COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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Through: Jeff Lawrence, Director
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Date: September 1, 2023

Subject: **Request for Rulemaking Hearing**
Proposed Creation of 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations* with a request for a rulemaking hearing to be set for November 15, 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 schedule a rulemaking hearing to consider adoption of 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 proposed 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, including revising the name of 6 CCR 1010-21 to the *Colorado Wholesale Food and Shellfish Regulations*.

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.) 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 proposed rulemaking addresses the changes codified in SB23-271 by establishing requirements associated regulated hemp products in a new regulation, 6 CCR 1010-24, *Colorado Hemp Product and Safe Harbor Hemp Product Regulations*.

This request for rulemaking proposes to maintain the requirements of 21 Code of Federal Regulations (C.F.R.) 100-111, 113-170, and 172-190 (April 1, 2017), as applicable to 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.

At the time of this request for rulemaking package submittal a few items still remained in discussions with stakeholders. Those items include:

- The potential to add additional definitions to the regulations;
- Establishing serving limits in milligrams for certain non-intoxicating cannabinoids;
- Determining the implementation date for new labeling requirements to allow time for manufacturers to develop new labels and exhaust existing stock; and
- A few labeling requirement refinements.

These items have been previously discussed in open stakeholder meetings and final edits are being considered and will be presented to stakeholders on September 15, 2023.

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=0345494EJAA5ZjE0MDIyYy1kNzZkLTRkNzktYTkxMS04YmJhNjBlNWUwYzYKAFBvZENhdGFsb2e4CaPI4cak6laXLCWyLBO9&crid=28abbed8-56f4-44da-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.

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 would 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, would provide 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,* revisions to *Colorado Wholesale Food, Industrial Hemp and Shellfish Regulations,* 6 CCR 1010-21 are also proposed which remove all requirements associated with hemp products in Colorado from that regulation and continue the regulation's specific applicability to wholesale food manufacturers, storage facilities, and shellfish operations.

The proposed regulatory requirements 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 are currently subject to the federal wholesale food requirements incorporated by reference. The incorporation by reference and application of 21 C.F.R. 100-190 (2017), except for 112 and 171, 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 consider 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 directed 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 around the safe harbor provision, based on the clear legislative direction, these proposed rules do not consider these issues and instead focus on implementing 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 where held during the SB22-205 task force meetings and at the legislature when developing SB23-271 on 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 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 grams x 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 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 grams x 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.

Therefore, 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 spectrum[2] 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 contains 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. Therefore, in order for a hemp product to be sold in Colorado this regulation would require laboratory test results 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 and therefore Colorado manufacturers should be able to compete and take advantage of the allowances within other states.

- ***Manufacturing requirements***

The proposed regulations maintains 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 the state of 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 allowance to co-locate a safe harbor hemp product manufactures with hemp product manufactures and were developed to prevent cross-contamination between the product types.

- ***Testing requirements***

The proposed regulations maintains the current testing requirements 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;
- Reducing the action limits in most cases on solvents from 1,000 parts per million (ppm) to 100 ppm; 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 department's State Public Health Laboratory, Disease Control and Public Health Response Division's, *Hemp Testing Laboratory Certification*, 5 CCR 1005-5 and inclusion in these regulations was redundant and created confusion.

- **Packaging and labeling requirements**

The current regulation requires product packaging to conform to the federal labeling requirements for dietary supplement 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, how to label and disclose THC or other cannabinoids in the product, and added 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 would be required to include a consumer notice statement that informs the consumer of 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;
- Directing 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 product that contain CBD would be required to include a notice statement that informs the consumer of the presence of the CBD, and include at least the following notices:

- Directing those that are pregnant, may become pregnant, or are breastfeeding to consult with their physician about the use of these products;
- 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 shall not be sold commercially in Colorado or shipped or transported to addresses in 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 of the stakeholders, the division anticipates testimony at the formal rulemaking hearing in November, if this request for rulemaking is moved forward.

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

- Correlate the federal dietary supplement and food-labeling requirements to these product’s stakeholders;
- Meet the intention of the law with regard to consumer notice requirements;

- Ensure and 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 and this was identified as a potential health impact in GW Pharmaceuticals new drug application ("NDA") to FDA for approval of their hemp-based CBD drug Epidiolex.*
- A desire to have the notices to have more prescriptive language:
  - *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 clear to distributors the prohibition and simplify surveillance and enforcement of the statutory requirement. This labeling requirement aligns with the offenses established in law (mirrored in this proposed regulation) which indicates:*

    "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?

_X_ Yes, the bill number is SB23-271. Rules are _X__ authorized _X__ required.

__ No

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

_X_ Yes URL https://ecfr.io/Title-21/

__ No

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

__ Yes

_X_ No

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

_X_ 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.
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

proposed 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 the State of 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), are transported and disposed properly, and that appropriate records are retained.

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 passing of SB23-271 stakeholder outreach, and the division's stakeholder processes. 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), as applicable 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 the State of 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 the full health potential of all Coloradans.

Economic outcomes

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

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

C: 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 the division's early stakeholder engagement process and are a continuation of already established requirements. In order to minimize impacts of the changes to the

labeling requirements those provisions would not be put into effect until June 1, 2024 to allow for the development of new labels and reduce cost wasted on labels already in stock.

S: No anticipated financial costs or benefits to the department or any state regulatory agency were identified.

B: No anticipated financial costs were identified, but the consumer will benefit from proposed amendments by ensuring that food, dietary supplements, or cosmetics containing hemp that is manufactured or processed in Colorado is unadulterated, safe, and honestly presented.

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

C: 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 the necessary clarity regarding the manufacturing, testing and labeling requirements for the production of hemp and safe harbor hemp products in Colorado.

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, that all ingredients come from approved sources, tested for potency and purity at a CDPHE certified laboratory, packaged and labeled in accordance with 21 C.F.R. 101(A-G) (2017) and the department's labeling requirements, subject to an established written recall plan (if necessary), transported and disposed in accordance with the law, and that appropriate records are retained.

B: The ultimate customer of hemp product manufacturing and processing, the Colorado consumers, will benefit from the proposed revisions by ensuring that the sale and distribution of Colorado's hemp products is consistent with established federal food and dietary supplement safety requirements, additional requirement to ensure product safety that are unique to this industry and are honestly represented and safe.

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

A. Anticipated CDPHE personal services, operating costs or other expenditures: $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 (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:

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

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

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of 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. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ 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
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. ___ 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.

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. ___ Ensures access to breastfeeding-friendly environments.
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. ___ 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).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023. ___ 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.
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. ___ Conducts a gap assessment. ___ Updates existing plans to address identified gaps. ___ Develops and conducts various exercises to close gaps.
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. ___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. ___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. ___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.
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.

___ Implements the CDPHE Digital Transformation Plan. ___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
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. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations
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. ___ Used a budget equity assessment

_X_ Advances CDPHE Division-level strategic priorities.

The DEHS 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 proposed 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 proposed 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 and thus the creation of requirements for hemp products proposed within this regulation. Proposed 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 proposed regulation creation incorporates stakeholder input from the SB22-205 task force, SB23-271 statutory amendments, and the division's stakeholder engagement, and are necessary to refine and clarify manufacturing and testing requirements for the production of hemp products in the State of 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, packaged 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-term 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 being held on July 28, 2023 and subsequent meetings held on August 11 and August 25, 2023. What is anticipated to be a final meeting is scheduled for September 15, 2023. These stakeholder meetings were the culmination of separate but related processes/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 failed to execute its responsibilities to regulate consumable products containing hemp ingredients after the passage of the 2018 Farm Bill. FDA delays continue it has also failed to expand their authority on existing product safety regulations to encompass hemp products (except where products make egregious drug claims).
- In part due to the FDA's failure to act, 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, are often 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 – *"Intoxication 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 department 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).

_X_ 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 proposed regulations represent consensus of the stakeholders, the division anticipates testimony at the formal rulemaking hearing in November, if this request for rulemaking is moved forward.

The proposed requirements within this regulation represent the division 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 and 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 and this was identified as a potential health impact in GW Pharmaceuticals new drug application ("NDA") to FDA for approval of their hemp-based CBD drug Epidiolex.*
- A desire to have the notices to have more prescriptive language:
  - *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 clear to distributors the prohibition and simplify surveillance and enforcement of the statutory requirement. This labeling requirement aligns with the offenses established in law (mirrored in this proposed regulation) which indicates:*

    "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:_____ _____

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

COLORADO HEMP PRODUCT AND SAFE HARBOR HEMP PRODUCT REGULATIONS

6 CCR 1010-24

Adopted by the Board of Health on_____; effective,_____.

24.1 Authority

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

24.2 Scope and Purpose

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

B. This regulation shall govern the registration of hemp product manufacturers or storage facilities and safe harbor hemp product manufacturers or storage facilities. Along with the powers and duties delineated in Section 25-5-420 *et seq.*, C.R.S., Section 25-5-427 *et seq.*, C.R.S., provides the department the power and duty:

1. To grant or refuse to grant registration and to grant or refuse to grant the annual renewal of a registration;

2. To deny, suspend, or revoke a registration;

3. To issue a cease-and-desist order or clean-up order to address violations; and

4. To review any records of a hemp product manufacturers or storage facilities and safe harbor hemp product manufacturers or storage facilities necessary to verify compliance.

C. This regulation does not apply to:

1. Wholesale food manufacturers and the premises or places wherein manufactured foods are produced, manufactured, packed, processed, prepared, treated, packaged transported, or held for distribution governed by the *Colorado Wholesale Food and Shellfish Regulations*, 6 CCR 1010-21.

2. Retail food establishments governed by the *Colorado Retail Food Establishment Regulations*, 6 CCR 1010-2;

3. Facilities or conditions governed by the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4;

4. Entities engaged in the business of possessing, cultivating, dispensing, transferring, transporting, or testing Medical Marijuana or Retail Marijuana governed by the *Colorado Marijuana Rules*, 1 CCR 212-3;

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

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

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

D. Nothing in this rule shall be construed to limit the department's statutory authority under the "Pure Food and Drug Law", Section 25-5-401 et seq., C.R.S., the "Shellfish Dealer Certification Act," Section 25-4-1801 et seq., C.R.S., Section 25-1.5-101. C.R.S., Section 25-1.5-102, C.R.S. or under the "Sanitary Regulations", Section 25-4-101, C.R.S.

24.3 Applicability

A. This rule establishes registration requirements for hemp manufacturers or storage facilities and safe harbor manufacturers or storage facilities, Section 25-5-427, C.R.S.

1. These regulatory requirements 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.

B. Pursuant to Section 24.6, this rule incorporates by reference 21 Code of Federal Regulations (CFR) 100-111, 113-170, and 172-190 (April 1, 2017).

C. This rule establishes enforcement standards for hemp product manufacturers or storage facilities and safe harbor hemp product manufacturers or storage facilities pursuant to Sections 25-1.5-102(1)(c), 25-5-406, 25-5-420, and 25-5-427(8)(a)-(d), C.R.S.

24.4 Definitions

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

1. Approved Source means:

a. Cultivated hemp from a state that has an approved United States Department of Agriculture hemp program; or

b. A product from a wholesale food manufacturer, hemp product manufacturer or storage facility registered with the department in

accordance with Section 25-5-426 or 427, C.R.S; or

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

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

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

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

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

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

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

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

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

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

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

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

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

9. Generally Recognized As Safe (GRAS) means any substance that is intentionally added to food which is a food additive, that is subject to premarket review by the U.S. Food and Drug Administration (FDA), unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definitions of food additive.

10. Hemp has the meaning set forth in Section 35-61-101 (7) C.R.S.

11. Hemp manufacturer or storage facility means a facility where hemp products are manufactured or stored.

12. Hemp product means a finished product that contains hemp and that:

a. Is a cosmetic, a dietary supplement, a food, a food additive, or an herb;

b. Is intended for human use or consumption;

c. Contains any part of the hemp plant, including naturally occurring cannabinoids, compounds, concentrates, extracts, isolates, or resins;

d. Is produced from hemp;

e. Contains no more than 1.75 milligrams of tetrahydrocannabinol (THC) per serving; and

f. Contains a ratio of cannabidiol (CBD) to THC of greater than or equal to 15 to one (15:1).

13. Herb means any plant with leaves, seeds, or flowers used as a flavoring, food, food additive, or dietary supplement ingredient.

14. Intoxicating cannabinoid means any of the following in an amount that exceeds the amount established by rule or, if no rule establishes the amount, in any amount:

a. Delta-10 THC and its isomers;

b. Delta-9 THC and its isomers;

c. Delta-8 THC and its isomers;

d. Delta-7 THC and its isomers;

e. Delta-6a, 10a THC and its isomers;

f. Exo-tetrahydrocannabinol;

g. Metabolites of THC, including 11-hydroxy-THC, 3-hydroxy-THC, or 7-hydroxy-THC;

h. Hydrogenated forms of THC, including hexahydrocannabinol, hexahydrocannabiphorol, and hexahydrocannabihexol;

i. Synthetic forms of THC, including dronabinol;

j. Ester forms of THC, including delta-8 THC-O-acetate, delta-9 THC-O-acetate, and hexahydrocannabinol-O-acetate;

k. Tetrahydrocannabivarins, including delta-8 tetrahydrocannabivarin but excluding delta-9 tetrahydrocannabivarin (THCV);

l. Analogues or tetrahydrocannabinols with alkyl chain of four or more carbon atoms, including tetrahydrocannabiphorols, tetrahydrocannabioctyls, tetrahydrocannabihexols, or tetrahydrocannabutols; and

m. Any combination of the compounds, including hexahydrocannabiphorol-o-ester.

15. Labeling means a display of written, printed, or graphic matter upon a food, cosmetic, dietary supplement, ingredient container, or package and includes product inserts, and other promotional materials including digital communications.

16. Law means applicable local, state, and federal statutes, regulations and ordinances.

17. Manufacturing or processing, manufacturing, manufacture, process, or processing has the meaning set for in Section 25-5-426(2)(h) C.R.S.

18. Non-intoxicating cannabinoid means:

a. Full spectrum hemp extract that contains no more than 1.75 milligrams of THC per serving and contains a ratio of cannabidiol (CBD) to THC of greater than 15 to one (15:1);

b. Broad spectrum hemp extract;

c. Cannabidiol (CBD);

d. Delta-9 tetrahydrocannabivarin tetrahydrocannabivarin (THCV);

e. Cannabichromene (CBC);

f. Cannabicitran (CBT);

g. Cannabicyclol (CBL);

h. Cannabielsoin (CBE);

i. Cannabigerol (CBG);

j. Cannabidivarin (CBDV); and

k. Cannabinol (CBN);

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

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

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

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

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

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

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

24. Regulated hemp facility means:

a. A hemp manufacturer or storage facility; or

b. A safe harbor manufacturer or storage facility.

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

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

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

a. Semi-synthetic cannabinoid includes cannabinoids, such as cannabinol (CBN) that was produced by the conversion of cannabidiol (CBD).

b. Semi-synthetic cannabinoid does not include cannabinoids produced via decarboxylation of naturally occurring acidic forms of cannabinoids, such as tetrahydrocannabinolic acid, into the corresponding neutral cannabinoid, such as THC, through the use of heat or light, without the use of chemical reagents or catalysts, and that results in no other chemical change.

28. Serving means the size or portion customarily consumed per eating occasion, expressed in a common household measure as establish in Table 2 of 21 CFR 101.12.

29. State licensing authority has the meaning set forth in Section 44-10-103(69), C.R.S.

30. Synthetic cannabinoid means a cannabinoid-like compound that was produced by using chemical synthesis, chemical modification, or chemical conversion, including by using in-vitro biosynthesis or other bioconversion of such a method.

a. Synthetic cannabinoid does not include:

(1) A compound produced through the decarboxylation of naturally occurring cannabinoids from their acidic forms; or

(2) A semi-synthetic cannabinoid.

31. Tetrahydrocannabinol (THC) means the substance contained in the plant cannabis species, in the resinous extracts of the cannabis species, or a carboxylic acid of, derivative of, salt of, isomer of, or salt or acid of an isomer of these substances.

a. Tetrahydrocannabinol (THC) includes:

(1) Delta-10 THC and its isomers;

(2) Delta-9 THC and its isomers;

(3) Delta-8 THC and its isomers;

(4) Delta-7 THC and its isomers;

(5) Delta-6a, 10a THC and its isomers; and

(6) Exo-Tetrahydrocannabinol;

b. Tetrahydrocannabinol or THC may also contain:

(1) Products or metabolites of any of the compounds listed in 31(a).

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

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

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

c. Intended for human use.

33. Total THC means the sum of the percentage by weight of the THCAs multiplied by 0.877 plus the percentage by weight of THC [i.e., (% THCA x 0.877) + % THC].

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

24.5 Registration Requirements

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

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

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

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

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

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

a. The safe harbor hemp product 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; and

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

c. The safe harbor hemp product is manufactured, produced, tested, labeled, stored, and distributed in accordance with all applicable rules; and

d. The safe harbor hemp product manufacturer or storage facility is:

(1) Not a registered hemp manufacturer or storage facility or a registered wholesale food manufacturer or storage facility; or

(2) If the safe harbor hemp product manufacturer or storage facility is a registered wholesale food or hemp manufacturer or storage facility, each safe harbor hemp product is:

(A) Physically separated from hemp or food products during the manufacturing, production, storage, and distribution of the safe harbor hemp product; or

(B) 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.

24.6 Incorporation by Reference

A. The department shall utilize material incorporated by reference as appropriate to assure that regulated hemp facilities comply with the "Pure Food and Drug Law".

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

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

1. 21 CFR 112, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*.

2. 21 CFR 171, *Food Additive Petitions*.

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

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

Pursuant to Section 24-4-103(12.5)(V)(b), C.R.S., the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by

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

D. The incorporated materials are available at:

https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

24.7 Regulated Hemp Facility Manufacturing Requirements

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

1. Be registered with the department;

2. Obtain any other necessary State or local licenses, permits, registrations or approvals.

3. Comply with state law, local ordinances, these governing regulations and all other applicable state and local regulations; and

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

B. Ingredients

1. All ingredients must come from approved sources;

2. All ingredients shall be clearly identified to allow for appropriate traceability. Identification includes:

a. Name of ingredient;

b. Identifying batch or lot number from original package;

c. Date the ingredient was manufactured;

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

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

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

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

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

(1) Not practicable to remove immediately; or

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

C. Approved Solvents

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

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

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

D. Testing

1. Analytical testing shall be performed by a certified laboratory 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.

2. Any exceedance of the potency or contaminant action limits presented in this Section 24.7(D) shall be reported to the department by the regulated hemp facility within 48 hours of receipt of the confirmed analytical testing results.

   a. If a regulated hemp facility product is found to contain a contaminant at levels exceeding those permissible under this regulation, then it shall be considered to have failed contaminant testing.

   b. Notwithstanding the permissible levels established in this regulation, the department reserves the right to determine, upon good cause and reasonable grounds that a particular hemp product or safe harbor hemp

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 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 other than a broad or full spectrum product and contains no more than 25 milligrams per serving of cannabinol (CBN) or other non-intoxicating cannabinoids as defined in 24.4(18) of this rule.

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)

Substance	**Action Limits** Per gram (g), unless otherwise indicated

Salmonella spp.	Absent in 25 g
Shiga-toxin producing Escherichia coli (STEC) - Bacteria	Absent in 25 g
Total coliforms	< 10^2 cfu/g
Total aerobic plate count	< 10^4 cfu/g
Total yeast and mold	< 10^3 cfu/g

b. Mycotoxins

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

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.

Abamectin	Acephate	Acequinocyl
Acetamiprid	Aldicarb	Allethrin
Atrazine	Azadirachtin	Azoxystrobin
Benzovindiflupyr	Bifenazate	Bifenthrin
Boscalid	Buprofezin	Carbaryl
Carbofuran	Chlorantraniliprole	Chlorphenapyr
Chlorpyrifos	Clofentezine	Clothianidin
Coumaphos	Cyantraniliprole	Cyfluthrin
Cypermethrin	Cyprodinil	Daminozide
Deltamethrin	Diazinon	Dichlorvos
Dimethoate	Dimethomorph	Dinotefuran
Diuron	Dodemorph	Endosulfan sulfate
Endosulfan-alpha	Endosulfan-beta	Ethoprophos
Etofenprox	Etoxazole	Etridiazole
Fenhexamid	Fenoxycarb	Fenpyroximate

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

d. Heavy Metals

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

e. Residual Solvents

Substance	**Action Limits** Parts per million (ppm)
Acetic acid	< 100
Acetone	< 100
Anisole	< 100

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

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

E. Packaging and Labeling Requirements

1. Packaging shall be food-grade or GRAS

2. Labeling of safe harbor products 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 Colorado.

3. Labeling shall be performed in accordance with 21 CFR 101, subparts A-G and the department's labeling requirements for hemp products, which include:

a. All information appearing on the principal display panel or the information panel must appear prominently and conspicuously, but in no case may the letters and numbers be less than one-sixteenth inch (1/16") in height unless the regulated hemp facility product meet the exemption pursuant to section 24.7(10).

b. Product Identity Statement which indicates the common or usual name of the ingredient;

(1) Product identity Statement must appear on the principal display panel in bold type;

(2) If the product contains THC or other intoxicating cannabinoids an indication on the principal display panel that the product "Contains THC" and list any other intoxicating cannabinoids.

c. Net Weight Statement placed as a distinct item parallel to the base of the package in the bottom third of the principal display panel.

d. List of ingredients, in descending order of predominance by weight, including:

(1) Identify hemp as an ingredient; and
(2) Identify each isolated cannabinoid as an ingredient and the amount per serving and per individual product package in milligrams.

e. Identify, in milligrams, the total THC content per serving, total THC content per individual product package, and the ratio of cannabidiol (CBD) to THC per serving in the ingredient list or directly below the ingredient list in bold type;

(1) If a serving contains more than 1.25 mg of total THC, and less than a 20:1 CBD to THC ratio, labeling that indicates individuals

must be 21 years or older to purchase on the principal display panel.

f. Any major food allergens, milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, sesame, wheat and soybeans shall be clearly identified and listed separately.

g. For hemp products, the serving and number of servings per product package in accordance with Table 2, 21 CFR 101.12.

h. Manufacturing address or a qualifying phrase which states the firm's relation to the product if contract manufactured, relabeled, or distributed by another company (e.g., “manufactured for” or “distributed by”).

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

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

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

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

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

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

b. The potential for these products to create impairment;

c. Indication that these products have not been evaluated for safety or efficacy;

d. Directing those that are pregnant, may become pregnant, or are breastfeeding to consult with their physician about the use of these products;

e. Indication to keep out of the reach of children.

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

a. Directing those that are pregnant, may become pregnant, or are breastfeeding to consult with their physician about the use of these products;

b. 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.

9. The consumer notice statement requirements in 24.7(E)(7) and (8) must appear on the label in at least one-sixteenth inch (1/16”) letter height and in bold type.

10. The letter height requirement for a tincture package is subject to the alternative heights requirements listed in 21 CFR 101.2 (F) where, a type size smaller than one-sixteenth inch (1/16”) in height or labeling attached to or inserted in the package is acceptable if it appears prominently and conspicuously.

F. Record Keeping

1. The following records shall be maintained:

a. Certificates of analysis of ingredients;

b. Source of ingredients;

c. Batch production records including;

(1) Any records required based on department approval for co-location and use of equipment for hemp and safe harbor products in accordance with Section 24.8 of this rule.

d. Certificate of analysis of finished products;

e. Recalled product information;

f. Adverse health event reporting, including to the extent known after reasonable diligence to ascertain the information, the name and contact information of the complainant, the date the complaint was received, the nature of the complaint, the production batch or lot number, any other identifying information found on the label of the regulated hemp facility product, corrective steps taken, and recall activities completed;

g. Consumer complaints; and

h. Other records as required by the department (e.g., corrective action logs, equipment calibration records, equipment cleaning records as applicable).

2. Records shall:

a. Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original record(s), or electronic records;

b. Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

c. Be accurate, indelible, and legible;

d. Be created concurrently with performance of the activity documented;

e. Be as detailed as necessary to provide history of work performed, and include:

(1) Information adequate to identify the plant or facility (e.g., the name and, when necessary, location of the plant or facility);

(2) The date and time of the activity documented, when appropriate;

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

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

3. Records shall be retained:

a. At the plant or facility for at least 2 years after the date they were prepared for products identified as foods, food additives and cosmetics; and

b. For one year past the shelf life date, if shelf life dating is used, or two years beyond the date of distribution of the last batch of dietary supplements.

G. Recalls

1. Regulated hemp facilities shall establish a written recall plan in accordance with 21 CFR 117.139, *Recall Plan*, that includes procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

a. Directly notify the direct consignees of the hemp product or safe harbor hemp product being recalled, including how to return or dispose of the affected product;

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

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

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

H. Transportation

1. Transfer of hemp products shall be conducted in accordance with the law.

2. Hemp products and safe harbor products shall be transported in a manner where they will be protected from adulteration, allergen cross-contact, environmental contamination and any other hazards.

I. Waste and Hazardous Waste Management

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

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

3. Waste management shall be conducted in accordance with the *Colorado Hazardous Waste Regulations* (6 CCR 1007-3) and the *Colorado Solid Waste Regulations* (6 CCR 1007-2).

24.8 Additional Requirements for Safe Harbor Manufacturers

A. Safe Harbor hemp product manufacturers shall maintain records for at least two years indicating:

1. Distributor, retailer or individual that purchased the safe harbor product;

2. The state the sale was made to, and records documenting the product is not prohibited in the state where sale was completed;

3. THC or other cannabinoid concentration limits from the receiving state per serving and/or per container for each product;

4 Labeling requirements from the receiving state that differ from those listed in this rule in section 24.7(E).

And

B. Physical separation, as defined in Section 24.4(20) of this rule, is required for a safe harbor hemp manufacturer or storage facility and a hemp product manufacturer or storage facility.

Or

C. The safe harbor hemp product registrant has received approval from the department on a process validation that demonstrates no cross contamination between products and includes all of the following:

1. A comprehensive list of products being manufactured, including a list of cannabinoids in the products;

2. Equipment used in production;

3. Production methodologies;

4. Procedures and chemicals used in cleaning equipment;

5. Test results of equipment and products for residual cannabinoids;

6. Environmental swab protocol to include frequency, location, contaminant or organism of concern, results and response to positive results;

7. Packaging materials and distribution methods;

8. Record keeping; and

9. Quality assurance program, including change management.

Or

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

1. Sampling protocols for testing finished products for residual cannabinoids;

2. Product hold or release criteria; and

3. Enhanced recall response procedures that ensures notification to consumers, distributors and retailers of contaminated product and when necessary, removal of product from commerce and the market.

24.9 Offenses

A. The manufacture, production, or distribution of a hemp product or safe harbor hemp product that is also a synthetic cannabinoid is prohibited.

B. The manufacture, production, or distribution of a hemp product that contains potentially intoxicating cannabinoids is prohibited, unless specifically allowed by regulation.

C. The manufacture, production, or distribution of a hemp product that contains intoxicating cannabinoids other than THC within allowed limits is prohibited.

D. The chemical modification, conversion, or synthetic derivation of cannabinoids or other hemp-derived compounds, except for those defined as non-intoxicating cannabinoids for use as a hemp product or ingredient in a hemp product is prohibited.

E. The manufacture of a product containing hemp that is not a cosmetic, a dietary supplement, a food, a food additive or an herb is prohibited.

F. The manufacture of a hemp product that contains more than 1.75 milligrams of total THC per serving is prohibited.

G. The manufacture of a hemp product that has a ratio of cannabidiol (CBD) to THC of less than fifteen to one (15:1) is prohibited.

H. The manufacture of a hemp product in a package with more than five servings is prohibited if the hemp product:

1. Has more than 1.25 milligrams of total THC per serving with a ratio of cannabidiol (CBD) to THC of less than fifteen to one (15:1).

2. This Section does not apply to:

a. Broad spectrum hemp products;

b. Tinctures;

c. Cosmetics; or

d. A hemp product that the United States Food and Drug Administration has determined is general recognized as safe under the “Federal Food, Drug and Cosmetic Act”, 21 U.S.C. SEC. 301 et. seq.

I. The manufacture of a hemp product in a package with more than thirty servings is prohibited if the hemp product:

1. Has more than 1.25 milligrams of total THC per serving with a ratio of cannabidiol (CBD) to THC of less than twenty to one (20:1).

2. This Section does not apply to:

a. Broad spectrum hemp products;

b. Tinctures;

c. Cosmetics; or

d. A hemp product that the United States Food and Drug Administration has determined is general recognized as safe under the "Federal Food, Drug and Cosmetic Act", 21 U.S.C. SEC. 301 et. seq.

J. The distribution of a hemp product without the required age labeling and consumer notice statements as listed in Sections 24.7(E)(3)(c)(1) and 24.7(E)(7) and (8) of this rule is prohibited.

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

24.10 Enforcement

A. Hemp product manufacturers or storage facilities that fail to submit a complete and accurate annual application for registration, or fail to remit fees in accordance with Section 25-5-427(5), C.R.S., are not considered an approved source for introduction of hemp products into commerce.

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

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

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

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

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

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

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

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

3. Falsified records or information submitted to the department.