California's AB 45

Summary of the Bill's Provisions

Governor Gavin Newsom has signed AB 45, legislation that was passed overwhelmingly in the California legislature, by votes of 64-3 in the Assembly and 29-2 in the Senate. The bill was initially aimed at explicitly legalizing the retail sale of hemp-derived CBD products in the Golden State, in response to enforcement actions that had been taken pursuant to 2018 state agency guidance that declared CBD products illegal. In the course of the intervening years, the bill was amended to tackle several other issues relating to hemp products.

AB 45 became effective law immediately upon the Governor's signature. But that's not the end of the story – and there is much work ahead of us. The California Department of Public Health is expected to soon promulgate emergency regulations to implement the program. Subsequently, there are a number of issues left open by the statute that may be resolved through the standard regulatory process, with a comprehensive opportunity for public notice and comment. Further, once the U.S. Food and Drug Administration acts to regulate hemp-derived CBD products, the state agency is then required to adopt new regulations to comply with the federal standards. Finally, legislation will be introduced in the 2022 legislative session to address open questions such as the tax regime on smokable hemp products. The U.S. Hemp Roundtable will be fully engaged throughout this process.

The following summary outlines the key provisions of AB 45 and highlights those issues that will or may be subject to further regulation and/or additional statutory changes. Also highlighted are the instances where California's requirements differ from other state regulatory schemes for hemp products.

(Abbreviations: HSC – Health and Safety Code. BPC – Business and Professions Code. DPH – Department of Public Health)

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- **Non-intoxicating hemp-derived extracts such as CBD are explicitly permitted for sale as dietary supplements and food and beverage ingredients.**
    - Food, beverage and dietary supplement products are not adulterated by the inclusion of hemp provided they meet the requirements in this law. (*HSC 110611*)
    - Cosmetic products are not adulterated by the inclusion of hemp provided they meet the requirements in this law. (*HSC 111691*)
    - Contrary to some inaccurate reports, regulatory protections are in place for all non-intoxicating hemp extracts and cannabinoids, not simply for CBD.

- **Intoxicating cannabis products are not considered to be hemp, and must be sold through adult-use cannabis channels. The definition of "intoxicating" may be developed through the standard regulatory process, with a comprehensive opportunity for public notice and comment.**
    - Hemp products must contain less than 0.3% THC.
    - THC is defined as THC-A and any tetrahydrocannabinol, including Delta 8, 9, and 10, however derived, although DPH can exclude one or more isomers of THC through regulation if they are determined to be non-intoxicating. THC will also include any other cannabinoid, other than CBD, that DPH determines causes intoxication through regulation. Such determinations may initially be issued as guidance (but only after public comment) but must be confirmed by formal regulations no more than 18 months after the initial determination. (*HSC 111921.7*.)
        - <u>These definitions are unique to California, although the THC language is somewhat similar to other states like Michigan, Oregon and New York that have updated their definitions to account for Delta-8, 10, etc.</u>
    - DPH may adopt regulations, through the full notice and comment process, that cap the total THC in milligrams based on product form, volume, number of servings, ratio of cannabinoids to THC or other factors. (*HSC 111925*)

- **Hemp extract products are subject to a broad range of safety requirements.**
    - Testing requirements are established to ensure that hemp is tested in raw extract final form before being incorporated into a product, is tested by an independent testing laboratory, and does not exceed 0.3% total THC for final form or concentration levels set by DPH for raw extract. (*HSC 111925*)
        - <u>Most states require testing of hemp products; however, in most cases it's not clear that the extract/ingredient in "final form before being incorporated" must be tested as is required here, versus the final product itself.</u>
    - Testing is required for levels of contaminants to be the same as for cannabis and DPH may adjust specific contaminant levels by regulation. (*HSC 111925.4*)
        - <u>These contaminant limits may be unique to California, as they are based on the state's adult use cannabis limits.</u>
    - A product batch may be reprocessed or remediated if it fails testing. A product batch that is not or cannot be reprocessed or remediated must be destroyed. *(HSC 111925.6*)
    - A certificate of analysis is required that confirms both that (1) the extract, does not exceed THC concentration of an amount determined allowable by the department in regulation, or the mass of the industrial hemp extract used in the final form product does not exceed a THC concentration of 0.3 percent, and (2) that the industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising. (*HSC 111921)*
        - <u>This differs from other states, in particular because the *mass* of the hemp extract cannot exceed 0.3%. While other states may interpret their laws</u>

this way (even if "dry weight basis" is mentioned explicitly), California clearly requires the concentration to be based on the mass of extract that will be used in the finished hemp product. In addition, California's THC definition is somewhat unique, and must be considered when calculating concentration for compliance purposes, especially if additional forms of THC or cannabinoids are added to the definition of "THC or comparable cannabinoid." The second requirement is somewhat unique, and it's also unclear what type of testing is expected. However, given the context, it appears the state is looking for the usual potency testing you would find on a COA, specifically for "marketed" hemp derivatives, i.e., those called out on the label or in marketing. This is likely to get further attention as DPH promulgates implementing regulations.

- A certificate of analysis is required on all raw hemp products that confirms that testing was on a representative batch of the hemp by an independent laboratory, the sample did not exceed 0.3% total THC, and the sample did not contain contaminants unsafe for human or animal consumption. (*HSC 111925.2*)
  - "Raw hemp product" is defined as a product that is derived from industrial hemp that is intended to be included in a food, beverage, dietary supplement, or cosmetic.
  - We believe that total THC, as referred to in this section, is defined as the sum of THC and THCA, which must be calculated using the following equation: total THC concentration (mg/g) +/- the measurement of uncertainty, as defined by USDA. This will likely be clarified in regulation.
- DPH can, through regulation, determine serving sizes, cannabinoid concentration per serving size, the number of servings per container, and other requirements for foods and beverages. The law also requires food and beverages to be prepackaged and shelf stable. (*HSC 111922.3)*
- DPH may adopt regulations to impose an age requirement on hemp products. (*HSC 111921.3)*

- **Hemp extract products are subject to a broad range of labeling and marketing requirements.**
  - Health-related statements regarding hemp/hemp derivatives published or disseminated in labeling, advertising or marketing that are untrue in any particular manner are prohibited. Structure and function claims made for dietary supplements are explicitly exempted from the scope of this requirement. (*HSC 110407*)
    - While the exact language of this section is unique, other states have similar restrictions on false and misleading claims made for hemp/cannabinoid products.
  - Manufacturers, distributors and retailers are required to follow current law relative to packaging, labeling, and advertising – prohibiting a manufacturer from targeting children or persons who are pregnant or breastfeeding in advertising

and marketing, and advertising and marketing only where it is reasonably expected that 70% of the audience is 18 years of age or older. (*HSC 111926*)
    - This is unique to California and is purposely identical to cannabis requirements.
- All food, beverage, and dietary supplement products manufactured 90 days or more after the legislation's enactment are required to be labeled with the following information (*HSC 111926.2*):
    - A label, scannable barcode, internet website, **or** quick response (QR) code linked to the certificate of analysis of the final form product batch by an independent testing laboratory that provides all of the following information:
        - The product name.
        - The name of the product's manufacturer, packer, or distributor, and their address and telephone number.
        - The batch number, which matches the batch number on the product.
        - The concentration of cannabinoids present in the product batch, including, at minimum, total THC and any marketed cannabinoids or ingredient, as required by the department in regulation.
        - The levels within the product batch of contaminants.
    - Product expiration or best by date, if applicable
    - Statement indicating children or persons who are pregnant or breastfeeding should avoid using the product prior to consulting with a health care professional about its safety, and a statement that products with cannabinoids should be kept out of the reach of children.
        - Both of the above are unique to California, but appear to allow some flexibility, i.e., similar statements may be used, not the exact statements listed here.
    - Statement: "The FDA has not evaluated this product for safety or efficacy."
        - Colorado is currently the only other state requiring this statement.
- All cosmetic products must be labeled with the same information listed above, excluding the two statements about children or pregnant and breastfeeding persons.

- **Products sold in California can use hemp grown outside the state, under certain requirements.**
    - Hemp may not be used in supplements or food unless the manufacturer demonstrates that it comes from a state or country that has an established and approved industrial hemp program that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human or animal consumption, and the industrial hemp cultivator or grower is in good standing

and in compliance with the governing laws of the state or country of origin. (*HSC 110469(b))*
    - Note that in another section (*HSC 111921)*, hemp is required to be sourced from a grower in compliance with state law or licensed under USDA requirements from other states. This appears to conflict with the language above allowing hemp to be used in a food or DS if it comes from another country. This conflict is likely to be harmonized when DPH promulgates implementing regulations.
  - An out-of-state hemp manufacturer is required to reimburse DPH for any onsite inspections to ensure compliance. (*HSC 111923.7*.)
    - Other states have registration requirements for hemp product manufacturers, some for out-of-state entities, but the requirement to provide reimbursement for inspections is unique, as far as we know.

- **It is made explicitly legal to include hemp in pet products.**
  - Processed pet food is not adulterated by the addition of hemp provided that the product meets the requirements of this law. (*HSC 113091*).
  - A pet product manufacturer is required to additionally comply with the laws relative to processed pet food. (*HSC 111922.3*)

- **A pathway is outlined for the sale of smokable hemp products.**
  - Immediately, it is permissible to farm for, and manufacture, inhalable products to be sold in other states.
  - Inhalable products can be sold in California once the Legislature passes a tax on inhalable hemp products. *(HSC 111921.6)*
  - Inhalable products may not be sold to persons under 21 years of age. Elements that cannot be included in an inhalable product: flavorings other than natural terpenes, polyethylene glycol, vitamin E acetate, medium chain triglycerides, squalene, or other substances DPH finds a danger to public health. (*HSC 111929*)

- **There are a variety of prohibited hemp products.**
  - These include medical devices, non-FDA approved prescription drugs, products containing nicotine lor tobacco, alcoholic beverages, and any other product that poses a risk to human or animal health, as determined by regulation. (*HSC 111921)*

- **The integration of cannabis licenses into the hemp supply chain will be studied and a report issued.**
  - The Department of Cannabis Control will prepare a report by July 1, 2022. (*BPC 26013.2*)
  - Full integration will require follow-up legislation.

- **There are a variety of manufacturing registration requirements.**
  - A wholesale food manufacturer must register with DPH. (*HSC 110469*)

- A manufacturer of a food or beverage, cosmetic or pet hemp product must register under existing statutory protocols specific to each industry. (*HSC 111923.3*)
- A hemp manufacturer is required to also obtain an industrial hemp enrollment and oversight authorization from DPH. A fee will be assessed to cover the costs of implementing this law. (*HSC 111923.5)*

- **The law provides enforcement discretion for 90 days:**
  - For manufacturers and retailers if they are operating in good faith compliance with the law (*HSC 111923.9)*
  - To meet labeling requirements (*HSC 111926.2(b)*)

- **There are no new regulatory burdens placed on hemp growers under this legislation.**
  - Contrary to inaccurate reports, hemp farming is not addressed by this legislation, and growers continue to be regulated under previously existing statute. Furthermore, neither hemp growers, nor processors, nor manufacturers are subject to the oversight of the state Department of Cannabis Control.