>	<u>< 1000</u>
<u>Benzene*</u>	<u>< 2</u>
<u>Butanes</u>	<u>< 100</u>
<u>1-Butanol</u>	<u>< 1000</u>
<u>2-Butanol</u>	<u>< 1000</u>

<u>Substance</u>	<u>Action Limits</u> Parts per million (ppm)
<u>Butyl acetate</u>	< 1000
<u>tert-Butylmethyl ether</u>	< 1000
<u>Ethanol</u>	< 5,000
<u>Ethyl Acetate</u>	< 1000
<u>Ethyl ether</u>	< 1000
<u>Ethyl formate</u>	< 1000
<u>Formic acid</u>	< 1000
<u>Heptane</u>	< 1000
<u>Hexane*</u>	< 10
<u>Isobutyl acetate</u>	< 1000
<u>Isopropyl acetate</u>	< 1000
<u>Methanol</u>	< 100
<u>Methyl acetate</u>	< 1000
<u>2-Methyl-1-propanol</u>	< 1000
<u>Methylene chloride</u>	<3
<u>3-Methyl-1-butanol</u>	< 1000
<u>Methylethyl ketone</u>	< 1000
<u>Pentane</u>	< 1000
<u>1-Pentanol</u>	< 1000
<u>Propane</u>	< 100
<u>1-Propanol</u>	< 1000
<u>2-Propanol (isopropyl alcohol)</u>	< 1000
<u>Propyl acetate</u>	< 1000
<u>Toluene*</u>	< 20
<u>Triethylamine</u>	< 100
<u>Total Xylenes (m, p, o-xylenes)*</u>	< 40
<u>Any other solvent not permitted for use</u>	<u>None detected</u>

* 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.

E. Packaging and Labeling Requirements (effective June 1, 2024)

1. Packaging shall be food-grade or GRAS

2. Labeling of safe harbor products at retail point of sale point of retail sale to consumer shall be in accordance with the requirements listed in 24.7(E), unless compliance with these provisions is not in conformance with the requirements of the state to which the product is being distributed.

a. Safe harbor product labels and packaging shall include a notice that identifies that the product shall not be sold commercially in Colorado or

shipped or transported to addresses in is approved for sale outside of Colorado.

- 1
2
3
4 3. Labeling shall be performed in accordance with 21 CFR 101, subparts A-G and
5 the department's labeling requirements for hemp products, which include:
6
7 a. All information appearing on the principal display panel or the
8 information panel must appear prominently and conspicuously, but in no
9 case may the letters and numbers be less than one-sixteenth inch
10 (1/16") in height unless the regulated hemp facility product meet the
11 exemption pursuant to section 24.7(10).
12
13 b. Product Identity Statement which indicates the common or usual name
14 of the ingredient;
15
16 (1) Product Identity Statement must appear on the principal display
17 panel in bold type;
18
19 c. Net Weight Statement placed as a distinct item parallel to the base of
20 the package in the bottom third of the principal display panel.
21
22 d. Identify on the principal display panel or the information panel that the
23 product is produced from hemp, then sequentially:
24
25 (1) If applicable, identify as broad spectrum product;
26
27 (2) If applicable, identify as full spectrum product;
28
29 (3) Identify additional isolated cannabinoids;
30
31 (4) Identify additional ingredients, in descending order of
32 predominance by weight.
33
34 e. Identify, in milligrams, the total THC content per serving, total THC
35 content per individual product package, and the ratio of cannabidiol
36 (CBD) to THC per serving in the ingredient list or directly below the
37 ingredient list in bold type;
38
39 (1) If a serving contains more than 1.25 mg of total THC, and less
40 than a 20:1 CBD to THC ratio, labeling that indicates individuals
41 must be 21 years or older to purchase on the principal display
42 panel.
43
44 f. Any major food allergens, milk, eggs, fish, crustacean shellfish, tree
45 nuts, peanuts, sesame, wheat and soybeans shall be clearly identified
46 and listed separately.
47
48 g. For hemp products, the serving and number of servings per product
49 package in accordance with Table 2, 21 CFR 101.12.
50
51 h. Manufacturing address or a qualifying phrase which states the firm's
relation to the product if contract manufactured, relabeled, or

1 distributed by another company (e.g., “manufactured for” or
2 “distributed by”).

3
4 i. A code or numbering system that identifies the date and location of
5 manufacturing and packaging.

6
7 4. Qualified health claims for hemp products must follow Federal Trade
8 Commission (FTC) and FDA regulations and guidance, including marketing
9 materials and electronic communications.

10
11 5. A manufacturer, distributor, or seller shall not include on the label of the
12 product, or publish or disseminate in marketing or electronic communications,
13 any claims that the product can, or is intended to, diagnose, cure, mitigate,
14 treat, or prevent disease.

15
16 6. Labeling of a cosmetic shall bear a warning statement whenever necessary or
17 appropriate to prevent a health hazard that may be associated with the
18 product. This applies to qualified claims on products as well as ingredients,
19 aerosol products, deodorant products, foaming detergent bath products, coal
20 tar hair dyes, sun-tanning and sunscreen products.

21
22 7. With the exception of broad spectrum products and cosmetics, the label of
23 regulated hemp facility products that contains any tetrahydrocannabinol (THC),
24 potentially intoxicating cannabinoids, or intoxicating cannabinoids must include
25 a consumer notice statement that discloses the presence of the
26 tetrahydrocannabinol (THC), potentially intoxicating or intoxicating
27 cannabinoids, and includes at least the following notices:

28
29 a. The potential for these products to cause a positive drug test result;

30
31 b. The potential for these products to create impairment;

32
33 c. Statement that these products have not been evaluated for safety or
34 efficacy;

35
36 d. Recommending those who are pregnant, may become pregnant, or are
37 breastfeeding to consult with their physician about the use of these
38 products; and

39
40 e. Statement to keep out of the reach of children.

41
42 8. The label of regulated hemp facility products that contain cannabidiol (CBD)
43 must include a consumer notice statement that discloses the presence of the
44 CBD, and includes at least the following notices:

45
46 a. Recommending those who are pregnant, may become pregnant, or are
47 breastfeeding to consult with their physician about the use of these
48 products; and

49
50 b. The product may cause health problems including liver injury, damage
51 to male reproductive health, and sedative effects that may impair your
52 ability to drive a motor vehicle or operate machinery.

- 1
2 9. The consumer notice statement requirements in 24.7(E)(7) and (8) must appear
3 on the label in at least one-sixteenth inch (1/16") letter height and in bold
4 type.
- 5
6 10. If tincture or small product package labeling requires a type size smaller than
7 one-sixteenth inch (1/16"), the product must be accompanied by labeling, such
8 as a marketing layer, attached to the package that appears prominently and
9 conspicuously and meets the above type-size requirements.
- 10
11 11. Labels and packaging shall not be designed to appeal to children. Labels on
12 regulated hemp facility products shall not contain any content that reasonably
13 appears to target individuals under the age of 21, including but not limited to
14 cartoon characters or similar images.

15
16 F. Record Keeping

- 17
18 1. The following records shall be maintained:
- 19
20 a. Certificates of analysis of ingredients;
- 21
22 b. Source of ingredients;
- 23
24 c. Batch production records including;
- 25
26 (1) Any records required based on department approval for co-
27 location and use of equipment for hemp and safe harbor
28 products in accordance with Section 24.8 of this rule.
- 29
30 d. Certificate of analysis of finished products;
- 31
32 e. Recalled product information;
- 33
34 f. Adverse health event reporting, including to the extent known after
35 reasonable diligence to ascertain the information, the name and
36 contact information of the complainant, the date the complaint was
37 received, the nature of the complaint, the production batch or lot
38 number, any other identifying information found on the label of the
39 regulated hemp facility product, corrective steps taken, and recall
40 activities completed;
- 41
42 g. Consumer complaints; and
- 43
44 h. Other records as required by the department (e.g., corrective action
45 logs, equipment calibration records, equipment cleaning records as
46 applicable).
- 47
48 2. Records shall:
- 49
50 a. Be kept as original records, true copies (such as photocopies, pictures,
51 scanned copies, microfilm, microfiche, or other accurate reproductions
52 of the original records), or electronic records;

- 1
2 b. Contain the actual values and observations obtained during monitoring
3 and, as appropriate, during verification activities;
4
5 c. Be accurate, indelible, and legible;
6
7 d. Be created concurrently with performance of the activity documented;
8
9 e. Be as detailed as necessary to provide history of work performed, and
10 include:
11
12 (1) Information adequate to identify the plant or facility (e.g., the
13 name and, when necessary, location of the plant or facility);
14
15 (2) The date and time of the activity documented, when
16 appropriate;
17
18 (3) The signature or initials of the person performing the activity;
19 and
20
21 (4) The identity of the product and the lot code, when appropriate.
22

23 3. Records shall be retained:
24

- 25 a. At the plant or facility for at least 2 years after the date they were
26 prepared for products identified as foods, food additives and cosmetics;
27 and
28
29 b. For one year past the shelf life date, if shelf life dating is used, or two
30 years beyond the date of distribution of the last batch of dietary
31 supplements.
32

33 G. Recalls
34

- 35 1. Regulated hemp facilities shall establish a written recall plan in accordance
36 with 21 CFR 117.139, *Recall Plan*, that includes procedures that describe the
37 steps to be taken, and assigns responsibility for taking those steps, to perform
38 the following actions as appropriate to the facility:
39
40 a. Directly notify the direct consignees of the hemp product or safe harbor
41 hemp product being recalled, including how to return or dispose of the
42 affected product;
43
44 b. Notify the public about any hazard presented by the product when
45 appropriate to protect public health;
46
47 c. Conduct effectiveness checks to verify that the recall is carried out; and
48
49 d. Appropriately dispose of recalled product (e.g., through reprocessing or
50 reworking as appropriate, or diverting to a use that does not present a
51 safety concern, or destroying the product).
52

1 H. Transportation

- 2
- 3 1. Transfer of hemp products shall be conducted in accordance with all applicable
- 4 transportation laws.
- 5
- 6 2. Hemp products and safe harbor products shall be transported in a manner
- 7 where they will be protected from adulteration, allergen cross-contact,
- 8 environmental contamination and any other hazards.
- 9

10 I. Waste and Hazardous Waste Management

- 11
- 12 1. Waste THC shall be diluted to a concentration of less than 0.3%, converted, or
- 13 disposed of in accordance with the department's Hazardous and Waste
- 14 Management Division's *Marijuana and Marijuana-Related Waste Disposal*
- 15 Compliance Bulletin.
- 16
- 17 2. The facility owner/operator is responsible to secure and limit access to hemp-
- 18 derived THC with a concentration greater than 0.3%.
- 19
- 20 3. Waste management shall be conducted in accordance with the *Colorado*
- 21 *Hazardous Waste Regulations (6 CCR 1007-3)* and the *Colorado Solid Waste*
- 22 *Regulations (6 CCR 1007-2)*.
- 23

24 **24.8 Additional Requirements for Safe Harbor Manufacturers**

25

26 A. Safe harbor hemp product manufacturers shall maintain records for at least two years

27 indicating:

- 28
- 29 1. Distributor, retailer or individual that purchased the safe harbor product;
- 30
- 31 2. The state the sale was made to, and records documenting the product is not
- 32 prohibited in the state where sale was completed;
- 33
- 34 3. THC or other cannabinoid concentration limits from the receiving state per
- 35 -serving and/or per container for each product; and
- 36
- 37 4. Labeling requirements from the receiving state that differ from those listed in
- 38 this rule in section 24.7(E).
- 39

40 And

41

42 B. Physical separation, as defined in Section 24.4(20) of this rule, is required for a safe

43 harbor hemp manufacturer or storage facility and a hemp product manufacturer or

44 storage facility.

45

46 Or

47

48 C. The safe harbor hemp product registrant has received approval from the department

49 on a process validation that demonstrates no cross contamination between products

50 and includes all of the following:

51

- 1 1. A comprehensive list of products being manufactured, including a list of
2 cannabinoids in the products;
- 3
- 4 2. Equipment used in production;
- 5
- 6 3. Production methodologies;
- 7
- 8 4. Procedures and chemicals used in cleaning equipment;
- 9
- 10 5. Test results of equipment and products for residual cannabinoids;
- 11
- 12 6. Environmental swab protocol to include frequency, location, contaminant or
13 organism of concern, results and response to positive results;
- 14
- 15 7. Packaging materials and distribution methods;
- 16
- 17 8. Record keeping; and
- 18
- 19 9. Quality assurance program, including change management.

20
21 Or

22
23 D. The safe harbor hemp product registrant has received approval from department for
24 production, storage and distribution procedures. Procedures must include elements
25 listed in 24.8(C)(1-4, 6, 7, 8, 9) along with:

- 26
- 27 1. Sampling protocols for testing finished products for residual cannabinoids;
- 28
- 29 2. Product hold or release criteria; and
- 30
- 31 3. Enhanced recall response procedures that ensures notification to consumers,
32 distributors and retailers of contaminated product and when necessary,
33 removal of product from commerce and the market.
- 34

35 24.9 Offenses

- 36
- 37 A. The manufacture, production, or distribution of a hemp product or safe harbor hemp
38 product that is also a synthetic cannabinoid is prohibited.
- 39
- 40 B. The manufacture, production, or distribution of a hemp product that contains
41 potentially intoxicating cannabinoids is prohibited, unless specifically allowed by
42 regulation.
- 43
- 44 C. The manufacture, production, or distribution of a hemp product that contains
45 intoxicating cannabinoids other than THC within allowed limits is prohibited.
- 46
- 47 D. The chemical modification, conversion, or synthetic derivation of cannabinoids or
48 other hemp-derived compounds, except for those defined as non-intoxicating
49 cannabinoids, for use as a hemp product or ingredient in a hemp product is prohibited.
- 50
- 51 E. The manufacture of a product containing hemp that is not a cosmetic, a dietary
52 supplement, a food, a food additive or an herb is prohibited.

- 1
2 F. The manufacture of a hemp product that contains more than 1.75 milligrams of total
3 THC per serving is prohibited.
4
- 5 G. The manufacture of a hemp product that has a ratio of cannabidiol (CBD) to THC of
6 less than fifteen to one (15:1) is prohibited.
7
- 8 H. The manufacture of a hemp product in a package with more than five servings is
9 prohibited if the hemp product:
10
- 11 1. Has more than 1.25 milligrams of total THC per serving with a ratio of
12 cannabidiol (CBD) to THC of less than fifteen to one (15:1).
13
- 14 2. This Section does not apply to:
15
- 16 a. Broad spectrum hemp products;
17
- 18 b. Tinctures;
19
- 20 c. Cosmetics; or
21
- 22 d. A hemp product that the United States Food and Drug Administration
23 has determined is general recognized as safe under the “Federal Food,
24 Drug and Cosmetic Act”, 21 U.S.C. Sec. 301 et seq.
25
- 26 I. The manufacture of a hemp product in a package with more than thirty servings is
27 prohibited if the hemp product:
28
- 29 1. Has more than 1.25 milligrams of total THC per serving with a ratio of
30 cannabidiol (CBD) to THC of less than twenty to one (20:1).
31
- 32 2. This Section does not apply to:
33
- 34 a. Broad spectrum hemp products;
35
- 36 b. Tinctures;
37
- 38 c. Cosmetics; or
39
- 40 d. A hemp product that the United States Food and Drug Administration
41 has determined is general recognized as safe under the “Federal Food,
42 Drug and Cosmetic Act”, 21 U.S.C. Sec. 301 et seq.
43
- 44 J. The distribution of a hemp product without the required age labeling and consumer
45 notice statements as listed in Sections 24.7(E)(3)(c)(1) and 24.7(E)(7) and (8) of this
46 rule is prohibited.
- 47 K. The distribution of a safe harbor product in Colorado or to a state that prohibits the
48 product is prohibited.
49

24.10 Enforcement

- 50
- 51
- 52 A. Hemp product manufacturers or storage facilities that fail to submit a complete and
53 accurate annual application for registration, or fail to remit fees in accordance with

1 Section 25-5-427(5), C.R.S., are not considered an approved source for introduction of
2 hemp products into commerce.

3
4 B. Safe harbor hemp product manufacturers or storage facilities that fail to submit a
5 complete and accurate annual application for registration, an attestation form,
6 evidence of inspection from an approved third party auditor, or fail to remit fees in
7 accordance with Section 25-5-427(5), C.R.S., are prohibited from introducing safe
8 harbor hemp products into commerce.

9
10 C. Adulterated or misbranded hemp products and safe harbor hemp products, including
11 hemp products and safe harbor hemp products from unapproved sources, may be
12 embargoed in accordance with Section 25-5-406, C.R.S.

13
14 D. In accordance with Section 25-1.5-102(1)(c), C.R.S., the department may require
15 hemp product or safe harbor hemp product manufacturers to recall adulterated or
16 misbranded products in order to investigate and control the causes of epidemic and
17 communicable diseases affecting public health.

18
19 E. Pursuant to Sections 25-5-420 and 25-5-427(9), C.R.S., if the department has
20 reasonable cause to believe a violation of this regulation has occurred and immediate
21 enforcement is necessary, it may issue a cease-and-desist order, which shall set forth
22 the provisions alleged to have been violated, the facts constituting the violation, and
23 the requirement that all violating actions immediately cease.

24
25 1. At any time after service of the order to cease and desist by certified mail, the
26 person for whom such order was served may request a hearing to determine
27 whether such violation has occurred. Such hearing will be conducted in
28 conformance with the provisions of article 4 of title 24, C.R.S. and shall be
29 determined promptly.

30
31 F. To the extent and manner authorized by law, the department may issue letters of
32 admonition or may deny, suspend, refuse to renew, restrict, or revoke any regulated
33 hemp facility the regulated hemp facility has:

34
35 1. Refused or failed to comply with any provision of this regulation, requirements
36 of 25-5-427 C.R.S., or any lawful order of the department;

37
38 2. Refused to provide the department with reasonable, complete, and accurate
39 information when requested by the department; or

40
41 3. Falsified records or information submitted to the department.
42