# Senate Bill 22-205:

## Intoxicating Hemp and Tetrahydrocannabinol Products

Concerning the regulation of cannabis-related products that may potentially cause a person to become intoxicated when used.

Task Force Report

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## State Agencies Supplement

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# Introduction

The Department of Public Health and Environment (CDPHE) and Marijuana Enforcement Division (MED), (collectively "agencies") appreciate the SB 22-205 Task Force's efforts to develop recommendations regarding intoxicating hemp in Colorado. The agencies support the Task Force's recommendation to maintain the two existing frameworks, and have significant interest in ensuring that intoxicating products, whether derived from hemp or marijuana, are regulated by the MED, while non-intoxicating products derived from hemp are regulated by the CDPHE. The agencies' feedback is based on three overarching goals:

1. Protect public health and safety;
2. Clarify existing laws and regulations;
3. Resolve statutory and regulatory gaps.

The following feedback, commentary, and recommendations are based on the Task Force's discussions and final report recommendations, which are inextricably intertwined. Staff for the CDPHE and MED collaborated on this feedback and emphasize that this document represents the agencies' aligned perspectives, concerns, and recommendations, unless noted otherwise.

# THC in Hemp Products

**Limits**

The Task Force recommends that the legislature adopt the following standard for finished hemp products to be sold in Colorado:

- No greater than 2.5 mg THC per serving; AND
- The formulation shall contain a ratio of CBD:THC of greater than or equal to 15:1 CBD:THC;
- The foregoing limitations do not apply when a finished hemp product exclusively contains one or more Non-Intoxicating Compounds (i.e. CBD isolate; CBG isolate; CBN isolate); provided, however, that CBN shall be restricted to no more than 25 milligrams per serving;
- No container limits;
- Non-intoxicating compounds do not need to meet these requirements. Hemp products that contain only non-intoxicating compounds are not subject to these limitations. It is also important to note that the definition of THC includes all of its isomers. Hemp companies will also be able to use other potentially intoxicating compounds if they can prove that those products are considered non-intoxicating by review of the standing scientific committee.

*Beginning on page 19 of Final Report*

**Agency Commentary / Recommendation**

**The agencies agree with the Task Force's recommendation to limit THC in hemp products based on both the ratio of CBD to THC and with a milligram limit. The agencies specifically support the recommended 15:1 CBD:THC ratio when coupled with a milligram limit that is less than 2.5 milligrams.**

Considerations:

- During the SB 22-205 legislative process, the agencies initially proposed a milligram per serving limit that was lower than 2.5 milligrams; however, as evidenced by the Task Force's suggestion of

ratio limits and discussion on how that impacts potential intoxication, the agencies recognize the evolving nature of this issue.

- As it relates to establishing THC limits for finished hemp products, the General Assembly and stakeholders engaged in the legislative process should consider the following:
    - First, the proposed limits should apply to "Total THC," which can be accomplished either by defining "Total THC" or expanding the current statutory definition of tetrahydrocannabinol.
    - Second, while the Task Force is not recommending container limits at this time, the General Assembly should authorize the agencies to promulgate rules regarding container limits based on product type.
    - Third, any product that exceeds the per serving ratio and milligram limits should be considered a non-compliant hemp product (subject to appropriate enforcement measures). Facilities desiring to produce or sell products exceeding the established limits should be required to hold the appropriate MED license(s).
    - Fourth, titles 25 and 44 should expressly provide that Industrial Hemp Products must not contain only THC, absent an MED license (requiring such products be manufactured in an MED-licensed facility).
    - Lastly, while this recommendation proposes to limit the ability for hemp products to be intoxicating, a comprehensive understanding of the science associated with CBD:THC ratios is still evolving. Therefore, while not specifically addressed by the Task Force, CDPHE believes there should be consideration given to establishing an age limit of 21 for purchasing all hemp products.
- Other states and jurisdictions have also considered or adopted limits on THC in products. For example:
    - Oregon: 0.5 mg/serving, 0.5 mg/container
        - Oregon adult-use hemp (21+): 2 mg/serving, 20 mg/container
            - An adult-use hemp structure does not exist in CO.
    - European Commission:
        - Hempseed Oil: 0.00075% (7.5 mg per kilogram)
        - Dried products: 0.0003% (3 mg per kilogram)

**Agency Rulemaking Authority**

MED and CDPHE should have rulemaking authority to amend the proposed limits to serving size and containers as well as ratios of Non-intoxicating Cannabinoids to Intoxicating Cannabinoids (i.e. CBD:THC) along with making other timely changes to regulations based on evolving science to be protective of public health.

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**Agency Commentary / Recommendation**

**The MED and CDPHE agree with this recommendation and have an interest in ensuring statutory rulemaking authority is broad enough to remain nimble and responsive to emerging scientific data.**

Considerations:

- MED and CDPHE agree with the recommendation.
- The agencies may look to what other states or jurisdictions have adopted to inform any future rulemaking.
- There is already broad authority in CDPHE's governing statute, sections 25-5-420(1) and 25-5-426(4)(e), C.R.S., that may be inclusive enough to cover the rulemaking authority discussed in this and other recommendations.

## Manufacturing Safe Harbor

The Task Force expressed an interest in statutory allowances for industrial hemp-derived and synthetically-derived cannabinoid products manufactured in Colorado (e.g. Delta-8 THC) to be exported pursuant to the following recommendations (*beginning on page 24 of Final Report )*:

**Establishment of a Safe Harbor:** The Task Force recommends that the legislature establish a "safe harbor" for manufacturers to manufacture finished industrial hemp products which do not meet the finished product requirements required to be sold in Colorado, but which may be lawfully sold in another state.

**Rulemaking Authority:** The Task Force recommends that manufacturers maintain recordkeeping in accordance with CDPHE regulations sufficient to distinguish between batches of products intended for sale in Colorado versus those intended for sale in other states.

**In-Process Exception for Delta-8 & HHC**: The Task Force recommends that Colorado-based manufacturers shall be permitted to manufacture delta-8 THC and hexahydrocannabinol strictly as an in-process material for use in the process of making a Non-Intoxicating Cannabinoid (e.g. CBN). Such in-process material may be transferred between CDPHE-registered facilities.

**Agency Commentary**

- The agencies do not object to both the hemp and marijuana industries' desires to maintain avenues for future production and interstate commerce, while recognizing the importance of balancing public health and safety for Coloradans, and recognizing that other states may set their own standards, noting our lack of interstate jurisdiction.

## Classification, Assessment, and Approval of Cannabinoids & Compounds

Because of the complexities and nature of the following related recommendations, the agencies have consolidated their commentary.

**Classification of Cannabinoids** (*Beginning page 17 of Final Report*): The Task Force recommends that the legislature create classifications of cannabinoids (and other cannabis-derived compounds) to

distinguish under what circumstances, if any, such cannabinoids and compounds may be used in manufacturing of Industrial Hemp Products.

- Non-intoxicating Cannabinoids: The Task Force recommends these cannabinoids may be freely used as ingredients in the manufacture and sale of Industrial Hemp Products, in accordance with the potency and other requirements recommended herein and as required by CDPHE.
- Potentially Intoxicating Compounds: The Task Force recommends these [potentially intoxicating] compounds not be allowed to be manufactured within Colorado or incorporated into Industrial Hemp Products for sale within Colorado, except as provided for in the Safe Harbor provisions hereof (if at all), unless and until these cannabinoids are further assessed by the MED/CDPHE [and a standing scientific committee] and any (if at all) exceptions are made on specific cases and scenarios.
- Intoxicating Cannabinoids: The Task Force recommends these cannabinoids shall not be allowed to be manufactured within Colorado or incorporated into Industrial Hemp Products for sale within Colorado, except as provided for in the Safe Harbor provisions hereof (if at all), unless and until these cannabinoids are further assessed by the MED/CDPHE [and a standing scientific committee].

**Approval of Certain Non-Intoxicating Hemp Products** (*See page 21 of Final Report*): The MED/CDPHE, or CDPHE in coordination with MED shall create a process whereby manufacturers of Industrial Hemp Products that exceed permissible levels of THC or other intoxicating compounds can obtain approval for sale in Colorado, based upon a reasonable determination that the product is safe and non-intoxicating.

**Assessment of Novel Cannabinoids** (*See page 22 of Final Report*): The MED/CDPHE, or CDPHE in coordination with MED will establish a process for the assessment of Novel Cannabinoids to determine whether they are non-intoxicating when consumed.

**Synthetic Cannabinoids** (*See page 23 of Final Report*): The Task Force recommends that statutory changes should be made to ensure MED/CDPHE, or CDPHE in coordination with MED, have sufficient authority to create approval processes on the production and sale of synthetic cannabinoids in Colorado.

**Agency Commentary / Recommendation**

**If the General Assembly directs the agencies to establish a process that is less rigorous than the FDA new drug application process then the agencies will not and cannot make determinations of safety, resulting in consumers being exposed to unknown risks. Further, if the production of synthetic cannabinoids and/or compounds is permitted, any statutory language should be clear that the starting material must be cannabis (whether hemp or marijuana).**

Considerations:

- **Tie to Standing Scientific Committee**: The recommendations to classify cannabinoids, approve certain non-intoxicating compounds, assess novel cannabinoids, and allow synthetic cannabinoids are all tied to and constrained by the Task Force recommendation to establish a standing scientific committee. The challenges with establishing and implementing a standing scientific committee are outlined below and it is important to consider all of these recommendations in tandem when evaluating the operability and potential impacts of implementation.

- **Safety Evaluations / Assessments**: The Task Force recommends that the standing scientific committee and state agencies evaluate, assess, and approve cannabinoids and compounds for manufacture and sale both within Colorado and outside Colorado. The following considerations identify operability and implementation challenges:
    - Foremost, it is critical to recognize the difference between determining whether a cannabinoid or compound is "intoxicating" versus "safe" versus produced in a safe manner. Additionally, the Task Force recommends that a product that is manufactured in a "safe" manner be permitted for export to other states for sale under the proposed "safe harbor" provision; however, this determination (if made) is not equivalent to a determination that the product itself is either safe or non-intoxicating.
    - Many of these compounds do not have established safety information.
        - For example: CBT (cannabicitran) and CBE (cannabielsoin) are practically unknown to regulators. There is almost no information available on the methods of production, uses, safety, or effects of CBT or CBE. Similarly, CBL (cannabicyclol) has been detected in lab testing as a trace byproduct of synthetic THC production. Little, if any, information is available on human consumption of CBL. A study found CBL caused convulsions and death in rabbits. (https://cbdoracle.com/cannabinoids/cbl)
    - Some of these compounds may exhibit intoxicating or other effects at certain doses.
        - For example: CBN (cannabinol) may cause drowsiness at normal doses, but has been reported to cause THC-like effects at higher doses. THCV (tetrahydrocannabivarin) has indications that higher doses may cause THC-like effects.
    - Typically in other industries, the industry operators take on the burden of establishing safety standards, yet within this recommendation, the question still looms regarding who will be responsible for gathering data and evidence to support a determination of intoxication and/or safety.
    - Neither MED nor CDPHE have evaluated any cannabinoid for safety.
    - The Task Force proposes the state and standing scientific committee step into the FDA's role to evaluate cannabinoids and compounds for safety and intoxication; however, the FDA has not been silent on this issue. FDA has approved several drugs that contain CBD or THC through their rigorous and appropriate new drug application process (NDA). An NDA includes animal and clinical trials and whether the benefits of the drug outweigh the risks. FDA has not approved cannabinoids as a food ingredient or a dietary supplement based on a number of concerns that include, chronic health impacts concerns, dose relationships, interactions with other products (drugs and supplements), liver toxicity, male reproductive health and production methods that result in unknown byproducts. Further, to the agencies' knowledge, no manufacturer has pursued the GRAS or NDA processes for the FDA to consider approval as a safe product.
        - The Task Force discussions centered around the state agencies and standing scientific committee establishing a process similar to, but likely less rigorous, than the well-established FDA processes.
        - If the General Assembly aims to direct the agencies and standing scientific committee to make true safety determinations, then the process must align with the

requirements the federal government imposes and agencies must be allotted significant resources to accomplish implementation of such program.

- **Creation of Synthetic Cannabinoids & Testing**:
    - **Synthetic Cannabinoids**: While a determination of "safety" of any cannabinoid creates challenges as described above, that determination is solely about the cannabinoid. Since many of the cannabinoids in question do not naturally occur at levels high enough in the plant to simply be extracted and concentrated, the cannabinoids are either converted from other cannabinoids or synthetically generated.
        - As discussed throughout the Task Force meetings, there are currently products that are derived both from the cannabis plant and from other starting materials. At the outset, if synthetic cannabinoids are permitted to be manufactured within Colorado, whether for sale within the state or out of state, the agencies believe it critical that the starting material must be derived from cannabis (hemp, hemp products, regulated marijuana, or regulated marijuana products).
        - There is widespread discussion across the United States and the world regarding whether to permit or prohibit the production of synthetic cannabinoids. By way of example: Germany's approach to this issue is an express prohibition of any synthetic cannabinoids based on the existence of a regulatory framework for cannabis.
        - Currently in Colorado, the creation of synthetic cannabinoids is prohibited. *See* sections 18-18-102(34.5), 18-18-406.1, 18-18-406.2, 18-18-406.3, C.R.S.
        - An alternative to allowing the production of synthetic cannabinoids derived from hemp is to adjust the Marijuana Code and MED rules to allow processes to create CBN (and other synthetic cannabinoids) within MED-licensed facilities. This adjustment could help reduce diversion of high-concentration delta-9 THC derived from hemp without disrupting or limiting access to CBN products.
        - Lastly, if the General Assembly adopts statutory provisions directing the agencies to allow and establish an approval process for synthetic cannabinoids / compounds and products, the agencies believe there will be widespread impacts on the marijuana market, including but not limited to, reduction in marijuana cultivation operations resulting in reduced excise tax revenue, and greater risks to public health and safety due to the uncertainty and lack of scientific data about prolonged use of synthetic cannabinoid products.
    - **Testing**: Both converting or synthetically generating cannabinoids present concerns on what residuals and byproducts may be present in the finished product, the harm they may present, and the ability to understand what could be present and how to test for residual chemicals / byproducts. Testing performed on these products routinely finds unknown (unidentifiable) compounds and the endless combinations of solvents and chemicals that can be used in the synthesis process create significant challenges in testing.
- **Occupational & Environmental Concerns**: Occupational and environmental concerns have been identified in the production of different cannabinoids. Long-term occupational impacts from exposure to chemicals and byproducts during the production process are not well understood, nor are the environmental impacts. Moreover, what has been observed in these operations is the use of unapproved, and often hazardous, chemicals and solvents (toluene, chloroform, dichloromethane, methylene chloride, hydrochloric acid, muriatic acid and more) in the production of synthetic and semi-synthetic cannabinoid products. The use or misuse of solvents exacerbate the occupational

and environmental issues along with the "safety" of the products themselves. Even if these issues are resolved and/or appropriate control regulations/mechanisms are put into place, issues remain related to:

- Unknown by-products in the finished products and how to test for these "unknowns"
- Potential long-term health impacts with the use of the products or exposure to the unknown by-products. Examples of some safety issues at synthetic cannabinoid manufacturers:
  - Large volumes of solvents and/or other chemicals stored on site, exceeding fire code allowances, other hazards to workers and first responders;
  - Dangerous solvents: toluene, dichloromethane, chloroform;
  - Dangerous chemicals: Highly flammable or toxic substances such as pyrophoric organometallic reagents, dimethylaminopyridine, isopropyl amine;
  - Unsanitary Conditions;
  - Environmental Concerns/Toxic Waste Disposal: Air pollution, chemicals/solvents being dumped down sewer drains, dead birds around facilities;
  - Not Cannabis-derived: Starting materials at some locations are olivetol and citral (not from cannabis), typically purchased in bulk and sourced from foreign countries.

- **Purpose of Classifications**: The Task Force agreed that the existing lanes through CDPHE registration for hemp products and MED licensing for marijuana products should be utilized for the purpose of regulating intoxicating hemp products, however, it is unclear to the agencies what categorizing compounds as "potentially intoxicating" accomplishes outside of the "Safe Harbor" proposal. The "potentially intoxicating compound" classification may create a loophole for operations that are neither compliant with CDPHE regulations nor MED regulations.
- **Required Clarity & Direction**: If the General Assembly moves forward with this recommendation, the agencies request direction regarding the records, studies, evidence, and information that should be relied upon and clarity regarding the intended or desired outcome of this assessment process. For example, as noted above, is the intent that such assessment would result in findings of safety and/or intoxication?

## Standing Scientific Committee

**Establishment of Scientific Committee**

The Task Force recommends that the legislature consider (i) a newly established standing scientific committee or (ii) an expansion of scope of an existing committee, such as the Retail Marijuana Public Health Advisory Committee, where such committee is enabled to assist the agencies in the ongoing evaluation of scientific data and research related to cannabinoid research and the evaluation of cannabinoids for their safety profiles and intoxicating potential of cannabinoids, including the appropriate classification of cannabinoids (based on the classifications recommended herein). Such standing scientific committee should be primarily comprised of representatives of academia stakeholders as well as representatives of industry stakeholders and applicable regulatory agencies.

*Beginning on page 21 of Final Report*

**Agency Commentary / Recommendation**

**The Task Force recommendation to establish a standing scientific committee would likely result in circumventing the current and well-established FDA process that is available to cannabinoid manufacturers, yet has not been pursued, could put public health and consumers of these products at risk.**

Considerations:

- There are several aspects of the proposed standing scientific committee that require further clarity and definition if it is going to be incorporated into a bill and implemented.
    - First, there should be clear expectations for what responsibilities or duties the committee is tasked with and how the committee is expected to accomplish those responsibilities and duties. For example, the General Assembly should clarify how the committee will determine safety, including but not limited to, which party (committee, state, or businesses) bear the burden of demonstrating safety.
        - It is the agencies' position that the burden of demonstrating safety must be on the submitter to provide sufficient evidence that the novel product does not pose a threat to health and safety
        - Further, the committee should have clear direction on what types of studies are required to demonstrate safety and who is responsible for conducting such studies.
    - Second, if a standing scientific committee is established, the General Assembly should clearly provide who will be responsible for making appointments to the committee and what eligibility requirements may be imposed.
    - Third, based on Task Force discussions and the final recommendation, it is unclear whether the Task Force envisions the committee's review role as aligned with that of the federal Food and Drug Administration (FDA) when it reviews new dietary ingredients or new drugs. If the proposed process and review is less rigorous than that of the FDA's then the committee should not be directed to determine whether a cannabinoid, compound, or product is "safe."
- The Retail Marijuana Public Health Advisory Committee should not be expanded to take on the task of evaluating safety and intoxication of cannabinoids, compounds, or products.
    - The RMPHAC monitors the science and literature of health effects from marijuana, and that scope should be expanded to include monitoring and evaluating literature and emerging research for all cannabinoids and cannabis compounds to translate the science into meaningful public health statements.
- If the committee is reviewing information provided by private companies related to their intellectual property and other proprietary information, it will be important to include a confidentiality provision in statute (similar to 44-10-204, C.R.S.) to allow the designated regulatory body (CDPHE or MED), the ability to review information provided by licensees for the assessment of novel cannabinoids, the evaluation of known cannabinoids, and for investigative or enforcement purposes.
    - While the scope of the duties of the proposed standing scientific committee is not clear at this time, any group evaluating cannabinoids must be able to access all proprietary information of a company in order to evaluate the processes used to convert hemp to a cannabinoid, including any information related to inputs used or byproducts produced in the process, data related to cannabinoids, or any other proprietary information. Without

strong confidentiality, any group evaluating cannabinoids will not be able to obtain complete disclosures required to complete these evaluations.

- Additionally, the proposed effective dates for regulations may not be operable for the agencies to establish rules for the committee review process, appoint members, and initiate meetings within the proposed time frame.
- The FDA process for new drug applications (NDA) and generally regarded as safe (GRAS) is available to cannabinoid manufacturers. However, the agencies are unaware of a manufacturer in this industry pursuing that pathway. Additionally the FDA has approved cannabinoid pharmaceuticals, both naturally occurring and synthetic (i.e., Epidiolex, Marinol, nabilone).

## Definitions

**Total THC**

We recommend the final definition of Total THC be left to regulation. As we have seen, the calculation for total THC will need to be adjusted as science evolves and amended more quickly than statutory changes allow. Further, federal legislation and/or regulation or enforcement guidance may impact this definition in the future. A regulatory definition will allow for more flexibility as we continue to learn about THC and as relevant federal regulation evolves.

*Beginning on page 16 of Final Report*

**Agency Commentary / Recommendation**

**The definition of tetrahydrocannabinol must be amended throughout the Colorado Revised Statutes and the statutory authority to define "Total THC" through rulemaking should clearly state "Total THC" will consider the sums of delta-9 tetrahydrocannabinol, its acid form, and the isomers of delta-9 tetrahydrocannabinol and their acid forms.**

Considerations:

- While rulemaking authority to define "Total THC" is sufficient, the statutory definition of "tetrahydrocannabinols" must be amended to clarify its meaning and scope."
    - The current statutory definition of "tetrahydrocannabinols" in Titles 18 and 27 of the Colorado Revised Statutes uses an obsolete chemical molecule naming convention, contains typographical errors (missing a "delta" symbol), and is otherwise in need of revisions/modernization to provide the clarity needed to properly understand and enforce such statutes. While the Task Force has proposed definitions for "intoxicating cannabinoids," "potentially intoxicating cannabinoids," and "non-intoxicating cannabinoids," it has not proposed a definition for "tetrahydrocannabinols" that comprehensively considers the use of the term throughout several different sections of statute (titles 18, 27, 35, 44), as well as how modernization of the definition is needed to provide clarity for state and local agencies as the legal landscape surrounding tetrahydrocannabinols, marijuana, and hemp evolves.

**Potentially Intoxicating Compound**

Such term should be defined to capture potentially intoxicating cannabinoids, as well as other potentially intoxicating constituents of hemp, when isolated and/or synthesized to create a distinct "article" with the intent to use such article as an ingredient. Certain cannabinoids are likely to be intoxicating at certain levels; similarly, research is scarce as to the intoxicating potential of other compounds derived from hemp, when isolated and/or synthesized and concentrated into a distinct "article." The law should direct the agencies [and standing scientific committee] to evaluate such Potentially Intoxicating Compounds as more scientific research and data becomes available. The law should define a standard for intoxication and that standard should be applied to isolated, synthesized cannabinoids or other compounds which are distinct "articles," and should specifically exclude (i) [Non-Intoxicating Cannabinoids] and (ii) cannabinoids or compounds when comprising a naturally derived full spectrum hemp extracts or broad spectrum hemp extracts

*Beginning on page 16 of Final Report*

Considerations:

- While the Task Force was clear that the recommended THC limits in hemp products were not intended to indicate a standard of intoxication, a standard of intoxication still needs to be determined and defined in order to provide guidance and direction to the responsible agencies and to the standing scientific committee, if established.
    - As noted by the Task Force, dose/serving size and potency/intoxication need to be considered together for cannabinoids that may exhibit a greater or lesser affinity for intoxication than delta-9 THC.
- The Task Force report references throughout the lack of scientific studies and evidence to support determinations related to intoxication and safety. There needs to be greater clarity regarding who will be responsible for conducting the needed research and any guardrails in place to provide guidance on the evaluation of that data.

**Synthetic cannabinoid**

Means a cannabinoid like compound that was produced using chemical synthesis, chemical modification, or chemical conversion (including in-vitro biosynthesis and bioconversion) of any method or type except for those produced through the decarboxylation of natural occurring cannabinoids from their acidic form.

*Beginning on page 16 of Final Report*

**Agency Commentary / Recommendation**

**The agencies recommend that the definition for synthetic cannabinoid maintain the current exclusion ("except for those produced through the decarboxylation of natural occurring cannabinoids from their acidic form") if adopted into statute.**

Considerations:

- See also considerations under the Classification, Assessment, and Approval section.

**Novel cannabinoid**

Means any cannabinoid that has not been assessed by MED/CDPHE, or CDPHE in coordination with MED for safety and intoxication profiles.

*Beginning on page 16 of Final Report*

Considerations:

- See also considerations under the Classification, Assessment, and Approval section

**Serving Size**

***Note:*** *specific request for CDPHE to inform this definition*

*Beginning on page 16 of Final Report*

**Agency Commentary / Recommendation**

**The agencies must maintain and/or be granted appropriate authority regarding serving size limits and product-type container limits.**

Considerations:

- Task Force members agreed the establishment of a serving size definition was needed. CDPHE has the current regulatory authority to do so.
- Traditional foods have labeling and serving size requirements established in federal regulations in 21 CFR 101 and 117 that are incorporated by reference in Colorado regulations and means.
    - "Serving or serving size means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food. Examples include: A 12oz drink, typical candy bar, bag of candy are 1 serving;
- While traditional foods have labeling and serving size requirements, current compliance activities at these operations is not a significant function of the program. Incorporating these functions into hemp compliance activities would necessitate additional resources for more dedicated oversight.
- While further recommendations address total THC limits per serving and establish CBD:THC ratios; Serving size may not be the only necessary control to ensure hemp products are not intoxicating. Large bulk containers meeting both of these requirements could still have THC limits that far exceed container limits established for marijuana products.
- The Task Force did not address container limits. While a singular container limit for all products does not seem appropriate. Container limits by product type should be considered. Product types could include; tinctures, foods, and dietary supplements. Considering establishing authority in law to establish container limits in regulation via the collaborative rulemaking process.

**Relevant Resources:**

- 21 CFR 101.12(b) and the procedures described in 21 CFR 101.9(b)
- Table 2 in 21 CFR 101.12

- 6 CCR 1010-21

## Labeling & Marketing

**Labeling**

The Task Force recommends that the legislature should direct CDPHE, in coordination with MED, to promulgate regulations for labeling Industrial Hemp Products which distinguish those products which contain synthetic/synthesized cannabinoids from those which only contain naturally occurring cannabinoids.

*Beginning on page 20 of Final Report*

**Agency Commentary / Recommendation**

**The agencies agree with the Task Force recommendation to require labeling to distinguish between synthetic and naturally occurring cannabinoids in products.**

Considerations:

- Throughout the Task Force discussions, members raised considerations that regulated marijuana products and industrial hemp products should be treated similarly, to the extent possible, with regard to labeling whether a product contains synthetic cannabinoids.
- As noted in the Task Force recommendations, other statutory provisions must be revised to clarify the allowance to produce synthetic cannabinoids.

**Marketing**

The Task Force further recommends that Industrial Hemp Products shall not be marketed as, or promoting, containing THC or other Potentially Intoxicating Cannabinoids. Notwithstanding the foregoing, the Task Force recommends that CDPHE promulgate regulations requiring a notice statement (versus a warning statement) that such product includes THC and other Potentially Intoxicating Compounds. Nothing herein shall preclude manufacturers from including potency and other required disclosures of content of THC and Potentially Intoxicating Cannabinoids.

*Beginning on page 20 of Final Report*

**Agency Commentary / Recommendation**

**If the Task Force's recommendation is adopted, statutory provisions should be clear that labeling is distinct from marketing, and declaration of all cannabinoids should be included on labels.**

Considerations: Agency feedback is dependent on the limits established for certain products and the impacts of consuming such products (impacting drug testing and potential impaired driving).

# Enforcement and Education; Appropriations -

**Funding**

- The Task Force recommends the state needs to allocate sufficient funding to enforce against in-state and out-of-state actors violating the law and placing public safety at risk.
- The initial funding provided to the AG's Office must be maintained and expanded upon to ensure there are staff to conduct the necessary enforcement to protect public safety.
- Additionally, funding should be provided to CDPHE and MED primarily for the enforcement of these proposed regulations, as well as existing regulations, and secondarily to develop and create resources to educate Coloradans about the health risks posed by intoxicating hemp products and specific messaging for parents about the ability for youth to purchase these products online.
- Current registration fees are not adequate to support the necessary compliance activities, enforcement provisions are outdated and the penalty provisions are limited and do not function as an adequate deterrent to willful non-compliance.
- Though the Task Force is not equipped to determine specific penalties or funding appropriations, the Task Force supports a modernization of the enforcement provisions that align with other environmental health programs at CDPHE. Correspondingly, the Task Force recommends that CDPHE make recommendations to the legislature of the additional funding and penalties necessary to support the necessary inspections, compliance and related support, as determined by CDPHE.

*Beginning on page 23 of Final Report*

**Agency Commentary / Recommendation**

**CDPHE has collected data on the resources that would be necessary to both inspect these operations at a more frequent cadence, conduct necessary follow-up activities, ensure identified issues are resolved, and penalty provisions that would align with other environmental penalty structures that would act as deterrents to willful and/or ongoing noncompliance.**

Considerations:

- Both agencies fully support the recommendation for additional funding and modernization of enforcement and fees.
- The agencies further request that this recommendation extend to include MED who, under the recommendations will have a distinct role in regulating intoxicating hemp and see an opportunity for the agencies to continue working together. Excluding MED from this recommendation will impact CDPHE's ability to enforce as what has been discovered is that in many situations there is a dual agency role and both agencies will need to be resourced appropriately to ensure the issues are addressed and resolved.

**Adverse Health Event Reporting**

A system must be established for members of the public to report unsafe or intoxicating products, such as adverse reactions and false or misleading labeling claims.

*Beginning on page 23 of Final Report*

**Agency Commentary / Recommendation**

**The agencies agree with the Task Force's recommendation.**

Considerations: While both agencies support this recommendation, additional resources will be required to ensure reports can be appropriately followed up on.

## Implementation

**Timeline**

- January 1, 2024: Complete rulemaking re: regulatory limits, prohibitions, authorizations for THC
- January 1, 2024: approval process for ingestible consumable IHP that fall outside established limits
- July 1, 2024: process to assess Novel Cannabinoids, PIC, and Intoxicating Cannabinoids
- July 1, 2024: effective date of 1/1/24 regulations
- January 1, 2025: effective date for novel cannabinoids and intoxicating compounds assessment

*See page 23 of Final Report*

**Agency Commentary / Recommendation**

**The effective dates should provide the agencies more time and flexibility to implement regulations based on the statutory provisions that are ultimately adopted. Additionally, the agencies will need the ability to coordinate on regulations to ensure consistency.**

Considerations:

- While the agencies recognize and appreciate the Task Force's intent to ensure progress is made towards building to the proposed regulatory structure, the effective dates should provide the agencies more time and flexibility to implement regulations in order to:
    - Continue working through the challenges identified by the Task Force related to lack of scientific studies and evidence that can be relied upon for both establishing processes to evaluate and assess intoxication, safe manufacturing processes, and product safety. At this time, it is not clear whether sufficient work / studies are likely to be completed within the proposed time that could inform agency rulemaking;
    - Identify any additional gaps or challenges that need to be addressed through rulemaking; and
    - Conduct intentional and thoughtful stakeholdering through the rulemaking processes, while identifying opportunities to streamline corresponding or overlapping programs.

- Agencies should have authority to require compliance with regulations as soon as is practicable (while complying with rulemaking requirements) to protect public health and safety.
- In light of the complexities involved in the Task Force's recommendations, statutory provisions should provide a sufficient framework to guide and direct the agencies' implementation. Additionally, the effectives dates should reflect reasonable timelines for the agencies to implement adopted statutory provisions. As one approach to consider, the General Assembly can identify areas most critical for immediate implementation and establish a phased-in approach for implementation of all other statutory and regulatory provisions.

## Other Agency Recommendations:

**TABOR, Fees, and Taxes**

**Agency Commentary / Recommendation**

**Any legislation should include payment of excise and special sales taxes and should authorize the CDPHE and MED to impose fees in amounts sufficient to support the direct and indirect costs of regulating cannabis products, including intoxicating cannabinoids, potentially intoxicating compounds, and non-intoxicating cannabinoids.**

Considerations:

- The legal manufacture, sale, and use of intoxicating hemp will likely impact the state's residents and state resources, including but not limited to potential impacts on state excise tax revenue, local tax revenues, state agency resource expenditures, and public health and safety.
- To offset these costs and impacts, any legislation should include the payment of regulatory fees in amounts sufficient to support the regulation of this product.
- Excise and special sales taxes for intoxicating hemp products should align with what is currently in place for regulated marijuana.
- TABOR may impact how the legislature can include taxes and fees.
- While it might be possible to tax intoxicating hemp without voter approval, this will depend on how the legislation is drafted and what taxes are imposed.