

2023 CONSUMABLE HEMP PRODUCT REPORT: A Comparative Examination of the Commonwealth's Approach to Hemp-Derived Product Regulation with Other State Approaches, Updates on Regulatory Activity at the Federal Level, and Recommendations for Future Legislative Consideration Publication Date: October 30, 2023 Author: Virginia Cannabis Control Authority Legislative Mandate: 4th enactment clause of Chapters 744 and 794 of the 2023 Acts of Assembly



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#### **Executive Summary**

In the last few years, the market for edible hemp products and hemp products intended for smoking (collectively, "consumable hemp products") has exploded in popularity due in large part to their accessibility and potential to produce intoxicating effects comparable to the "high" experienced from marijuana. The public health risks posed by these products are numerous and grave. They include, but are not limited to, minors' relatively unhindered access to the products, unwitting consumption of the products because of their resemblance to other commonly consumed non-intoxicating goods, and the potential ingestion of products contaminated by residual solvents, microbials, and pesticides. These dangers have spurred state-level efforts to regulate the consumable hemp products market.

Virginia has made significant regulatory changes to address the challenges presented by consumable hemp products. An examination of other states' efforts to limit the risks associated with consumable hemp products reveals other regulatory strategies for Virginia to consider as it explores additional methods to bring this difficult problem under control.

This report surveys the market for consumable hemp products, identifies public health concerns, and discusses common state approaches to addressing these problems. It also examines difficulties states have faced as they adopt restrictions limiting sales of consumable hemp products, including ongoing legal challenges and uncertainty over the implications of potential federal legislation. The report concludes with recommendations, which include (1) imposing robust contaminant testing requirements for all consumable hemp products; (2) requiring ingredient limits on consumable hemp products and implementing a preapproval process for consumable hemp products; (3) addressing access by minors to consumable hemp products at retail locations and through online sales; and (4) imposing further limits on online sales of consumable hemp products.

#### **Background & Methodology**

The Cannabis Control Authority ("Authority" or "CCA") prepared this report in response to the 2023 General Assembly's directive in the 4<sup>th</sup> enactment clause of Chapters 744 and 794 of the 2023 Acts of Assembly. The General Assembly tasked the CCA, in consultation with Virginia Department of Agriculture and Consumer Services (VDACS), to:

conduct a study regarding edible hemp products and hemp products intended for smoking and report the following: (i) a summary of the approaches taken by other states to address the public safety and health challenges posed by the online and in-person sale of hempderived products and a recommendation as to whether the Commonwealth may benefit from adopting one or more of these approaches or another approach and (ii) a summary and the implications of any pending federal legislation on hemp-derived products.

To create this report, the Authority tracked legislative and regulatory activity in states across the country and at the federal level.<sup>1</sup> This included reviewing proposed legislation and engaging cannabis regulators in other states. The CCA also is monitoring developments related to potential legislation in Congress.



#### Introduction

The need to regulate consumable hemp products arose after the United States Congress enacted the Agriculture Improvement Act of 2018 ("2018 Farm Bill").<sup>2</sup> The legislation amended the federal Controlled Substances Act to remove hemp from the definition of marijuana. Federal law defines hemp as "plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis."<sup>3</sup> Delta-9 tetrahydrocannabinol (THC) is the most well-known compound in cannabis, the one people most associate with marijuana's intoxicating effects.

The primary goals of removing hemp from the definition of marijuana were to legalize "low THC" cannabis as an agricultural commodity used for industrial products such as fiber, rope, paper, and mulch and to allow the sale of products containing nonintoxicating cannabidiol (CBD). However, by removing hemp from the definition of marijuana, the 2018 Farm Bill inadvertently facilitated the creation of a new market for consumable products containing a wide range of hemp-derived cannabinoids.<sup>4</sup>

Despite their widespread availability, many products containing hemp-derived cannabinoids present public health and safety concerns like those presented by marijuana products. Products that do not exceed the delta-9 THC limit of 0.3 percent may still contain large amounts of other naturally occurring or semi-synthetic cannabinoids, some of which have intoxicating properties. Some semi-synthetic cannabinoids currently found in consumable hemp products are delta-8-THC, delta-10-THC, THC-O acetate, THCV, THCP, HHC, HHC-O-acetate, HHCP, and CBN.<sup>5</sup> These semi-synthetic cannabinoids are created through chemical processes that may introduce dangerous solvents into the products.

Further, the THC limit set in the 2018 Farm Bill ensures "low THC" for the consumer only when it applies to plant material. Consumable hemp products are usually denser. As a result, even products that have less than 0.3 percent delta-9 THC when measured "on a dry weight basis" may contain significant amounts of delta-9 THC, sometimes more than allowed for sale within any existing adult-use retail market. For example, a typical chocolate bar could contain 150 mg of delta-9 THC and still fall under the 0.3 percent threshold; by comparison, most adult-use retail marijuana programs allow no more than 100 mg of delta-9 THC in a single package.<sup>6</sup>

Under the 2018 Farm Bill, the Food and Drug Administration (FDA) maintains its authority to regulate foods, beverages, dietary supplements, and cosmetics containing hemp or hemp-derived cannabinoids through powers granted to it under the federal Food, Drug, and Cosmetic Act. In June 2022, the FDA issued an advisory letter to warn consumers about the accidental consumption of products containing THC by children, especially products intended to mimic the appearance or branding of candy, snacks, cereals, and other child friendly foods. The letter was driven largely by increasing poison center reports across the country, including in Virginia, of hospitalizations of minors following their ingestion of hemp-derived products.<sup>7</sup> In July 2023, the FDA issued a warning letter to six companies illegally selling what they called "copycat food products" containing delta-8 THC.<sup>8</sup> To date, the FDA has not followed up with any additional letters or disciplinary action.



Absent consistent FDA regulation and enforcement actions, there is minimal federal regulatory oversight of consumable hemp products to protect consumers and minors. Because there is no minimum age to purchase hemp-derived products under the 2018 Farm Bill, these products became easily accessible in traditional retail stores across the country. These traditional retail stores typically do not have vigorous age-verification processes that stores would be required to have if they were selling intoxicating marijuana subject to a comprehensive regulatory framework and state-issued license. Similarly, there is little stopping online retailers from selling hemp-derived products to purchasers under 21 years of age.

The intoxication of minors, including very young children, which often results from the inadvertent consumption of hemp-derived products, is a serious public health concern. As noted, many hemp-derived products imitate other commonly consumed products. These products can be enticing to children and pose significant risks of accidental ingestion. Poison center reports from across the United States indicate children frequently consume intoxicating cannabinoid hemp products — often provided by unsuspecting parents and caregivers — under the false impression the products were candy or some other appealing snack. These products can cause severe reactions in children, including drowsiness, lowered blood pressure, slurred speech, and increased heart rate.<sup>9</sup> The most recently available national data show the number of accidental ingestions of edible cannabis products by children under six years-old increased to 3,054 in 2021—a 1,375% increase from the 207 reported in 2017.<sup>10</sup> While reporting of events involving children under the age of six has grown most dramatically, the number of reported cannabis ingestions has increased across all age groups for minors over recent years.

The Commonwealth has experienced similar increases in accidental underage ingestions. The University of Virginia Blue Ridge Poison Center has documented the increase in accidental ingestion of cannabis by minors. From 2021 to 2022, the number of reported accidental ingestions of cannabis products nearly tripled — from 26 to 77.<sup>11</sup> Data from Virginia's Poison Control centers, which service the Richmond and Hampton Roads areas, reveal a similar increase. In 2022, the Centers reported 88 calls regarding pediatric ingestions, up from three pediatric cases in 2018. Even with the recorded alarming uptick, the data may understate the problem, as public health officials suggest the actual number of accidental ingestions could be much larger than those reported.<sup>12</sup>

Lack of federal oversight also entails considerable risks for adult consumers of consumable hemp products. Although intoxicating cannabinoids are created through chemical processes that may introduce dangerous solvents, there are no federally required testing standards to ensure the final products do not have unhealthy levels of residual solvents and to curb the risks of products containing other contaminants, such as heavy metals and microbials. There are also no federal labeling standards for consumable hemp products. As a result, consumers lack consistent and reliable information about what they are buying and consuming.

This report looks at the responses of Virginia and other states to address the public health problems created by the lack of federal oversight of consumable hemp products. It identifies additional approaches taken by other states that could inform future attempts in Virginia to further regulate consumable hemp products. The report also considers how federal legislative action could begin to mitigate public health and safety concerns presented by consumable hemp products.



#### **Regulation of Consumable Hemp Products in Virginia**

Virginia has adopted statutory changes over the past two years to address problems caused by insufficient federal oversight of consumable hemp products. In 2022, a budgetary amendment included new statutory language prohibiting the sale of products containing THC to those under 21 years of age, requiring products containing THC to be sold in child-resistant packaging, and mandating cannabinoid testing and labeling standards for products containing THC. <sup>13</sup> The amendment also prohibited the manufacture or sale of any hemp product that "depicts or is in the shape of a human, animal, vehicle, or fruit," or is sold in packaging intended to mimic or bear similarity to famous trademarks or commonly known products.<sup>14</sup>

In addition to these statutory changes, the Secretary of Agriculture and Forestry, in conjunction with the Secretary of Public Safety and Homeland Security and Secretary of Health and Human Resources, convened a task force in the summer of 2022 to discuss the safety and sale of hemp products intended for human consumption.<sup>15</sup> The task force issued a report with its recommendations and findings in November 2022.<sup>16</sup> The task force's findings informed the development of Senate Bill 903 and its companion House Bill 2294, which expanded VDACS' oversight of consumable hemp products, curbed the availability of intoxicating hemp products, and ensured that hemp-derived products sold in Virginia meet certain standards for consumers.

Senate Bill 903, as enacted, contained several provisions aimed at curtailing the unchecked sale of consumable hemp products across Virginia. It included new requirements for product manufacturers, limits on products sold at retail, and packaging and labeling requirements. Key provisions include:

- Packaging, labeling, and testing requirements specific to consumable hemp products.
- Granting VDACS authority to issue regulated hemp product retail facility registrations.
- Defining a hemp product to be a product that contains industrial hemp that, when offered for retail sale, contains (i) no more than 0.3% *total* THC rather than 0.3% of delta-9 THC and (ii) no more than two milligrams of total THC per package, unless the product has a CBD to THC ratio of 25:1.
- Defining total THC to include "the percentage by weight of naturally occurring or synthetic [THC] and the percentage by weight of tetrahydrocannabinolic acid."
- Removing THC from Virginia's Schedule I list of controlled substances.
- Updating the definition of "marijuana" to exclude substances containing THC that the Board of Pharmacy placed into one of the schedules of the Drug Control Act.
- Requiring a person to obtain a food permit before manufacturing, selling, or offering for sale a substance intended to be consumed orally that contains an industrial hemp-derived cannabinoid.
- Adding a new provision to the Virginia Consumer Protection Act restricting the sale of "any substance intended for consumption, orally or by inhalation, that contains a synthetic derivative of [THC]."<sup>17</sup>
- Requiring that topical hemp products include a label stating that the product is not intended for human consumption.



The bill also established greater enforcement and compliance tools for VDACS, including new civil penalties for businesses that fail to comply with the new standards. Manufacturers and retailers of industrial hemp-derived extracts intended for use in edible hemp products are also now subject to inspections by VDACS for compliance with the new requirements in the Virginia Food and Drink Law. These inspections may be unannounced and may include the sampling and testing of products.

As noted, Senate Bill 903 expanded the testing and labeling requirements for consumable hemp products. Labels must "contain the total percentage and milligrams of all tetrahydrocannabinols included in the substance and the total number of milligrams of all tetrahydrocannabinols that are contained in each serving."<sup>18</sup> Retailers of consumable hemp products must also provide proof of THC testing by a laboratory that meets standards for total THC established by statute.

Virginia's efforts to protect consumers from unregulated consumable hemp products are currently facing a legal challenge. On September 1, 2023, two hemp businesses and an individual plaintiff filed a lawsuit against several Commonwealth of Virginia defendants.<sup>19</sup> The plaintiffs argue that the total THC standard for hemp products established by Senate Bill 903 is unenforceable because it is more restrictive than the delta-9 standard for hemp established under federal law by the 2018 Farm Bill. The plaintiffs also argue that Virginia's laws violate the dormant Commerce Clause because they restrict interstate commerce and burden sales to out-of-state buyers.<sup>20</sup> As of the date of publication of this report, the plaintiffs' motion for preliminary injunction and the Commonwealth's motion to dismiss the case are pending before the court.

#### **Regulatory Frameworks for Consumable Hemp Products in Other States**

States across the country have pursued regulatory solutions to the problems posed by the proliferation of consumable hemp products available in traditional retail stores and online. Some states have folded regulation of consumable hemp products into their adult-use retail markets,<sup>21</sup> while other states have established separate regulatory paths or taken a hybrid approach.<sup>22</sup> Regardless of the specific regulatory pathway adopted, most states' approaches incorporate similar elements to protect consumers against contaminated products, increase consumers' knowledge of product contents, and limit the access of minors to intoxicating products. This report will not discuss in detail the state approaches that overlap with Virginia's existing laws on consumable hemp products.<sup>23</sup> Instead, it will identify approaches taken in other states that differ from, or expand upon, concepts found in current law in the Commonwealth.

#### Ensuring Safer Products Through Testing, Ingredient Restrictions, and Pre-Approval

One of the overarching objectives when regulating consumable hemp products is to ensure the products available for sale are subject to strict oversight and sufficient testing standards. States regulating consumable hemp products take varying approaches to ensure the safety of products sold to consumers, including establishing robust testing standards, imposing ingredient restrictions (particularly on inhalable hemp products), and requiring pre-approval of consumable hemp products.

Many states have established robust testing standards for consumable hemp products that are similar to rigorous testing requirements for contaminants that apply to marijuana sold in adult-use retail markets.



Comparable testing requirements apply to medical cannabis in Virginia, which must pass microbiological, mycotoxin, heavy metal, residual solvent, and pesticide testing.<sup>24</sup>

Numerous states have applied similar testing requirements to hemp-derived cannabinoids through either statute or rulemaking.<sup>25</sup> For example, in Kentucky, licensees manufacturing hemp products must provide a sufficient sample for testing from each batch of products to ensure consistency in the hemp products within the batch. Kentucky regulations also require testing for cannabinoids, microbial impurities, mycotoxins, residual pesticides, heavy metals, and residual solvents and processing chemicals. In Virginia, regulations adopted pursuant to Article 5 of the Virginia Food and Drink Law require manufacturers of industrial hemp extracts used in food to adhere to the contaminant levels set forth in the medical cannabis program.<sup>26</sup> However, there are no similar testing requirements imposed on hemp products intended for smoking in Virginia.

Another strategy states have used to improve the safety of consumable hemp products sold to consumers is to establish limits on the ingredients used in products. It is common in states with adult-use cannabis markets and medical cannabis programs to limit the substances that can be added to certain consumable hemp products depending on the products' mode of use.

The e-cigarette, or vaping, product use-associated lung injury (EVALI) crisis in 2019 highlights the risks certain chemicals can pose when inhaled. The crisis prompted adult-use and medical cannabis regulators to impose additional restrictions on substances used in extraction for cannabinoids intended for inhalation.<sup>27</sup> The Virginia medical cannabis program prohibits using vitamin E acetate in cannabis oil intended to be vaporized or inhaled.<sup>28</sup> A few states have applied similar restrictions to consumable hemp products sold outside of adult-use cannabis markets.<sup>29</sup> For example, consumable hemp products in Kentucky cannot contain (1) Vitamin E acetate (VEA); (2) Medium-chain triglycerides (MCT); (3) Polyethylene glycol (PEG); (4) Propylene glycol (PG or PPG); (5) 2,3-butanedione (Diacetyl); and (6) Myclobutanil.<sup>30</sup> These ingredients may cause short-term and long-term health effects when vaped.<sup>31</sup>

Restrictions on ingredients in consumable hemp products are not limited to hemp products intended for inhalation. Other restrictions on ingredients reduce polysubstance use or prevent other health risks.<sup>32</sup> Kentucky prohibits treating consumable hemp products with caffeine, nicotine, or "[o]ther chemicals that may increase carcinogenicity or cardiac events."<sup>33</sup> Currently, Virginia does not impose similar limits on ingredients used in consumable hemp products.

Product review and preapproval is yet another approach states use to protect consumers from potentially dangerous consumable hemp products. In Louisiana, for example, consumable hemp processors must submit product information for regulatory approval before distribution or sale of the product.<sup>34</sup> To receive approval, processors must provide test results for products that identify THC potency and any detected solvents, pesticides, microbials, and heavy metals. This process serves as an additional filter to prevent unsafe products from reaching the market. It also creates a central database of approved products in the market, accessible to regulators, which provides useful information regarding consumption trends; the data also can be used to help identify future regulatory needs. Notably, Virginia requires pre-approval of medical cannabis products, but not consumable hemp products, before they can be sold in the Commonwealth.



#### Restricting Access to Consumable Hemp Products by Minors and Regulating Online Access Generally

Through recent legislative efforts, Virginia has made considerable strides in preventing purchases and consumption of consumable hemp products by minors. However, other states' efforts illustrate further steps Virginia could take to strengthen the protection of minors in the Commonwealth.

The widespread availability of, and ease of access to, consumable hemp products help fuel accidental and intentional consumption of these products by minors, creating a serious public health challenge; the products can be easily found on the shelves of many traditional retail stores. A foundational restriction applied to most adult-use cannabis retail businesses is that only individuals over the age of 21 years can enter locations selling marijuana. A handful of states have sought to effectively replicate for consumable hemp products the protections for minors found in adult-use cannabis regulations by limiting where and how stores can display consumable hemp products.<sup>35</sup> Kentucky requires consumable hemp products to "[b]e secured in the retail setting to prevent theft or other access to persons under the age of twenty-one."<sup>36</sup> Likewise, under Tennessee law it is a misdemeanor to fail to maintain consumable hemp products behind the counter in an area inaccessible to a customer.<sup>37</sup> Virginia does not have anything comparable in law when it comes to limiting the physical access of minors to consumable hemp products in retail stores.

In the digital age, sales of unregulated products online can undermine state regulatory efforts. In recognition of this, mail and shipping services published guidance stating hemp products can be mailed only when the sender has complied with all state laws and regulations regarding hemp products.<sup>38</sup> Some states have prohibited online sales of consumable hemp products completely, either through hemp product-specific regulations or by folding consumable hemp products into their adult use retail market.<sup>39</sup> In contrast, West Virginia allows online sales of consumable hemp products, but only for online retailers that have complied with the same registration requirements that apply to brick-and-mortar retailer.<sup>40</sup>

Virginia law requires a person selling a consumable hemp product to obtain a retail facility registration requirement but does not explicitly address online retailers.<sup>41</sup> Nor do any current provisions of Virginia law explicitly prohibit online sales of consumable hemp products. Virginia Code section 18.2-371.2 imposes minimal restrictions only on the online sales of hemp products intended for smoking, not those intended for consumption through other means. Under Virginia law, a person selling hemp products online that are intended for smoking must (1) verify the customer is at least 21 years of age prior to the sale and (2) "use[] a method of mailing, shipping, or delivery that requires the signature of a person at least 21 years of age before the . . . hemp product intended for smoking will be released to the purchaser."<sup>42</sup> However helpful this preventative measure is when applied to products intended for smoking, Virginia does not currently place similar requirements on online sales of edible hemp products.

#### **Federal Action**

The patchwork nature of state-level approaches to the regulation of consumable hemp products exists primarily because of the absence of federal regulatory efforts. Despite the FDA's advisory letter warning consumers about the safety of delta-8 products, it remains uncertain what role the FDA will play in the regulation of hemp-derived products and the extent to which the agency will exert its authority. The FDA issued a statement in January 2023 concluding that "existing regulatory frameworks for foods and



supplements are not appropriate for cannabidiol," and the agency would attempt to address the situation with Congress.<sup>43</sup> Other stakeholders believe the FDA already possesses the necessary regulatory authority to regulate hemp-derived products. In July 2023, the House Energy and Commerce Committee issued a request for information regarding stakeholder feedback on FDA regulation of CBD and the market for hemp-derived cannabinoids as part of an effort to carve out a clear regulatory path moving forward.<sup>44</sup>

Apart from the FDA using existing or modified authority to address the gap in regulation, amendments to the 2018 Farm Bill are another potential avenue to close the loopholes that allow the proliferation of consumable hemp products. The 2018 Farm Bill has several provisions that expire in 2023, and Congress began the process of developing the 2023 Farm Bill in late 2022.<sup>45</sup> Many state regulators hope Congress will consider potential modifications to the current federal regulatory treatment of hemp that will facilitate tighter regulation of consumable hemp products, or at least create more latitude for strong state regulation in this area. <sup>46</sup> The Cannabis Regulators Association (CANNRA), a nonpartisan association representing cannabis and hemp regulatory agencies from more than 45 member states and U.S. territories, sent a letter to Congress in September 2023 recommending specific changes to address the risks associated with federally unregulated consumable hemp products that are widely available throughout the country.<sup>47</sup> CANNRA asked Congress to consider:

(1) adding a definition for "Hemp-Derived Cannabinoid Products," (2) defining THC in terms of both THCA and delta-9 THC, (3) clarifying that the 0.3% THC threshold applies only to the plant and naming a regulator to set appropriate thresholds for intermediate or final hemp-derived cannabinoid products, (4) naming a federal regulatory agency with a timeline for implementing regulations to protect consumer safety, and (5) ensuring that states are not preempted from going beyond federal policies (which should set minimum standards) to protect consumer safety and public health.<sup>48</sup>

Because of the complexities involved in reauthorizing the farm bill, as well as competing legislative priorities in Congress, action on the 2023 Farm Bill, including any changes affecting hemp, is more likely to occur in 2024 than in 2023.

As of the publication of this report, no action on the farm bill has occurred. Without further action from Congress addressing the loopholes created through the 2018 Farm Bill, hemp-derived product manufacturers, distributors, and retailers will remain emboldened to challenge any state-level efforts to impose restrictions on hemp-derived products.

#### **Conclusion and Recommendations**

Future congressional action may address the regulatory challenges created by the current gaps in federal law. Until that time, Virginia should consider strengthening its laws to improve protections for minors and adult consumers in the Commonwealth. While other state regulatory frameworks for addressing consumable hemp products are all relatively new and still in the early stages of implementation, they offer ideas for Virginia to consider as it seeks to further strengthen its laws regulating consumable hemp products. The CCA recommends Virginia consider adopting laws and policies that would:



- (1) Impose robust contaminant testing requirements for all consumable hemp products. Virginia requires testing of consumable hemp products to determine the product's THC concentration. It only requires contaminant testing for industrial hemp extracts used in food. The CCA recommends requiring all regulated hemp products, as defined in Va. Code § 3.2-4112, to undergo testing for pesticide chemical residue, heavy metals, residual solvents, mycotoxins, moisture, and microbiological contaminants. Requiring contaminant testing for <u>all</u> consumable hemp products will enhance public safety and protect consumers.
- (2) Impose ingredient limits on consumable hemp products and implement a preapproval process for consumable hemp products.

Most states' adult-use retail or medical cannabis programs prohibit the use of vitamin E acetate in products intended to be vaporized or inhaled, including Virginia's medical cannabis program. States also limit ingredients—such as alcohol, caffeine, and nicotine—that encourage polysubstance use or create other health risks. The CCA recommends establishing a list of prohibited ingredients for consumable hemp products much like those used in other states. To ensure manufacturers only produce products with approved ingredients, Virginia also should implement a preapproval process for consumable hemp products.

(3) Address access by minors to consumable hemp products at retail locations and through online sales.

Ease of access to consumable hemp products on the shelves of traditional retail stores contributes significantly to the risk of inadvertent and intentional ingestion of consumable hemp products by minors. To address this concern, the CCA recommends Virginia follow the lead of other states and restrict where businesses can display consumable hemp products to ensure all customers, particularly minors, do not have physical access to them without first producing government identification substantiating they are at least 21 years old. Virginia also should extend its age verification requirements for online sellers of consumable hemp products intended for smoking to the online sale of all edible hemp products. This would further limit the access of minors to consumable hemp products.

(4) Impose further limits on online sales of consumable hemp products.

Online sales of consumable hemp products also can endanger the health of adult consumers if the products do not have to satisfy the same requirements as products sold in brick-and-mortar retail stores. To close this gap in treatment and mitigate the public health risks associated with online sales under current law, Virginia should explicitly require that online sellers of consumable hemp products can sell consumable hemp products into Virginia <u>only if</u> they register as a retail facility (like physical retailers are currently required to do) and are, therefore, subject to the same set of regulations that apply to physical retailers. This action will ensure online products sold into Virginia are safer because they will be subject to state regulation, which could include the enhanced testing and ingredient restrictions proposed in this report.



#### Endnotes

<sup>1</sup> The CCA reviewed legislative and regulatory activity in the following states: Alaska, Arkansas, California, Colorado, Kentucky, Louisiana, Maryland, Minnesota, Montana, New York, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Vermont, Washington, and West Virginia. The CCA has compiled excerpts from the consumable hemp products laws and regulations in these states in Appendix A.

<sup>2</sup> H.R.2 - Agriculture Improvement Act of 2018 115<sup>th</sup> Congress. Retrieved from

https://www.congress.gov/bill/115th-congress/house-bill/2.

<sup>3</sup> 7 U.S.C. § 1639o(1).

<sup>4</sup> The market for consumable hemp products is strong. Some estimates hold that sales of products containing one such cannabinoid, delta-8 THC — one of the most well-known and widely available cannabinoids found in consumable hemp products on the market — have generated \$2 billion in a two-year period. *See* Sabaghi, D. (2023, January 18). *Delta-8 THC generated \$2 billion in revenue in two years, report finds.* Forbes. Retrieved from https://www.forbes.com/sites/dariosabaghi/2023/01/16/delta-8-thc-generated-2-billion-in-revenue-in-2-years-report-finds/.

<sup>5</sup> CANNRA, "An Overview of Regulatory Challenges for Cannabinoid Hemp." See Appendix B.

<sup>6</sup> CANNRA, "An Overview of Regulatory Challenges for Cannabinoid Hemp." See Appendix B.

<sup>7</sup> U.S. Food and Drug Administration. (2022, June 16). FDA warns consumers about the accidental ingestion by children of food products containing THC [Advisory]. Retrieved from https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accident/

https://www.fda.gov/food/alerts-advisories-safety-information/fda-warns-consumers-about-accidental-ingestion-children-food-products-containing-thc.

<sup>8</sup> U.S. Food and Drug Administration. (2023, July 5). FDA, FTC warn six companies for illegally selling copycat food products containing delta-8 THC [Press release]. Retrieved from

https://www.fda.gov/news-events/press-announcements/fda-ftc-warn-six-companies-illegally-selling-copycat-food-products-containing-delta-8-thc.

<sup>9</sup> Shaker, K., Nillas, A., Ellison, R., Martin, K., Trecki, J., Gerona, R., & Aldy, K. (2023). Delta-8-tetrahydrocannabinol exposure and confirmation in four pediatric patients. Journal of Medical Toxicology, 19(2), 190–195. https://doi.org/10.1007/s13181-022-00927-x.

<sup>10</sup> Change, E. (2023, Jan 3). *Steep increase of kids accidentally eating cannabis edibles, data shows*. The Washington Post. Retrieved from https://www.washingtonpost.com/parenting/2023/01/03/edibles-kids-increasing/.

<sup>11</sup> University of Virginia Health. (2023, March 22). UVA Health's Blue Ridge Poison Center identifies emerging poisoning trends. [Press Release] Retrieved from

https://newsroom.uvahealth.com/2023/03/22/uva-health-blue-ridge-poison-center-identifies-emerging-poisoning-trends/.

<sup>12</sup> University of Virginia Health. (2023, January 21). *Calls for kids accidentally eating marijuana edibles nearly tripled in 2022, Blue Ridge Poison Center reports* [Press release]. Retrieved from https://newsroom.uvahealth.com/2023/01/17/calls-kids-accidentally-eating-marijuana-edibles-nearly-tripled-2022/.

<sup>13</sup> H.B. 30 Item 4-14 #5c, 162nd Gen. Assem., 2022 Spec. Sess. (Va. 2022). Retrieved from https://budget.lis.virginia.gov/amendment/2022/2/HB30/Introduced/CR/4-14/5c/.

<sup>14</sup> H.B. 30 Item 4-14 #5c, 162nd Gen. Assem., 2022 Spec. Sess. (Va. 2022). Retrieved from https://budget.lis.virginia.gov/amendment/2022/2/HB30/Introduced/CR/4-14/5c/.



<sup>15</sup> The 15th enactment of Item 4-14 of the 2022 Appropriation Act mandated the taskforce, which was comprised of 16 Virginia state officials and convened two meetings in July and August of 2022 to gather information and feedback from public health officials and industry stakeholders. The task force met a third time to review the draft version of the report before its release.

<sup>16</sup> Lohr, M. J. (2022). Report of the Task Force to Analyze and Make Recommendations Regarding Whether Any Statutory or Regulatory Modifications are Necessary to Ensure the Safe and Responsible Manufacture and Sale of Industrial Hemp Extracts and Other Substances Containing Tetrahydrocannabinol that are Intended for Human Consumption in the Commonwealth. https://rga.lis.virginia.gov/Published/2022/RD679/PDF.

<sup>17</sup> Va. Code § 59.1-200(A)(69) (defining "synthetic derivative" as "a chemical compound produced by man through a chemical transformation to turn a compound into a different compound by adding or subtracting molecules to or from the original compound").

<sup>18</sup> Va. Code § 3.2-4123(A)(2)(iii).

<sup>19</sup> Northern Virginia Hemp & Agriculture LLC v. Commonwealth of Virginia, No 1:23-cv-01177-LMB-IDD (E.D. Va.).

<sup>20</sup> Many other states that have imposed restrictions on consumable hemp products have faced legal challenges in state or federal courts filed by consumable hemp product manufacturers, distributors, retailers, and customers alleging claims which mirror those asserted against Virginia. *See, e.g., Bio Gen, LLC v. Sanders*, No. 4:23-cv-00718-BRW (E.D. Ark); *Duke's Investments LLC v. Char*, No. 22-00385 JAO-RT (D. Haw.); *C.Y. Wholesale v. Holcomb*, No. 1:19-cv-2659-SEB-TAB (S.D. Ind.), *Maryland Hemp Coalition, Inc. v. Moore*, No. C-21-CV-23-348 (Cir. Ct. Wash. Cnty Md.); *Delta Extraction LLC v. Dept. of Health and Senior Services*, No. 23-0608 (Mo. Admin. Hearing Comm'n).

<sup>21</sup> See, e.g., Maryland, Minnesota, and Washington. Proponents of having one regulator for both cannabis and intoxicating hemp products (the so-called "unified" regulator approach) point to the similar physical effects of each product, the need for extensive public health safeguards for each type of product, and the interdependence of the two products' markets. They also note a single regulator makes it more likely that regulation of the two, similar categories of products will be carried out more consistently.

<sup>22</sup> See, e.g., Kentucky, Rhode Island, Tennessee, Texas, West Virginia.

<sup>23</sup> Some common approaches include: required testing for THC levels; serving size and/or per-package limits on THC content; restrictions on sales to minors; required registrations or licensing.
 <sup>24</sup> 18 Va. Admin. Code 110-60-300.

<sup>25</sup> See, e.g., Alaska (Alaska Admin. Code tit. 11 § 40.600, 40.640, 40.645, 40.650); Arkansas (Ark. Code R. § 20-56-410); California (Cal. Health & Saf. Code § 111925.4 and California Code of Regulations tit. 4, §15714); Kentucky (Kentucky Rev. Stat. Ann § 902.45-190E); Louisiana (La. Rev. Stat. § 3:1483); New York (N.Y. Comp. Codes R. & Regs. tit. 9 § 114.10); Rhode Island (230 R.I. Code of Regs. 80-10-1.9(D)(1)); Tennessee (Tenn. Code Ann. Title 23, Chapt. 27); Texas (Texas Admin. Code Rule §300.301); West Virginia (W.V. Code of State Rules 61-30-9).

<sup>26</sup> 2 Va. Admin. Code 5-595-50.

<sup>27</sup> Centers for Disease Control and Prevention. (2021, August 3). *Outbreak of lung injury associated with the use of e-cigarette, or vaping, products*. https://www.cdc.gov/tobacco/basic\_information/e-cigarettes/severe-lung-disease.html; Meehan-Atrash, J., & Rahman, I. (2021). *Cannabis vaping: Existing* 



*and Emerging Modalities, Chemistry, and Pulmonary Toxicology. Chemical Research in Toxicology,* 34(10), 2169–2179. https://doi.org/10.1021/acs.chemrestox.1c00290.

<sup>28</sup> 18 Va. Admin. Code 110-60-280(G).

<sup>29</sup> Cal. Health & Saf. Code § 111929.2 (effective pending further legislation); 902 Kentucky Admin. Regs. 45:190E, section 7; N.Y. Comp. Codes R. & Regs tit. 9 § 114.8(3).

<sup>30</sup> 902 Kentucky Admin. Regs. 45:190E, section 7

<sup>31</sup> See, e.g., Oregon Liquor Control Commission. (2020, October 29). Non-Cannabis Additives in Inhalable Cannabinoid Products: Rationale for Rulemaking. Retrieved from

https://www.oregon.gov/olcc/Docs/commission\_agendas/2020/Non-Cannabis-Addtives-in-Inhalable-Cannabinoid-Products.pdf.

<sup>32</sup> Cal. Health & Saf. Code § 111921.5 (prohibiting industrial hemp in a product containing nicotine or tobacco, or an alcoholic beverage); Kentucky Rev. Stat. Ann § 902.45-190E; N.Y. Comp. Codes R. & Regs. Tit. 9 § 114.8 (a)(3) and (4) (prohibiting consumable hemp products "contain[ing] liquor, wine, beer, cider or meet the definition of an alcoholic beverage" or "contain[ing] tobacco or nicotine"). <sup>33</sup> Kentucky Rev. Stat. Ann § 902.45-190E.

<sup>34</sup> La. Rev. Stat. § 3:1483.

<sup>35</sup> See, e.g., 902 Ky. Admin Regs. 45:190E; 230 R. I. Code of Regs 80-10-1.11(J)(3); Tenn. Code. Ann. § 43-27-204/

<sup>36</sup> 902 Ky. Admin Regs. 45:190E, Section 6.

<sup>37</sup> Tenn. Code. Ann. § 43-27-204 (effective July 1, 2024) (including an exception that applies if the business limits entry to only customers over the age of 21). Another tactic is to require employees of retail stores selling consumable hemp products to sign "server awareness forms." Ark. Code R. § 20-56-406. These forms require employees to attest they understand the legal restrictions against sales of consumable hemp products, which ensures the retailer has given its staff minimal information and training regarding the laws applicable to consumable hemp products. Here are some examples of server awareness forms for alcohol and tobacco:

https://www.dfa.arkansas.gov/images/uploads/abcOffice/serverAwareness.pdf;

https://www.atc.arkansas.gov/wp-content/uploads/2020/05/ATC-R4-2-2020-SERVER-AWARENESS-FORM.pdf.

<sup>38</sup> See, e.g., United States Postal Service Publication 52, effective June 6, 2019. Retrieved from https://about.usps.com/postal-bulletin/2019/pb22521/html/updt\_002.htm); see also United Parcel Service of America (n.d.) Shipping Hemp and CBD. Retrieved from

https://www.ups.com/us/en/support/shipping-support/shipping-special-care-regulated-items/prohibited-items/hemp-cbd-marijuana.page.

<sup>39</sup> See, e.g., Ark. Code R. 20-56-411 (g)(1) (expressly prohibiting sales of hemp-derived products through "an order executed solely over the internet or similar means"); Wa. Admin. Code 314-55-079(5) (where adult-use cannabis restrictions apply to consumable hemp products "with any detectable amount of THC" and "[i]nternet sales and delivery of product to consumers is prohibited.").

<sup>40</sup> W.V. Code of State Rules 61-30-5.1. New York has a similar requirement. *See* N.Y. Comp. Codes R. & Regs. tit. 9 § 114.1(e).

<sup>41</sup> See Va. Code § 3.2-4122.

<sup>42</sup> Va. Code § 18.2-371.2(C).



<sup>43</sup> U.S. Food and Drug Administration. (2023, January 26). FDA Concludes that Existing Regulatory Frameworks for Foods and Supplements are Not Appropriate for Cannabidiol, Will Work with Congress on a New Way Forward [Press release]. Retrieved from https://www.fda.gov/news-events/pressannouncements/fda-concludes-existing-regulatory-frameworks-foods-and-supplements-are-notappropriate-cannabidiol.

<sup>44</sup> House Committee on Energy and Commerce. (2023, July 27). *Bicameral Health Committee leaders announce bipartisan request for information regarding FDA regulation of CBD*. Retrieved from https://energycommerce.house.gov/posts/bicameral-health-committee-leaders-announce-bipartisan-request-for-information-regarding-fda-regulation-of-cbd-1.

<sup>45</sup> Congressional Research Service. (2023, August 21). *Expiration of the Farm Bill*. Retrieved from https://sgp.fas.org/crs/misc/R47659.pdf; United States Senate Committee on Agriculture, Nutrition, & Forestry. (n.d.) The Farm Bill. Retrieved from https://www.agriculture.senate.gov/farm-bill.

<sup>46</sup> In July 2023, the congressional House Energy and Commerce Committee issued a Request for Information (RFI) though the bicameral Health Committee as part of the conversation surrounding CBD and hemp-derived product. Press release available at:

https://energycommerce.house.gov/posts/bicameral-health-committee-leaders-announce-bipartisan-request-for-information-regarding-fda-regulation-of-cbd-1. *See* Appendix C.

<sup>47</sup> Cannabis Regulators Association. (2023, September 15). *CANNRA calls for modifications to the 2023 farm bill to address cannabinoid hemp products* [Press release]. Retrieved from https://www.cann-ra.org/news-events/cannra-calls-for-modifications-to-the-2023-farm-bill-to-address-cannabinoid-hemp-products. *See* Appendix D.

<sup>48</sup> Cannabis Regulators Association. (2023, September 15). *CANNRA calls for modifications to the 2023 farm bill to address cannabinoid hemp products* [Press release]. Retrieved from https://www.cann-ra.org/news-events/cannra-calls-for-modifications-to-the-2023-farm-bill-to-address-cannabinoid-hemp-products. *See* Appendix D.



### Appendix A

### **APPENDIX A**

### **Summary of Consumable Hemp Product Laws**

	ALASKA
CONTAMINATE TESTING	For any processed hemp product intended for human or animal consumption, each batch of product shall be tested for (1) cannabinoid concentration and profile; (2) residual solvents; (3) microbials; (4) pesticides; and (5) heavy metal concentrations. 11 AAC 40.320. Industrial hemp products intended for human consumption shall be tested for: residual solvents (Acetone, Benzene, Butanes, Chloroform, Cyclohexane, Heptane, Hexane, Isopropanol, Methanol, Pentanes, Propane, Toluene, Xylenes), microbials (bacterial, fungus), mycotoxins, pesticides, and metals. 11 AAC 40.640.
PRODUCT APPROVAL	Any industrial hemp product processed beyond its raw form and intended for human or animal consumption must be endorsed by the division. 11 AAC 40.400.
INGREDIENTS	Processed industrial hemp products intended for human or animal consumption must be labeled with a list of all ingredients. 11 AAC 40.420.





### **ARKANSAS**

### CONTAMINATE TESTING

Industrial hemp for food for human consumption must be tested for non-approved pesticide or herbicide use. 209.02.18 Ark. Code R. § 004.11.



# CALIFORNIA

CONTAMINATE TESTING	Hemp products subject to contaminant testing established for adult-use cannabis products. Cal. Health & Saf. Code § 111925.4. This includes testing for heavy metals, microbial impurities, mycotoxins, moisture content and water activity, residual pesticides, and residual solvents and processing chemicals. California Code of Regulations tit. 4, §15714.
INGREDIENTS	<ul> <li>Inhalable products are not allowed until there is legislative action establishing a tax, but when they are allowed an inhalable product shall not contain any of the following:</li> <li>(a) Flavorings other than natural terpenes.</li> <li>(b) Polyethylene glycol (PEG).</li> <li>(c) Vitamin E acetate.</li> <li>(d) Medium chain triglycerides (MCT oil).</li> <li>(e) Squalene or squalane.</li> <li>(f) Any other substance that the department finds to be a danger to public health.</li> <li>Cal. Health &amp; Saf. Code § 111929.2.</li> </ul>
ADDITIONAL RESTRICTIONS	Industrial hemp cannot be included in medical devices, prescription drugs, a product containing nicotine or tobacco, or an alcoholic beverage. Cal. Health & Saf. Code § 111921.5.



## **COLORADO**

CONTAMINATE TESTING	Substances tested for include microbials, mycotoxins, pesticides, heavy metals, and residual solvents. 6 CCR 1010-21.7(5).
PRODUCT ACCESS OR AGE RESTRICTIONS	<ul> <li>Hemp products must be sold in adult-use stores if:</li> <li>1. The product has more than 1.25 mg of THC AND a ratio of less than 20:1 CBD:THC.</li> <li>2. The product has between 1.25 mg and 1.75 mg of THC per serving, a ratio of CBD to THC between 15:1 and 20:1, AND can contain up to 5 servings per package.</li> <li>3. The product has between 1.25 mg and 1.75 mg of THC per serving, a ratio of CBD to THC greater than 20:1, AND can contain up to 30 servings per package.</li> </ul>





### **KENTUCKY**

CONTAMINATE TESTING	Testing shall only be performed on the final product equivalent to what will be consumed. Hemp-derived cannabinoid concentrate, extract, or edible products shall be tested for cannabinoids, microbial impurities, mycotoxins, residual pesticides, heavy metals, and residual solvents and processing chemicals. All vaporizer delivery device or pressurized metered dose inhaler cartridge batches or process lots shall be tested for Vitamin E Acetate. 902 Ky. Admin. Regs. 45:190E(3).
PRODUCT ACCESS OR AGE RESTRICTIONS	All adult-use hemp-derived cannabinoid products shall be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21), and not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21). 902 Ky. Admin. Regs. 45:190E(6).
INGREDIENTS	A cannabinoid product, concentrate, cannabinoid extract, or edible product shall not be adulterated with any non- cannabinoid additive that increases toxicity or addictive potential, caffeine, nicotine, or any other chemicals that may increase carcinogenicity or cardiac effects. A manufacturer shall not use non-cannabinoid derived inactive ingredients not listed in the federal Food and Drug Administration inactive ingredient database in the manufacture of hemp-derived cannabinoid products and concentrates intended for use through a vaporizer delivery device or pressurized metered dose inhaler. The following substances shall be prohibited in hemp-derived cannabinoid extraction intended for inhalation: vitamin E acetate (VEA); medium-chain triglycerides (MCT); polyethylene glycol (PEG); propylene glycol (PG or PPG); 2,3-butanedione (Diacetyl); and myclobutanil. 902 Ky. Admin. Regs. 45:190E(2).





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# LOUISIANA

PRODUCT APPROVAL	Registration of all products is required before distribution or sale. Rev. Stat. § 3:1483(G).
INGREDIENTS	Any consumable hemp product that is manufactured, distributed, imported, or sold for use in Louisiana shall not contain any active pharmaceutical ingredient (API) recognized by the United States Food and Drug Administration other than cannabidiol. La. Stat. tit. 3 § 1483(B)(5). This restriction does not apply to products intended for topical application.
<b>ADDITIONAL</b> <b>RESTRICTIONS</b>	No person shall sell or offer for sale any part of hemp for inhalation. La. Stat. tit. 3 § 1482(a). Online retailers must register before selling consumable hemp products. La. Stat. tit. 3 § 1484(B)(1). A remote retailer is a person or entity who offers any consumable hemp product for sale at retail, or for any transaction of products in lieu of a sale, through a digital application, catalog, or the internet, that can be purchased and delivered directly to a consumer in Louisiana. La. Stat. tit. 3 § 1481(8).





### MARYLAND

CONTAMINATE TESTING	An independent testing laboratory shall issue a certificate of analysis for each lot, with supporting data, to report the presence of the following contaminants does not exceed the levels provided by the Commission: residual solvents, foreign materials, microbiological impurities, pesticide residue; and heavy metals. COMAR 10.62.23.04.
PRODUCT APPROVAL	A person may not sell or distribute a product intended for human consumption or inhalation that contains more than 0.5 milligrams of tetrahydrocannabinol per serving or 2.5 milligrams of tetrahydrocannabinol per package unless the person is licensed to operate a cannabis business. Md. Code § 36-1102.





# MINNESOTA

CONTAMINATE TESTING	A manufacturer of a product regulated under this section must submit representative samples of the product to an independent, accredited laboratory in order to certify that the product complies with the standards adopted by the board. At a minimum, the testing must confirm that the product does not contain more than trace amounts of any mold, residual solvents, pesticides, fertilizers, or heavy metals. Minn. Stat. §151.72.
PRODUCT ACCESS OR AGE RESTRICTIONS	Edible products other than products intended to be consumed as a beverage must be displayed in a locked case or behind a checkout counter where the public is not permitted. State law does not prohibit delivery of hemp-derived cannabinoid products (edibles, beverages, and topicals). However, prior to initiating a sale or otherwise providing a product, an employee of the retailer must verify that the person to whom the product is being provided is at least 21 years of age.
INGREDIENTS	An edible cannabinoid product must not contain an ingredient, other than a hemp-derived cannabinoid, that is not approved by the United States Food and Drug Administration for use in food. Minn. Stat. §151.72.
ADDITIONAL RESTRICTIONS	Products containing nonintoxicating cannabinoids intended to be smoked or vaped are not allowed. Nonintoxicating cannabinoid means substances extracted from certified hemp plants that do not produce intoxicating effects when consumed by any route of administration.



VIRGINIA Cannabis

Control **Authority** 

# MONTANA

### BACKGROUND INFORMATION

A newly enacted law includes redefining synthetic cannabinoids to include "any cannabinoids produced artificially, whether from chemical synthesis or biosynthesis using recombinant biological agents, including but not limited to yeast and algae." Synthetic cannabis products now "means marijuana or marijuana products that contain synthetic cannabinoids." Synthetic marijuana products are prohibited in Montana. The new law also includes establishment of Synthetic marijuana products advisory council. H.B. 948, 68th Legislature, 2023 Reg. Sess. (2023).





# **NEW YORK**

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CONTAMINATE TESTING	Laboratory testing requirements for cannabinoid hemp: heavy metals; microbial impurities; mycotoxins; residual pesticides; residual solvents and processing chemicals. N.Y. Comp. Codes R. & Regs. tit. 9 § 114.10.
PRODUCT ACCESS OR AGE RESTRICTIONS	Cannabinoid hemp retailers must have sufficient safeguards in place to verify an individual purchasing an inhalable or flower cannabinoid hemp product matches their ID and is 21 years of age or older. N.Y. Comp. Codes R. & Regs. tit. 9 § 114.11.
INGREDIENTS	Ingredients must be pharmaceutical grade unless otherwise approved and not include (i) synthetic terpenes, (ii) polyethylene glycol, (iii) vitamin E acetate, (iv) medium chain triglycerides, (v) medicinal compounds, (vi) illegal or controlled substances, (vii) artificial food coloring, (viii) benoic acid, (ix) diketones, (x) any other compound or ingredient determined by the office in regulation. N.Y. Comp. Codes R. & Regs. tit. 9 § 114.8 (d). Inhalable products cannot contain any flavors or flavoring agents (N.Y. Comp. Codes R. & Regs. tit. 9 § 114.8 (d)(4)). Cannabinoid hemp products cannot contain liquor, wine, beer, cider (N.Y. Comp. Codes R. & Regs. tit. 9 § 114.8 (a)).



# NORTH DAKOTA

PRODUCT APPROVAL	A hemp commodity or product may be approved in writing by the agriculture commissioner and will be considered an allowable hemp product. 4.1-18.1-01(5)(a) (5).
ADDITIONAL RESTRICTIONS	A hemp licensee may not: (1) Chemically modify or convert a hemp extract, or engage in any process that converts cannabidiol into delta-9, delta-8, delta-10- tetrahydrocannabinol, or other tetrahydrocannabinol isomers, analogs, or derivatives; and (2) Sell or distribute hemp or hemp commodities or products that contain chemically derived cannabinoids or were created by chemically modifying or converting a hemp extract.





# OREGON

CONTAMINATE TESTING	Industrial hemp-derived vapor items are to be tested for any microbioligcal contaminant, heavy metals, and other adulternats, pesticides, solvents, additives, or contaminants that may pose a risk to public health or safety, or are prohibited by law. Or. Rev. Stat. § 845-026- 5760(3).
PRODUCT APPROVAL	Requires labeling pre-approval process for industrial hemp-derived vapor items. Or. Rev. Stat. § 845-026- 7060.
INGREDIENTS	The following additives are not allowed in inhalable cannabinoid products, or any additives that contain these ingredients: squalene, vitamin E acetate, triglycerides, propylene glycol. Or. Rev. Stat. § 845-025-3265 (2).





# **RHODE ISLAND**

CONTAMINATE TESTING	Includes testing for pesticides, heavy metals, and microbial concentration on a dry weight or per volume basis. 230-RICR-80-10-1.9(D)(1).
PRODUCT ACCESS OR AGE RESTRICTIONS	A retail licensee shall place all hemp-derived consumable CBD products in a location separate from all other products sold by that retail licensee and that location must be prominently identified as containing hemp- derived consumable CBD products. 230-RICR-80-10- 1.11(J)(3).

### TENNESSEE

PRODUCT ACCESS OR AGE RESTRICTIONS A product containing a hemp-derived cannabinoid must be maintained behind the counter of a retail establishment in an area inaccessible to a customer. A violation of this section is a Class A misdemeanor. Pursuant to 43-27-204(a), a "retail establishment" does not include "a place of business for which entry is limited to persons twenty-one (21) years of age or older." TCA 43-27-204.



	TEXAS
CONTAMINATE TESTING	All hemp or hemp derivatives used in the manufacture of a consumable hemp product must be tested as appropriate for the product and process by an accredited laboratory to determine the presence or quantity of residual solvents, heavy metals, pesticides, and harmful pathogens. TAC §300.301.
ADDITIONAL RESTRICTIONS	Manufacturing and processing of consumable hemp products for smoking is prohibited within Texas.



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# WASHINGTON

CONTAMINATE TESTING	Adult-use cannabis restrictions apply. Testing required for pesticides, heavy metals, residual solvents, microbiological, mycotoxin. WAC 314-55-109.
PRODUCT ACCESS OR AGE RESTRICTIONS	Products "with any detectable amount of THC" must be processed by and sold by adult-use cannabis licensees. RCW 69.50.101(h)(1); 69.50.3251(3); 69.50.326(2)(a).
ADDITIONAL RESTRICTIONS	Adult-use cannabis restrictions apply to the online sale of hemp products. Internet sales and delivery of product to consumers is prohibited. WAC 314-55-079(5).



# WEST VIRGINIA

CONTAMINATE TESTING	Limited substances include pesticides, residual solvents, toxic metals, microbials, mycotoxins, water activity, and foreign materials. WV Rules 61-30-9.
PRODUCT APPROVAL	All hemp products and hemp product vendors must register with the Department. Registration packets, labels, and certificates of analysis must be accepted and approved by the Department before hemp products can be sold.

NOTICE: The Cannabis Control Authority prepared this document to summarize laws and regulations for informational purposes only. It is general in nature, not comprehensive, and should not be relied upon, or construed, as legal advice.





### **Appendix B**



#### AN OVERVIEW OF REGULATORY CHALLENGES FOR CANNABINOID HEMP

Following the federal legalization of hemp in 2018, a national industry has rapidly emerged to manufacture and sell consumable products that contain cannabinoids derived from hemp. The relative lack of federal regulation or enforcement of these products presents several challenges with implications for public health and safety and the ability of consumers to make informed choices about the products they consume. As a result, some states have stepped in to regulate hemp and hemp-derived products and others have followed federal agencies' lead. This has created a state-by-state patchwork of regulations that are often difficult for the industry, government bodies, and consumers to navigate.

#### LACK OF ENFORCEMENT OF FDA REGULATIONS

The 2018 Farm Bill placed the regulation of foods, beverages, dietary supplements, and cosmetics containing hemp, or substances like cannabidiol (CBD) that are derived from hemp, under the US Food & Drug Administration (FDA) through the FDA's enforcement of the federal Food Drugs, and Cosmetic Act (FDCA). The FDA has stated that CBD and tetrahydrocannabinol (THC) cannot be added to any food that is sold in interstate commerce and that CBD and THC cannot be marketed as dietary supplements, even if they are derived from hemp.

In addition to CBD and THC, there are dozens of cannabinoids present in the hemp plant, and even more that can be manufactured synthetically from hemp extracts. If the compounds are not excluded as drugs, it may be possible to use these other cannabinoids in FDA-regulated products if they go through an appropriate notification or approval process. However, to date, there are no records of any such hemp-derived products having completed the process to be allowed for use in foods, beverages, or dietary supplements.

A wide variety of hemp-derived foods, beverages, and dietary supplements containing CBD, THC, or other cannabinoids that are not in compliance with FDA regulations are being sold online and in traditional brick-and-mortar retail stores. To date, the FDA has taken minimal enforcement action, issuing warning letters to a small number of the manufacturers or sellers of hemp-derived products when there are health claims that put the product into the category of an unapproved drug.

Vape products and smokable hemp flower products such as "buds" and pre-rolls are outside the scope of the FDCA. Unless these products contain added nicotine, which is regulated by the FDA, these hemp vaping and smoking products are not subject to any federal regulation or oversight, which presents consumer safety issues.

#### PRODUCTS WITH INTOXICATING AMOUNTS OF DELTA-9-THC

"Low THC" is a relative term depending on the type of product. Under federal law, all hemp products are limited to no more than 0.3% delta-9-THC by weight. In dried plant material, this is a very small amount of THC compared with cannabis. But in foods and beverages, which weigh more than dried plant matter, 0.3% can be a lot of THC. The National Institute on Drug Abuse (NIDA) has established a "standard dose" of THC as 5 mg. With that dose in mind, at 0.3% THC by weight:

- Approximately one teaspoon of liquid (5.7 g) contains more than three doses of THC (17 mg)
- A "snack size" pack of fruit snacks (20 g) contains 12 doses of THC (60 mg)
- A typical chocolate bar (50 g) contains 30 doses of THC (150 mg)

Hemp-derived products are currently being sold that contain 100 mg, 200 mg, or even 400 mg of delta-9-THC, while still complying with the federal limit of 0.3% delta-9-THC by weight. These products sometimes contain more THC than states allow in their adult use cannabis programs, where the maximum serving size for an edible is typically 10 mg THC, with a maximum package size of 100 mg THC.

#### **SEMI-SYNTHETIC DERIVATIVES**

"Semi-synthetic cannabinoid" refers to certain types of substances that are produced by converting a cannabis extract into a different substance through chemical reactions. This type of process is commonly used to convert CBD, which is extracted

from hemp and alone is not intoxicating, into THC or other substances such as THC-O-acetates or hexahydrocannabinol (HHC). Semi-synthetic cannabinoids differ from naturally occurring cannabinoids in that they are manufactured via a chemical reaction. Some cannabinoids that are manufactured semi-synthetically also occur naturally in hemp, but typically in much smaller concentrations that are not cost effective to extract directly from the plant.

Semi-synthetic cannabinoids have proliferated in the market for a variety of reasons, including:

• Perceived legality: Federal law defines hemp as follows.

#### 7 USC § 16390 (1) Немр

The term "hemp" means the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

Because this definition includes "all derivatives," manufacturers of semi-synthetic cannabinoids argue that they are allowed to perform chemical reactions to convert CBD or other hemp-extracted substances into semi-synthetic cannabinoids if the final product contains no more than 0.3% delta-9-THC. This reasoning was supported by a recent decision in the Ninth Circuit relating to delta-8-THC products.

- Tax, Testing, and Regulation Avoidance: Semi-synthetic hemp-derived products are produced with little to no regulatory oversight. Most states with a regulatory system for hemp products have not addressed the hazards that can be introduced by the chemicals and processes used to manufacture semi-synthetic cannabinoids, and compliance with existing regulations remains low. State-regulated cannabis products, on the other hand, are subjected to a range of regulations put in place to protect consumer safety and public health, including testing and labeling requirements. Additionally, hemp plants and products are not subjected to the same taxes as cannabis in state-regulated programs. Between the savings from not needing to comply with testing and other regulatory requirements, and products not being subject to the same taxes as similar adult-use cannabis products, intoxicating semi-synthetic cannabinoids can be produced at a lower cost than regulated cannabis products.
- Access and Market Restrictions: In states where marijuana is illegal or difficult to obtain legally, semi-synthetic cannabinoids like delta-8-THC are popular among people that want to get "high." States with established legal cannabis programs are also seeing a surge in intoxicating, hemp-derived products because these intoxicating hemp-derived products are being sold online and at traditional retailers (gas stations, grocery stores, etc.) with little to no regulation, as opposed to state-legal cannabis products which can only be sold at specific adult-only licensed cannabis retailers.

Common semi-synthetic cannabinoids currently being sold include: delta-8-THC, delta-9-THC, delta-10-THC, THC-O-acetates, THCV, THCP, HHC, HHC-O-acetate, HHCP, and CBN.

#### YOUTH ACCESS AND LACK OF AGE RESTRICTIONS

Federal legalization of hemp focuses primarily on crop production, not end-products. The federal regulations did not impose any age restrictions on the purchase of hemp products. Presumably, this was based on the assumption that hemp products would not be intoxicating. The reality is that many businesses are now manufacturing and selling intoxicating hemp-derived products containing significant doses of delta-9-THC or intoxicating semi-synthetic cannabinoids. In response, some states have established age restrictions on the sale of potentially intoxicating hemp derived products, but in most parts of the country these intoxicating products are available for sale to minors. Even in states with age restrictions in place, online sales can occur to underage individuals.

#### LACK OF PACKAGING AND LABELING STANDARDS

In state-level efforts to legalize cannabis, most state regulatory programs include robust requirements around the packaging and labeling of marijuana products. These requirements typically:

- Inform consumers that the product they are purchasing may be intoxicating.
- Require labeling to show the amount of THC that is in the product, and in many cases, to indicate a dose or serving size.
- Reduce or prohibit packaging and labeling products in a manner that may be attractive to minors.

There are currently no federal standards requiring labels to disclose the THC content of hemp-derived products. As a result, products that may contain a significant amount of THC simply state that the product contains "less than 0.3% THC." If a CBD product contains 2 mg THC per serving, a consumer who takes one or two doses of the product two or three times per day may be consuming up to 12 mg THC over the course of the day, or more than two "standard doses" of THC as defined by NIDA.

Many consumers may be subject to drug testing, for example through their job or as ordered by a court as a condition of probation. For these consumers, it is especially important to know the THC content of any hemp products they might consume. Other consumers may work in jobs operating vehicles or heavy machinery, where it could be extremely dangerous for them to become unexpectedly impaired because they did not know the products they were consuming contained potentially impairing doses of THC or other cannabinoids.

#### LACK OF TESTING REQUIREMENTS

State-legal cannabis programs also typically establish robust testing requirements for marijuana products. These vary between states, but typically include:

- Potency testing to establish THC content of products.
- Pesticide testing to look for residues of pesticides, especially prohibited pesticides.
- Solvent testing to look for residual solvents from extraction processes.
- Mycotoxin or microbiological contaminant testing to look for potentially harmful contaminants.
- Heavy metal testing, since cannabis has the potential to accumulate significant amounts of potentially harmful metals from the environment.

At the federal level, hemp testing requirements are only established at the crop level, to confirm that a crop is hemp rather than cannabis. While hemp products are limited to no more than 0.3% delta-9-THC, there are no requirements or standards for finished product potency testing, or for testing for other harmful contaminants. Some individual hemp businesses choose to conduct potency or safety testing on their products, but there is no industry-wide requirement.

#### WHERE TO GET MORE INFORMATION?

For more information about hemp-derived products in your state, including state-specific programs, regulations, and initiatives, please reach out to your state cannabis regulator. If you don't know who your state cannabis regulator is, the Cannabis Regulators Association (CANNRA) can connect you. Please contact: <u>info@cann-ra.org</u>.

CANNRA is a national, nonpartisan, nonprofit 501(c)(4) organization of government officials involved in cannabis regulation across more than 40 states and US territories. This factsheet is intended to provide educational information and is not a formal policy position of CANNRA.



### **Appendix C**

#### Congress of the United States Mashington, DC 20515

July 27, 2023

To Interested Parties:

Cannabidiol (CBD) is a compound derived from the *Cannabis Sativa* plant. It is a nonpsychoactive cannabinoid that has been promoted for its use relative to a number of health conditions. Public Law 115-334, the Agriculture Improvement Act of 2018 ("the 2018 Farm Bill") expanded the definition of hemp to include "all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers," containing no more than 0.3% concentration of delta-9 THC. It also removed hemp from the definition of marijuana under the Controlled Substances Act (CSA), descheduling hemp-derived CBD.<sup>1</sup> However, the 2018 Farm Bill preserved the authority of the Food and Drug Administration (FDA) to oversee CBD in FDA-regulated products.<sup>2</sup>

Since the Farm Bill was enacted, FDA has maintained that hemp-derived CBD may not be marketed as a food additive or dietary supplement. Citing a provision included in the 1994 Dietary Supplement Health and Education Act (DSHEA) that prohibits articles from being marketed as a food or dietary supplement if they are studied or approved as a drug (the "exclusionary clause"), FDA asserts that it cannot permit hemp-derived CBD food and dietary supplement products for public consumption because there is currently an approved drug with CBD as an active ingredient on the market. However, even if the exclusionary clause did not apply, FDA has indicated that CBD would not meet the relevant statutory requirements for food or dietary supplement due to safety concerns.

Since hemp was descheduled five years ago, consumers, manufacturers, and policymakers have sought clarity regarding the legal status of CBD. Farmers, food and beverage groups, and state regulators have shared their policy priorities with Congress. However, questions remain about the best way to provide a legal pathway to market for CBD products.

#### **Purpose of the Request for Information**

In January 2023, FDA announced that it would like to work with Congress to craft a legislative approach to the regulation of CBD products. We are assessing the potential for a regulatory pathway for hemp-derived CBD products that prioritizes consumer safety and provides certainty to the U.S. market. We look forward to working with interested stakeholders on this process, and we ask for written responses on the following inquiries submitted to <u>CBD@mail.house.gov</u> and <u>CBD@help.senate.gov</u> by August 18. Please provide all data and primary source information, as is feasible, in answering the questions below.

<sup>&</sup>lt;sup>1</sup> P.L. 115-334 §10113.

<sup>&</sup>lt;sup>2</sup> 7 U.S.C. § 1639r.

#### Current Market Dynamics

- 1. What does the current market for CBD products look like? Please describe the types and forms of products available, manufacturing practices within the industry, market supply chain, how products are marketed and sold, the types of cannabinoids used in products, the marketed effects of CBD products, and the range of CBD doses currently found in the market.
- 2. How has the market changed since the passage of the 2018 Farm Bill?
- 3. How is the lack of national standards for CBD products affecting the market?

#### Pathway

4. Please comment on the concerns FDA has raised with regard to regulating most CBD products through existing pathways (i.e., conventional foods, dietary supplements, and cosmetics), and FDA's view that there is a need for a new regulatory pathway for CBD products. If existing regulatory pathways are sufficient for regulating CBD products, please explain how these existing pathways can be used to address the concerns raised by FDA, as appropriate.

#### <u>Scope</u>

- 5. How should CBD and/or cannabinoid-containing hemp products be defined? What compounds should be included and excluded from a regulatory framework?
  - a. Should Congress or FDA limit the amount of intoxicating or potentially intoxicating substances produced by *Cannabis sativa L*. in food and dietary supplements? Which substances, if any, warrant greater concern? How should these substances of concern be addressed? What products, if any, should not be allowed on the market?
  - b. How should Congress or FDA identify appropriate limits for THC and other cannabinoids in finished products? Relatedly, how should a framework account for "total THC," including tetrahydrocannabinol acid (THCA), in FDA's regulation of intermediate and finished products?
  - c. Should FDA regulate the manufacture and sale of "semisynthetic derivatives," or "biosynthetic cannabinoids," which are still scheduled under the CSA?
- 6. Other non-cannabinoid products are available on the market that have raised safety concerns among some individuals, which FDA has regulated without a substance-specific regulatory framework (e.g. kratom, caffeine, etc.). How has FDA dealt with products containing those substances? How might these products be implicated by a CBD-specific product framework?

- 7. How has the absence of federal regulation over CBD created a market for intoxicating, synthetically-produced compounds, such as Delta-8 THC, THC-O, THC-B, HHC-P, and others?
  - a. What is the public health impact of these novel compounds?
  - b. How have FDA and state regulators enforced against products containing these compounds?
  - c. How should Congress consider the inclusion of these products in a regulatory framework for cannabinoid hemp products, if at all?
- 8. CBD products are not limited to just ingestible routes of administration—some are interested in products with alternative routes of administration (e.g., inhalable, topical, ophthalmic drops, etc.).
  - a. For which non-ingestible routes of administration are consumers interested in consuming CBD products?
  - b. How should a regulatory framework for cannabinoid products account for noningestible routes of administration?

#### Federal-State Interaction

- 9. In the absence of federal regulation or enforcement over CBD products, many states have established state regulatory programs to safeguard public health and create market certainty for industry participants.
  - a. Which product standards relating to warning labels, minimum age of sale, manufacturing and testing, ingredient prohibitions, adverse event reporting, and others, have states adopted to protect consumer safety?
  - b. Which such standards, if any, should Congress look to as models?
- 10. How should Congress consider federal preemption as it works towards a regulatory pathway? Should states be able to continue to build upon federal regulation of CBD products?

#### Safety

- 11. What is currently known about the safety and risk-benefit profile of CBD and other hemp derived cannabinoids? What safety and toxicity data are available to support this knowledge. Please include in your answer any relevant information about safety with regard to specific populations, such as children and pregnant individuals.
- 12. What actions, if any, should the Federal government take to better understand the potential benefits or harms of CBD products and other cannabinoids?
- 13. How should a new framework for CBD products balance consumer safety with consumer access?
- 14. Some stakeholders have raised concerns that CBD products have inherent risks. What are those inherent risks, and at what levels of CBD do those risks present themselves? What

data and other evidence support the existence of such risks, and from which products are such data and evidence derived?

- 15. FDA approved Epidiolex, a drug containing CBD, based in part on a data package that included preclinical data from rodent safety models, as well as clinical trials. FDA has received safety data on CBD products from several manufacturers also based on rodent models. How should FDA consider data submitted for a CBD-containing drug as evidence to support that CBD is safe for human consumption in non-drug products, recognizing the inherent differences in the intended uses of such products?
- 16. Should there be limits on the amount of CBD in foods, dietary supplements, tobacco, or cosmetics? If so:
  - a. Should Congress or FDA set such limits, recognizing the time it can take to complete the legislative process and the regulatory process at FDA?
  - b. How should that amount be determined? What should the amount be?
  - c. Should such limits be applied on the amount per serving, and/or per package?
  - d. Could FDA set such limits under its current statutory regulatory authorities for foods and dietary supplements to potentially address safety concerns, notwithstanding exclusionary clause issues?
  - e. How should the experience of states inform the setting of limits on amounts of CBD in products?
- 17. How should a regulatory framework account for CBD products marketed in combination with other substances that may alter or enhance the effects of CBD (e.g., caffeine, melatonin, etc.)?
- 18. What precedent is there for FDA restricting certain otherwise allowable ingredients in legally marketed products? What amount and type of evidence has been required/demonstrated to support any such restrictions?
- 19. What functional ingredients combined with cannabinoids raise safety concerns?

#### Quality

- 20. How should Congress create an FDA-implemented framework to ensure that manufacturers provide appropriate consumer protections and quality controls?
  - a. How should such a framework compare to the current Good Manufacturing Practice (GMP) requirements that apply to food, dietary supplements, and cosmetics?
  - b. Are those food, dietary supplement, and cosmetics GMP frameworks adequate for regulating quality in CBD? Why or why not?
- 21. What are alternative quality approaches that Congress should consider for CBD products? For example, how should third parties be leveraged for the creation and auditing of manufacturing and testing requirements?

#### Form, Packaging, Accessibility, and Labeling

- 22. What types of claims should product manufacturers be permitted to make about CBD products? Please reference how such permitted claims compare to the types of claims that may be made about drugs, foods, dietary supplements, and cosmetics.
- 23. What is the evidence regarding the potential benefits of including a symbol or other marking on product labeling to provide clarity for consumers who would purchase products that contain CBD?
- 24. What are the potential benefits or drawbacks of an additional or substitute standardized label panel for CBD products, compared to the current Nutrition Facts Label and Supplements Label?
- 25. What precedent exists in foods, dietary supplements, tobacco, and cosmetics for requirements of labeling to present risks to special populations in labeling (e.g., children, pregnant and lactating women, consumers taking certain drugs, etc.)? What amount and type of evidence has been required to support such requirements?
- 26. Some suggest requiring labels for CBD products to include "potential THC content." Would THC content be unknown in a particular product? Is there precedent for such a labeling requirement?
- 27. How should access to CBD products by children be regulated? For example, would it be appropriate to have an age restriction on the purchase of CBD products? If so, what is an appropriate age limit?
- 28. What specific additional restrictions should apply to CBD products regarding their appeal to or use by children with regard to marketing, packaging, and labeling? Is there precedent in the food, dietary supplement, tobacco, or cosmetics space for restricting certain product features that would make products appealing to children? Please describe.
- 29. Some suggest requiring packages with multiple servings to be easily divisible into single servings. Does a framework like this exist today for any other product or substance?

Sincerely,

Cathy McMorris Rodgers Chair U.S. House Committee on Energy and Commerce

Bill Cassidy, M.D.

Bill Cassidy, M.D. Ranking Member U.S. Senate Committee on Health, Education, Labor, and Pensions

Frank Pallone, Jr.

Frank Pallone, Jr. Ranking Member U.S. House Committee on Energy and Commerce

B. J. Sanders

Bernard Sanders Chair U.S. Senate Committee on Health, Education, Labor, and Pensions



### **Appendix D**



CANNABIS REGULATORS ASSOCIATION

September 15, 2023

Chairman Glenn "GT" Thompson House Committee on Agriculture 1301 Longworth House Office Building Washington, DC 20515

Ranking Member David Scott House Committee on Agriculture 1301 Longworth House Office Building Washington, DC 20515 Chairwoman Debbie Stabenow Senate Committee on Agriculture, Nutrition, & Forestry 328A Russell Senate Office Building Washington, DC 20510

Ranking Member John Boozman Senate Committee on Agriculture, Nutrition, & Forestry 328A Russell Senate Office Building Washington, DC 20510

#### Re: Call for modifications to the Farm Bill to address hemp-derived cannabinoid products

The Cannabis Regulators Association (CANNRA), a nonpartisan association representing cannabis and hemp regulatory agencies from 45 member states and U.S. territories, urges Congress to consider changes to the 2023 Farm Bill to protect consumer safety and public health. The Agriculture Improvement Act of 2018 (the 2018 Farm Bill) was drafted with a focus on agricultural commodities and non-intoxicating hemp products. However, the language of the bill has inadvertently resulted in a thriving market for intoxicating cannabinoid products that are included (or claim to be included) within the definition of "hemp."

Accordingly, CANNRA calls on Congress to consider the following changes related to hemp and hemp-derived cannabinoid products:

1. Delineate the definition of hemp as an agricultural commodity grown for food, fiber, and feed from a definition of hemp that is grown for any other purpose, including the extraction of cannabinoids. This could be done by defining hemp and hemp-derived cannabinoid products as follows:

#### Definitions:

<u>Hemp</u>. The term "hemp" means the plant Cannabis sativa L. and any part of that plant, whether growing or not, with a total tetrahydrocannabinol concentration of not more than 0.3 percent in the plant on a dry weight basis. The term "hemp" does not include viable seeds from a Cannabis sativa L. plant if that plant exceeded a total tetrahydrocannabinol concentration of 0.3 percent in the plant on a dry weight basis.

<u>Hemp-derived cannabinoid products</u>. The term "hemp-derived cannabinoid products" means any hemp-derived product that is not the raw plant and is extracted, derived, infused, processed, or manufactured that contains cannabinoids in any form and is intended for human consumption or inhalation, including, but not limited to: combusted, aerosolized, or inhaled products, ingested products in any form, and topical products.

a. In defining total THC on a dry weight basis, include tetrahydrocannabinolic acid (THCA) and delta-9 THC, with regulatory authority to add limitations and restrictions to other cannabinoids as needed. THCA is the precursor to delta-9 THC and readily converts to delta-9 THC when heated, combusted, or aerosolized. For this reason, state cannabis programs define total THC in terms of THCA and THC.

#### For example:

Total tetrahydrocannabinol in hemp shall be calculated including the quantity of delta-9 tetrahydrocannabinolic acid contained in the applicable plant and plant parts described in [prior paragraphs/definitions] using the following equation: delta-9 THC + (delta-9 THCA\*0.877).

b. Because 0.3% THC can yield substantial amounts of THC in heavier items like chocolate bars and cookies, establish limits for THC in hemp plants (e.g., 0.3% total THC) that are different from limits a federal regulatory agency may establish for hemp-derived cannabinoid products.

For example:

The concentration of not more than 0.3% total tetrahydrocannabinol on a dry weight basis:

(i) applies only to the plant Cannabis sativa L. and any part of that plant, as described in the definition of hemp;

(ii) does not apply to any intermediate or final product made from a plant or plant part. [X federal agency] shall promulgate limits for tetrahydrocannabinol in intermediate or final products no later than [XX/XX/XXXX] date.

Establishing cannabinoid limits through rulemaking is essential to avoid removing all tetraydrocannabinoid limits from intermediate or final hemp-derived cannabinoid products. It also allows flexibility for regulations to adjust in response to real world conditions.

- 2. Identify, authorize, and fund a federal regulator with a background in public health and consumer protection to regulate cannabinoids and cannabinoid hemp products. Within a short and specified timeframe, require the regulatory agency to:
  - Provide clear boundaries and definitions for products that will be regulated under cannabinoids and cannabinoid hemp products.
  - Provide regulations that set minimum requirements for: processing and manufacturing approaches, ingredients, allowable modes of consumption and product types, contaminant and cannabinoid testing, packaging and labeling, and serving size and package limits.
  - Clarify whether semi-synthetic cannabinoids and biosynthetic cannabinoids are allowed under the definition of hemp-derived cannabinoids, and which production and manufacturing approaches are approved.
  - Establish and implement an education and enforcement approach to ensure compliance.

It will be essential to set regulations for hemp-derived cannabinoid products (as defined above) and to ensure that no additional loopholes are exploited from the statutory language.

#### For example:

The Commissioner of Food and Drugs and the Secretary of Health and Human Services shall promulgate rules for hemp-derived cannabinoid products no later than [XX/XX/XXXX date], including rules that specify allowable cannabinoid limits in hemp-derived cannabinoid products, required safety standards that must be met for manufacturing and sale of products, allowable product forms, required packaging and labeling standards, and compliance and enforcement.

3. Ensure that states and territories can go beyond federal policies to protect consumer safety and public health. Federal policies should set a minimum standard. There should not be a federal preemption of state and territorial regulatory policies related to hemp and cannabinoid products. States and territories need the ability to be nimble to react and adjust to issues that may pertain to their marketplace or population.

#### For example:

Nothing in [reference section] shall preempt a state or territory from enacting regulations that extend beyond federal regulations in order to further protect consumers or public health.

In the absence of federal clarity and regulation over finished cannabinoid products, state and territorial governments have been left to implement approaches to protect consumers. These approaches vary, and are generally different across jurisdictions, creating a regulatory patchwork for hemp-derived

products. Additionally, enforcement of state-based regulations by state agencies is difficult when hempderived products are produced out of state and shipped directly to consumers across state lines through the mail. For these reasons, federal regulatory engagement is warranted.

The aforementioned regulatory clarifications represent examples of key initial changes that are urgently needed in the Farm Bill to support state and territorial regulators, protect consumers, and set minimum standards for industry participants. CANNRA, and our member cannabis and hemp regulators continue to be available as an important resource to Congress as discussions about the Farm Bill reauthorization progress and a regulatory framework is considered.

Respectfully,

**Gillian Schauer, PhD** Executive Director Cannabis Regulators Association

**Dominique Mendiola (CO)** President-Elect Cannabis Regulators Association

**Chris Tholkes (MN)** Treasurer Cannabis Regulators Association

Vicole Ellioff

Nicole Elliott (CA) Board Member Cannabis Regulators Association

Willim Iill

Will Tilburg (MD) President Cannabis Regulators Association

1,14.

Tyler Klimas (NV) Past-President Cannabis Regulators Association

Adria Berry (OK) Board Member Cannabis Regulators Association

Andrew Turnage (GA) Board Member Cannabis Regulators Association

#### **CANNABIS REGULATORS ASSOCIATION**

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#### **Contact Us:**

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