Date of Hearing: April 27, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 45 (Aguiar-Curry) – As Amended April 14, 2021

SUBJECT: Industrial hemp products.

SUMMARY: Establishes a regulatory framework for industrial hemp under the Sherman Food, Drug, & Cosmetic Law (Sherman Law). Requires manufacturers of products containing industrial hemp or hemp products to obtain a process food registration and comply with good manufacturing practices. Contains an urgency clause to ensure to ensure the provisions of this bill go into immediate effect upon enactment. Specifically, **this bill**:

General Provisions

1) Deletes and recasts the existing definition of industrial hemp or hemp to mean an agricultural product, whether growing or not, that is limited to types of the plant Cannabis sativa L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, the resin extracted from any part of the plant, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9 tetrahydrocannabinol (THC) concentration of no more than 0.3% on a dry weight basis.

2) Deletes an outdated operative date on existing provisions relating to fees associated with the renewal of any permit or license.

3) Requires all laws and regulations pertaining to industrial hemp products to remain in effect until the adoption of regulations pursuant to the federal law that authorizes industrial hemp products. Requires the Department of Public Health (DPH) to adopt new regulations as necessary pursuant to federal law.

4) Authorizes DPH to adopt emergency regulations, including readopting emergency regulations but only one time for each regulation, as specified.

5) Exempts initial regulations adopted by DPH from the Administrative Procedure Act, as specified. Requires DPH to post the proposed regulations on its internet website for public comment for 30 days, as specified.

Hemp Provisions

1) Defines the following terms:

   a) "Established and approved industrial hemp program" means a program that meets any applicable requirements set forth in federal law regarding the lawful and safe cultivation of industrial hemp;
   b) "Final form product" is a product intended for consumer use to be sold at a retail premise;
   c) "Hemp manufacturer" means either of the following:
      i) A processor extracting cannabinoids from hemp biomass; or,

ii) A processor purchasing industrial hemp raw extract for the purpose of manufacturing a final form product.

d) "Independent testing laboratory" means a laboratory that meets all of the following requirements:
   i) Does not have a direct or indirect interest in the entity for which testing is being done;
   ii) Does not have a direct or indirect interest in a facility that cultivates, processes, distributes, dispenses, or sells raw hemp products in this state or in another jurisdiction;
   iii) Does not have a license issued by the Bureau of Cannabis Control (BCC) other than as a licensed testing laboratory;
   iv) Is either of the following:
      (1) A testing laboratory licensed by BCC if the licensed testing lab has notified the BCC; or,
      (2) Accredited by a third-party accrediting body as a competent testing laboratory pursuant to ISO/IEC 17025 of the International Organization for Standardization.

e) "Industrial hemp product" means a finished product containing industrial hemp that meets all of the following conditions:
   i) Is a cosmetic, food, food additive, dietary supplement, or herb;
   ii) Is for human or animal consumption, as specified.

   Excludes from this definition industrial hemp or a hemp product that has been approved by the United States Food and Drug Administration (FDA) or a hemp product that includes industrial hemp or hemp that has received Generally Recognized As Safe (GRAS) designation. Excludes from industrial hemp products, for purposes of nonfood applications, a hemp product that contains derivatives, substances, or compounds derived from the seed of industrial hemp.

f) Manufacture" or "manufacturing" means to compound, blend, extract, infuse, or otherwise make or prepare an industrial hemp product. States that manufacturing includes all aspects of the extraction process, infusion process, and packaging and labeling processes, including processing, preparing, holding, and storing of industrial hemp products; includes processing, preparing, holding, or storing hemp components and ingredients; and, excludes planting, growing, harvesting, drying, curing, grading, or trimming a plant or part of a plant.

g) "Raw extract" or "industrial hemp raw extract" means extract not intended for consumer use and that contains a THC concentration of not more than an amount determined by DPH in regulation.

h) "Raw hemp product" means a product that is derived from industrial hemp that is intended to be included in a food, beverage, dietary supplement, or cosmetic.

i) "Total THC" means the sum of THC and Tetrahydrocannabinolic acid (THCA). Total THC is to be calculated using the following equation: total THC concentration (mg/g) = (THCA concentration (mg/g) x 0.877) + THC concentration (mg/g).

2) Prohibits a manufacturer, distributor, or seller of an industrial hemp product from including on the label of the product, or from publishing or disseminating in advertising or marketing, any health-related statement that is untrue in any particular manner as to the health effects of consuming products containing industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp, as specified.

3) Defines health-related statement to mean a statement related to health, and includes a statement of a curative or therapeutic nature that, expressly or impliedly, suggests a relationship between the consumption of industrial hemp or industrial hemp products and health benefits or effects on health. Excludes from this definition statements required to be made pursuant to FDA regulations for active ingredients in prescription drugs, nonprescription over-the-counter drugs containing inactive ingredients, or structure-function claims allowed for dietary supplements made in accordance with the Federal Food, Drug, and Cosmetic Act, as specified.

4) Requires a wholesale food manufacturing facility that manufactures products that contain industrial hemp to obtain a process food registration and to comply with good manufacturing practices, as determined by DPH in regulation.

5) Prohibits using industrial hemp in dietary supplements or food products unless the manufacturer demonstrates both of the following:
   a) All parts of the hemp plant used in dietary supplements or food products come 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,
   b) The industrial hemp cultivator or grower is in good standing and in compliance with the governing laws of the state or country of origin.

6) Specifies that a dietary supplement, food, beverage, cosmetic, or pet food is not adulterated by the inclusion of industrial hemp, as long as the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established by this bill. States that the sale of a dietary supplement, food, beverage, cosmetic, or pet food that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp shall not be restricted or prohibited based solely on the inclusion of industrial hemp provided that the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements of this bill.

7) Prohibits the distribution or sale of an industrial hemp product in the state unless it conforms with all applicable state laws and regulations, as specified, and with documentation that includes both of the following:
   a) A certificate of analysis from an independent testing laboratory that confirms both of the following:
      i) The industrial hemp raw extract, in its final form, does not exceed THC concentration of an amount determined allowable by the department in regulation, or the final form product does not exceed THC concentration of 0.3%; and,
      ii) The industrial hemp product was tested for any hemp derivatives identified on the product label or in associated advertising, as specified.

   b) The industrial hemp product was produced from industrial hemp grown in compliance with the Food and Agricultural Code if sourced from within California, or licensed in

accordance with United States Department of Agriculture (USDA) requirements if sourced from outside the state.

8) Permits DPH to adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health based on scientific research.

9) Prohibits, unless explicitly approved by the FDA, industrial hemp from being included in products in any of the following categories:
   a) Medical devices;
   b) Prescription drugs;
   c) Processed smokable products, including, but not limited to, electronic cigarettes with nicotine;
   d) Smokable flower, including, but not limited to, hookah and shisha with nicotine;
   e) A product containing nicotine or tobacco; or,
   f) An alcoholic beverage.

10) Permits DPH, through regulation, to prohibit the inclusion of industrial hemp in other products when it poses a risk to human or animal health.

11) States that cannabis and cannabis products are not subject to 9) and 10) above.

12) Permits DPH, through regulation, to determine maximum serving sizes for hemp-derived cannabinoids, hemp extract, and products derived therefrom, active cannabinoid concentration per serving size, the number of servings per container, and any other requirements for foods and beverages.

13) Requires food and beverages to be prepackaged and shelf stable.

14) Requires a hemp manufacturer who produces raw extract that will only be used for dietary supplements, foods, beverages, and cosmetics, or a hemp manufacturer who produces industrial hemp products to comply with this bill and applicable provisions, as specified.

15) Requires a hemp manufacturer who produces processed pet food products to comply with this bill and existing law provisions on processed pet food, including good manufacturing practices, as specified.

16) Establishes the Industrial Hemp Enrollment and Oversight Fund for purposes of this bill, and prohibits moneys in this fund from being redirected for any other purpose.

17) Establishes the Industrial Hemp Research Fund for money received by DPH pursuant to 23) below and expended by the Regents of the University of California, upon appropriation by the Legislature, to carry out and implement 52) below.

18) Requires a hemp manufacturer who produces an industrial hemp product that is a food or beverage to register with DPH as processed food manufacturers consistent with existing law.

19) Requires a hemp manufacturer who produces an industrial hemp product that is a cosmetic to register with DPH.

20) Requires a hemp manufacturer who produces an industrial hemp product that is a processed pet food to obtain a license from DPH consistent with existing law.

21) Requires an in-state hemp manufacturer who produces raw hemp extract and who does not produce an industrial hemp product, or an out-of-state hemp manufacturer who produces raw hemp extract with the intent to import that raw hemp extract into this state, to register with DPH as a food processor.

22) Requires all hemp manufacturers to notify DPH immediately of any change of information in their application for a license of registration.

23) Requires, in addition to licensing and registration requirements and fees required under 18) to 20) above, a hemp manufacturer to obtain an industrial hemp enrollment and oversight authorization from DPH, to be renewed annually. States the following about the fees:
    a) Requires DPH to assess an authorization fee and renewal fee to cover the actual reasonable costs of implementing the regulatory program in this chapter, not to exceed $1,000 per company;
    b) Permits fees to be set at different amounts for different hemp manufacturer types, including food products, cosmetic products, and pet food products, based on the differing costs associated with regulatory requirements, including, but not limited to, the nature and scope of the authorization activities and oversight, inspection, and enforcement activities;
    c) Requires the fee to be adjusted, as specified; and,
    d) Permits fees to be prorated based upon the date of the renewal or issuance of the authorization.

24) Requires, in addition to the fees specified in 23) above, a hemp manufacturer to pay an annual fee of $250 to support research on the health effects of hemp-derived cannabinoids. States that this fee will not be prorated and the date of renewal to align with the renewal of the authorization specified in 23) above; and for the fee to be adjusted.

25) Requires a hemp manufacturer located outside the state to reimburse DPH for travel and per diem required to perform necessary onsite inspections at the facility to ensure compliance with this bill, as specified.

26) Permits a hemp manufacturer or retailer who is operating in conformance with this bill and in good faith compliance with their responsibilities to manufacture or sell industrial hemp products or raw hemp extract without authorization for three months after the effective date of this bill, as specified.

27) Permits DPH to adopt regulations for recordkeeping standards that apply to transporters, manufacturers, and retailers of industrial hemp product and raw extract.

28) Requires a hemp manufacturer to meet all of the following testing requirements:
    a) Industrial hemp to be tested in raw extract final form, to allow its use as an ingredient, prior to being incorporated into a product;

b) Testing to be completed by an independent testing laboratory; and,
c) The manufacturer of the hemp extract in its final form or the final form industrial hemp product to be able to prove total THC concentration does not exceed 0.3%. Requires a manufacturer of raw extract to be able to prove that the THC concentration meets DPH requirements on certificate of analysis, as specified in 30) below.

29) Permits DPH to regulate and restrict the cap on extract and cap the amount of total THC concentration at the product level based on the product form, volume, number of servings, ratio of cannabinoids to THC in the product, or other factors, as needed.

30) Prohibits a raw hemp product from being distributed or sold in this state without a certificate of analysis from an independent testing laboratory that confirms all of the following:
a) The raw hemp product is the product of a batch of industrial hemp that was tested by the independent testing laboratory;
b) A tested random sample of the batch of industrial hemp contained a total THC concentration that did not exceed 0.3% on a dry-weight basis; and,
c) The tested sample of the batch did not contain contaminants that are unsafe for human or animal consumption.

31) Requires testing requirements for contaminant levels to be the same as those for cannabis, as specified.

32) Permits DPH to adjust the specific contaminant levels for industrial hemp by regulation.

33) Permits a product batch to be reprocessed or remediated after failed testing, but prohibits the batch from being distributed or sold unless the reprocessed or remediated batch has been retested and successfully passed all the analyses required pursuant to bill.

34) Requires the destruction of a product batch that cannot be reprocessed or remediated. Prohibits from retesting a failed product batch is not reprocessed or remediated in any way. Prohibits a subsequent certificates of analysis produced without reprocessing or remediation of the failed product batch from superseding the initial regulatory compliance testing certificate of analysis. Allows a product batch to be retested when the certificate of analysis was obtained 12 months prior or more. States that reprocessing or remediation are an available remedy for failed product batches in all industrial hemp product categories and raw extract. Prohibits remediation once a product enters the retail market. Requires a failed product batch that cannot be reprocessed or remediated to be destroyed, at the expense of the owner, on video surveillance, as authorized by DPH, or under the supervision of an authorized agent of DPH.

35) Requires a manufacturer, distributor, or seller of an industrial hemp product to follow packaging, labeling, and advertising laws, including, federal laws, as specified.

36) Prohibits a hemp manufacturer from directly target advertising or marketing to children or to persons who are pregnant or breastfeeding.

37) Requires advertising or marketing placed in broadcast, cable, radio, print, or digital communications to only be displayed where at least 70% of the audience is reasonably expected to be 18 years of age or older, as determined by reliable, up-to-date audience

composition data.

38) Prohibits an industrial hemp product that is a dietary supplement, food, beverage, or cosmetic from being distributed or sold in the state without packaging and labeling on the product that includes all of the following information:
   a) A label, scannable barcode, internet website, or quick response 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:
      i) The product name;
      ii) The name of the product's manufacturer, packer, or distributor, and their address and telephone number;
      iii) The batch number, which matches the batch number on the product;
      iv) 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; and,
      v) The levels within the product batch of contaminants, as required.
   b) The product expiration or best by date, if applicable;
   c) Except for cosmetics, a statement indicating that children or those who are pregnant or breastfeeding should consult with a health care professional before using the product;
   d) Except for cosmetics, a statement that products containing cannabinoids should be kept out of reach of children; and,
   e) The following statement, "THE FDA HAS NOT EVALUATED THIS PRODUCT FOR SAFETY OR EFFICACY".

39) Applies the requirements in 38) above to products manufactured 90 days or more after enactment of those requirements.

40) Gives DPH seizure and embargo powers consistent with existing law in the enforcement of this bill.

41) Gives DPH the ability to recall industrial hemp products or raw extract that it determines to be dangerous to the public, as specified.

42) Permits DPH, in addition to the any authorized inspection authority provided, to inspect financial data, sales data, and personnel data, as needed to enforce this bill.

43) Permits state, local, or law enforcement officials to review paperwork from those handling or transporting industrial hemp plant material, raw extract, intermediary industrial hemp product, or final finished product and take samples at any point along the supply chain to test that sample for verification.

44) Requires, upon inspection, if the industrial hemp plant material, raw extract, intermediary industrial hemp product, or final finished product does not meet the definition of industrial hemp, the state, local, or law enforcement official to notify DPH.

45) Requires state, local, and law enforcement officials to immediately notify DPH of an arrest made for a violation over which DPH has jurisdiction under this bill.

46) Requires DPH to promptly investigate whether grounds exist for suspension or revocation of the authorization or if other actions are warranted under this bill.

47) Subjects violations of this bill to existing fines and penalties.

48) Requires the Department of Food and Agriculture (DFA) and DPH, in consultation with BCC, if necessary, to develop a process to share license, registration, cultivar, and enforcement information to facilitate compliance and enforcement against unlicensed manufacturers or the sale of industrial hemp that does not meet the requirements of this bill.

49) Prohibits communications shared between state agencies and local and law enforcement officials regarding license, registration, cultivar, and enforcement information of manufacturers and retailers of industrial hemp products and raw extract from being subject to the California Public Records Act and to be considered "official information," as specified.

50) Requires, on or before July 1, 2021, the cannabis licensing authorities, including BCC, to prepare a report to the Governor outlining the steps necessary to allow for the incorporation of hemp cannabinoids into the cannabis supply chain. Requires the report to include, but not be limited to, the incorporation of hemp cannabinoids into manufactured cannabis products and the sale of hemp products at cannabis retailers.

51) States the intent of the Legislature that objective scientific research regarding the safety of industrial hemp be conducted.

52) Permits, if the Regents of the University of California, by appropriate resolution, accepts the research responsibility outlined in this bill, the University of California to create the California Industrial Hemp Research Program (hemp research program).

53) Requires the hemp research program to develop and conduct studies intended to ascertain the general safety of industrial hemp. Permits the research program to solicit proposals for research projects to be included in the industrial hemp studies. Requires these proposals to demonstrate the use of key personnel, including clinicians or scientists and support personnel, who are prepared to develop a program of research regarding industrial hemp safety.

54) States that a processed pet food is not adulterated because it includes industrial hemp, or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements established in this bill. States that the sale of processed pet food that includes industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp is not be restricted or prohibited based solely on the inclusion of industrial hemp or cannabinoids, extracts, or derivatives from industrial hemp, if the cannabinoids, extracts, or derivatives from industrial hemp meet the requirements of this bill.

EXISTING LAW:

1) Establishes the Sherman Law, administered by DPH, to protect consumers against unlawful food, drugs, cosmetics and medical devices by regulating their packaging, labeling, and advertising of drugs and devices.

2) Prohibits any person from engaging in the manufacture, packing, or holding of any processed food unless the person has a valid registration as a food processing facility from DPH under the Sherman Law. Requires a manufacturer to comply with good manufacturing practices regulations for any food, drug, device, or cosmetic.

3) Defines "smoking" as inhaling, exhaling, burning, or carrying any lighted or heated cigar, cigarette, or pipe, or any other lighted or heated tobacco or plant product intended for inhalation, whether natural or synthetic, in any manner or in any form. Includes the use of an electronic smoking device that creates an aerosol or vapor, in any manner or in any form, or the use of any oral smoking device for the purpose of circumventing the prohibition of smoking.

4) Defines "tobacco product" as a product containing, made, or derived from tobacco or nicotine that is intended for human consumption, as specified, including an electronic device that delivers nicotine or other vaporized liquids to the person inhaling from the device, and any component, part, or accessory of a tobacco product, whether or not sold separately. Prohibits any product approved by the FDA for sale as a tobacco cessation product or for other therapeutic purposes, from being deemed a tobacco product.

5) Establishes the California Uniform Controlled Substances Act (UCSA), which among other provisions, classifies controlled substances into five designated schedules.

6) Defines under UCSA industrial hemp as a crop that is limited to types of the plant Cannabis sativa L. having no more than three-tenths of 1% THC contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom.

7) Subjects regulatory authority over industrial hemp to the DFA, as specified.

8) Requires, except when grown by an established agricultural research institution or by a registered seed breeder developing a new California seed cultivar, industrial hemp to only be grown if it is on the list of approved seed cultivars, as specified.

9) Requires, except for an established agricultural research institution, and before cultivation, a grower of industrial hemp for commercial purposes to register with county agricultural commissioner (CAC) of the county in which the grower intends to engage in industrial hemp cultivation, as specified.

10) Provides that, except when grown by an established agricultural research institution, and before cultivation, a seed breeder must register with the CAC of the county in which the seed breeder intends to engage in industrial hemp cultivation as specified.

11) Requires, except when grown by an established agricultural research institution or a registered seed breeder, industrial hemp to be grown only as a densely planted fiber or oilseed crop, or both, in acreages of not less than one-tenth of an acre at the same time.

12) Enacts the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA) to establish a comprehensive system to control and regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both medicinal cannabis and

cannabis products, and adult-use cannabis and cannabis products for adults 21 years of age and over.

13) Defines "cannabis," for purposes of MAUCRSA, as all parts of the plant Cannabis sativa Linnaeus, Cannabis indica, or Cannabis ruderalis, the seeds thereof, the resin, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. Excludes "industrial hemp," as defined in the UCSA from the definition of cannabis for purposes of MAUCRSA.

14) Prohibits, under the Alcoholic Beverage Control Act, the manufacture or sale of alcoholic beverages that contain THC or cannabinoids, regardless of the source.

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL**. According to the author, hemp is not marijuana and while both hemp and marijuana are members of the cannabis family, they are uniquely distinctive plants. Hemp-derived cannabidiol (CBD) does not produce a "high" because CBD derived from hemp contains only trace amounts of THC (less than 0.3%), the psychoactive component in marijuana products. The author points out that consumers seek out hemp-derived CBD because it can provide them with relief from pain, inflammation, anxiety, insomnia, and other conditions. Many people have been purchasing hemp-derived CBD topical products at their local natural foods shops, fitness centers, and health stores for some time. In fact, seniors are a significant portion of the people choosing to use hemp CBD, because they do not want to visit a marijuana dispensary. According to the World Health Organization (WHO), "CBD exhibits no effects indicative of abuse or dependence potential." "There is no evidence of any public health related problems associated with the use of CBD." The author concludes that hemp has become an increasingly important crop, it is easy to grow, can be cultivated without toxic pesticides, and serves well as a rotation crop. This is an opportunity for California to make it easier for its citizens to access a non-intoxicating-alternative product they want, and for farmers to establish themselves in a fast-growing industry.

2) **BACKGROUND.** Industrial hemp has been grown for thousands of years as a seed crop and for fiber. It is used for products such as paper, textiles, cosmetics and body care, food, and fabric. CBD products have grown in popularity and they can be eaten, rubbed on skin, added to soaps, gummy candies, and even pet treats. A 2019 Gallup poll found that 14% of more than 2,500 Americans surveyed used CBD products, mostly for pain, anxiety, and sleep problems. According to an April 2020 *New York Times* (*NYT*) article entitled "Should you Give your Kids CBD?" although statistics on CBD use by children are rare, it appears parents give them to kids for conditions including autism spectrum and attention deficit hyperactivity disorder. The article also cited a cannabis-focused magazine which released the results of a 2020 survey of more than 500 parents and found that 40% had given CBD products to their children for behavior related to autism spectrum.

   According to a report published in November of 2017 by the WHO, CBD exhibits no effects indicative of any abuse or dependence potential. The WHO stated that CBD is generally well tolerated with a good safety profile, and that to date, there is no evidence of recreational use of CBD or any public health related problems associated with CBD. Currently, about 23

countries grow hemp for commercial use. However, according to the FDA, CBD has the potential to harm and the harm can happen even before an individual becomes aware of it. For example, CBD can cause liver injury; can affect how other drugs work, potentially causing serious side effects; use of CBD with alcohol or other drugs that slow brain activity, such as those used to treat anxiety, panic, stress, or sleep disorders, increases the risk of sedation and drowsiness, which can lead to injuries; and male reproductive toxicity, or damage to fertility in males or male offspring of women who have been exposed, has been reported in studies of animals exposed to CBD. Additionally there is also concern on the unreliability of the purity and dosage of CBD products. According to the Mayo Clinic, a recent study of 84 CBD products bought online showed that more than a quarter of the products contained less CBD than labeled, and in addition, THC was only found in 18 products.

In July 2020, the FDA approved Epidiolex, a CBD oral solution for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients one year of age and older. Epidiolex was previously approved for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome. Epidiolex is the only FDA-approved drug that contains a purified drug substance derived from cannabis. It is also the second FDA approval of a drug for the treatment of seizures associated with TSC.

a) **Federal regulatory framework.** For decades, federal law did not differentiate hemp from other cannabis plants, all of which were effectively made illegal in 1937 under the Marijuana Tax Act and formally made illegal in 1970 under the Controlled Substances Act, which banned cannabis of any kind. However, the Agricultural Act of 2014 (2014 Farm Bill), allowed states to regulate hemp production or follow a USDA plan regulating hemp production and removed hemp from the federal Controlled Substances Act. Pilot programs were authorize by the 2014 Farm Bill and this allowed small-scale expansion of hemp cultivation for limited purposes. Subsequently, the 2018 Farm Bill expanded hemp cultivation, allowed the transfer of hemp-derived products across state lines for commercial or other purposes; puts no restrictions on the sale, transport, or possession of hemp-derived products, so long as those items are produced in a manner consistent with the law. However, the 2018 Farm Bill also included specific restrictions. Hemp cannot contain more than 0.3% THC (any cannabis plant that contains more than 0.3% THC would be considered non-hemp cannabis, or marijuana, under federal law and would thus face no legal protection). Second, there will be significant, shared state-federal regulatory power over hemp cultivation and production. State departments of agriculture must consult with the state's governor and chief law enforcement officer to devise a plan that must be submitted to the Secretary of USDA. A state's plan to license and regulate hemp can only commence once the Secretary of USDA approves that state's plan. In states opting not to devise a hemp regulatory program, the USDA will construct a regulatory program under which hemp cultivators in those states must apply for licenses and comply with a federally-run program.

   In 2020, the FDA released its guidance called "Cannabis and Cannabis-Derived Compounds: Quality Considerations for Clinical Research, Draft Guidance for Industry," which describes the FDA's current thinking on several topics relevant to clinical research related to the development of drugs containing cannabis or cannabis-derived compounds. According to the FDA, cannabis and cannabis-derived compounds may be used in drug manufacturing including botanical raw materials, extracts, and highly purified substances

of botanical origin. Although the FDA has taken a position that CBD is a drug ingredient and cannot be marketed as a dietary supplement or added to foods without its approval, its enforcement on this requirement has been limited to cease and desist letters. For example, in the first law enforcement crackdown on deceptive claims in the growing market for CBD products, the Federal Trade Commission (FTC) took action against six sellers of CBD-containing products for allegedly making a wide range of scientifically unsupported claims about their ability to treat serious health conditions, including cancer, heart disease, hypertension, Alzheimer's disease, and others. The FTC required each of the companies, and individuals behind them, to stop making such unsupported health claims immediately, and several will pay monetary judgments to the agency. The orders settling the FTC's complaints also bar the respondents from similar deceptive advertising in the future, and require that they have scientific evidence to support any health claims they make for CBD and other products.

b) California regulatory framework. SB 566 (Leno), Chapter 398, Statutes of 2013, established the Industrial Hemp Farming Act which regulated the cultivation and processing of industrial hemp upon federal approval. SB 566 required, among various provisions, except for an established agricultural research institution, and before cultivation, a grower of industrial hemp for commercial purposes to register with the CAC of the county in which the grower intends to engage in industrial hemp cultivation, as specified. Senate Bill 153 (Wilk), Chapter 838, Statutes of 2019, revised the provisions regulating the cultivation and testing of industrial hemp to conform to the requirements for a state plan under the 2018 Farm Bill. This year, SB 292 (Wilk), pending in the Assembly, would conform state law to USDA rules regarding reporting and testing of industrial hemp.

California has a regulatory framework that permits CBD derived from cannabis to be added to food products and sold to adults through licensed cannabis dispensaries. Outside of this framework, any product added to food is regulated by DPH's Food and Drug Branch under the Sherman Law. In 2018, DPH published an FAQ on industrial hemp and CBD in food products. In this FAQ, DPH pointed out that California incorporates federal law regarding food additives, dietary use products, food labeling, and good manufacturing practices for food. Because the FDA has concluded it is a prohibited act to introduce or deliver for introduction into interstate commerce any food (including animal food) to which THC or CBD has been added, DPH also prohibits CBD products. According to this FAQ: "Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food, or California makes a determination that they are safe to use for human and animal consumption, CBD products are not an approved food, food ingredient, food additive, or dietary supplement." Unlike the sporadic cease and desist orders from the U.S. FDA, DPH took a more active enforcement stance. According to DPH, in response to about 50 complaints concerning hemp-derived CBD foods and beverages, it issued 13 notices of violations, seven voluntary condemnation and destruction regulatory letters, and nine embargoes regarding prohibited industrial hemp-derived CBD products since DPH released the FAQ. However, DPH has since taken down this FAQ and instead focused on investigating CBD product complaints related to injury or illness. DPH has received one such complaint, alleging illness due to consumption of a CBD product, and initiated an investigation into that complaint, which is ongoing.

c) **Recent *NYT* Article on Delta-8 THC in hemp**. On February 27, 2021, *NYT* published an article, "This Drug Gets You High, and Is Legal (Maybe) Across the Country." This article suggested that a form of THC that is permissible in industrial hemp is being touted as an alternative to the psychoactive ingredient in cannabis. Under federal law, psychoactive Delta-9 THC is explicitly prohibited, but the law is silent on Delta-8 THC. According to this article, with Delta-8, entrepreneurs believe they have found a way to take advantage of the country's fractured and convoluted laws on recreational marijuana use, and have begun extracting and packaging it as a legal edible and smokable alternative. The article states that it's not quite that simple, and that federal agencies, including the Drug Enforcement Administration, are still considering their options for enforcement and regulation. According to the article, "Precisely what kind of high Delta-8 produces depends on whom you ask. Some think it as 'marijuana light,' while others are pitching it as pain relief with less psychoactivity." The article quotes an editor of Leafly.com, a popular source of information about cannabis, as saying that Delta-8 has become "extremely ascendant" and reflects "prohibition downfall interregnum," where consumer demand and entrepreneurial activity are exploiting the holes in rapidly evolving and fractured law.

3) **SUPPORT.** In support of this bill, the Cannabis Hemp Council (CHC) indicates that the hemp industry, especially the hemp CBD market, represents a major source of new state and local revenues that can be realized quickly. Based on national market projections for hemp derived CBD of over $2 billion annually for food and beverage alone, California could expect to bring in tens of millions in new annual tax revenue should this bill be approved. Many states, including Colorado, Florida, Texas, Virginia, New York, New Jersey, Kansas, Nevada, and Oklahoma have adopted laws that immediately allow hemp CBD to be used in food, beverages and dietary supplements. Companies deciding where to site their operations are looking first at those states that affirmatively want their business; companies already doing business in California are presently contemplating whether to move their operations and jobs to other states due to California's delay in opening up to the broader hemp market. CHC also states that this bill would establish the most expansive hemp CBD testing program in the nation, and the testing regimen for hemp CBD would be the same as testing for cannabis and consumers would have access to the test results for every product they purchase. By placing hemp products under the requirements of the Sherman Law and Current Good Manufacturing Practices, this bill would prohibit any person or business from engaging in the manufacturing, packing, or holding of any hemp product in California unless they have a valid registration from the DPH.

In its support of this bill, the California Cannabis Industry Association states that this bill establishes a comprehensive regulatory framework for hemp manufacturing in California, ensures manufactured hemp products are safe; Protects consumers with strong advertising and labeling standards, and ensures ongoing coordination between hemp, cannabis licensing agencies and law enforcement. However, it states there is more work to be done to make the bill even stronger to clarify portions that may be unclear and ensure the protection of the cannabis industry in this process, including closing loopholes to ensure that consumer products do not exceed 0.3% THC concentration or contain any psychoactive cannabinoids; establishing a clear pathway for the incorporation of hemp into the cannabis supply chain; and, developing a successful path to permit the manufacture and sale of smokable and inhalable hemp products.

4) **SUPPORT IF AMENDED.** California Norml states in its support if amended letter that amendments should be adopted to allow California consumers to have legal access to cannabis hemp smoking products, and its legality should not be contingent on FDA approval. Osiris Ventures/NorCal Cannabis states it supports sensible hemp policy but does not support the inclusion of hemp in the cannabis supply chain without material changes in cannabis policy to open up opportunities for legal cannabis businesses.

5) **OPPOSE UNLESS AMENDED**. The California Farm Bureau has taken an oppose unless amended position and states that this bill needs to ensure that state law is consistent with the federal rules for domestically produced hemp as published by the USDA. The Farm Bureau also points out that requiring processed and raw hemp extracts to be tested for contaminants consistent with cannabis standards is inappropriate since hemp is a federally recognized agricultural commodity, and that the contaminant levels required for hemp should conform to food standards. Lastly, the Farm Bureau indicates that it has concerns over the proposed prohibition on hemp to be included in smokable flower because this is an existing market in California that supports small scale hemp farmers.

   The Cannabis Distribution Association (CDA), in its oppose unless amended letter states that hemp should be tested to the same standards as cannabis for pesticides, heavy metals, and other contaminants; loopholes, including "percentage by weight" in the definition of THC, should be closed in statute to ensure that high-THC and psychoactive products are not sold as hemp; and that CBD content should be required to be physically labelled on hemp products. CDA points out that hemp should be tested in its final form, instead of raw extract; testing standards for hemp and cannabis should be the same; regulations should be adopted not only to comply with federal law but also state law and regulation.

   The United Cannabis Business Association, Long Beach Collective Association, Angeles Emeralds, Coachella Valley Cannabis Alliance Network, Social Equity LA, San Francisco Cannabis Retailers Alliance, and Santa Ana Cannabis Association state that this bill should be amended to require parity testing with all CBD products; there should be taxing, zoning parity and sales parity; and that the licensing fees should reflect the need for enforcement.

6) **OPPOSITION.** Getting it Right From the Start, in opposition, states that this bill would lead to a blanket authorization of the adulteration of food, beverages, dietary supplements, cosmetic products, and pet food with hemp-derived ingredients, and the sale of those products, specifically substances that are not GRAS for use in food products intended for human or animal consumption. These hemp derivatives pose a serious threat to consumer safety.

7) **RELATED LEGISLATION.**

   a) SB 235 (Allen) is the companion measure to this bill and both bills are identical. SB 235 is pending in the Senate Appropriations Committee.

   b) SB 311 (Hueso) requires a health care facility to permit a terminally ill patient, defined as a prognosis of one year or less to live, to use medical cannabis within the health care facility. SB 311 is pending in the Assembly.

8) **PREVIOUS LEGISLATION.**

a) AB 228 (Aguiar-Curry) of 2019 would have established a regulatory framework for industrial hemp products that contain no more than 0.3% THC and is a cosmetic, food, food additive, dietary supplement, or herb. AB 228 was held on the Senate Appropriations Committee suspense file.

b) AB 710 (Wood), Chapter 62, Statutes of 2018, provides that if CBD is federally rescheduled or otherwise made a legally prescribable controlled substance, it shall also be legal to prescribe under state law.

c) SB 94 (Committee on Budget and Fiscal Review), Chapter 27, Statutes of 2017, establishes a single system of administration for cannabis laws in California, combining the Medical Cannabis Regulation and Safety Act with the Adult Use of Marijuana Act.

d) AB 266 (Bonta), Chapter 689, Statutes of 2015, SB 643 (McGuire), Chapter 719, Statutes of 2015, and AB 243 (Wood), Chapter 688, Statutes of 2015 were a package of bills that established a licensing and regulatory framework for medical marijuana under the Medical Marijuana Regulation and Safety Act.

9) COMMENTS. To ensure public safety and consumer protection, the Committee recommends the following amendments:

a) Compliance with state law. SB 793 (Hill), Chapter 34, Statutes of 2020, prohibits a tobacco retailer or their agents or employees from selling flavored tobacco product or a tobacco product enhancer. California bans flavored tobacco, including menthol and this prohibition applies to all methods of smoking including vaping or e-cigarettes. The FDA has banned flavors in tobacco but menthol is permitted. A provision in this bill states that unless explicitly approved by the FDA, industrial hemp cannot be included in processed smokable products, including electronic cigarettes, or tobacco. If the FDA eventually approves hemp in smokable products, as written this bill could be construed to allow the addition of menthol. As such, the following amendments are recommended:

> Section 111921.5 (a) Unless explicitly approved by the federal Food and Drug Administration ***and only if permitted under state law***, industrial hemp shall not be included in products in any of the following categories:
> 1) Medical devices;
> 2) Prescription drugs;
> 3) Processed smokable products, including, but not limited to, electronic cigarettes with nicotine;
> 4) Smokable flower, including, but not limited to, hookah and shisha with nicotine;
> 5) A product containing nicotine or tobacco; or,
> 6) An alcoholic beverage.

b) Age requirements. As drafted, this bill allows DPH to impose an age requirement for the sale of certain hemp products upon a finding of a threat to public health based on scientific research. This scientific research threshold seems to ignore the reality that outbreaks associated with public health threats occur at a rapid pace that will not have the benefit of scientific research. For example, in 2019, emergency department visits related to e-cigarette and vaping products sharply increased and eventually there were people who died from lung damage. DPH urged everyone to refrain from vaping until investigations were completed and as indicated on DPH's website 244 patients were

hospitalized and five died from vaping related lung injuries in the state. To ensure that DPH can continue act as appropriate during a public health emergency, the following amendment is suggested:

> **Section 111921.3.** The department may adopt regulations imposing an age requirement for the sale of certain industrial hemp products upon a finding of a threat to public health. ***based on scientific research.***

c) Testing contaminants. This bill require testing contaminant levels for hemp to be the same as cannabis but allows DPH to adjust the contaminant levels. The Committee recommends the language to be amended as follows:

> **Section 111925.4** (a) As of the effective date of the act adding this chapter, testing requirements for contaminant levels shall be the same as those for cannabis, as established in paragraph (2) of subdivision (d) of Section 26100 of the Business and Professions Code and regulations adopted pursuant thereto.
> (b) The department may adjust the specific contaminant levels for industrial hemp by regulation ***to protect consumers.***

d) Adoption of regulations. This bill requires DPH to adopt regulations as necessary pursuant to federal law. The Committee recommends that this authority be amended as follows:

> **Section 110036.** All laws and regulations pertaining to industrial hemp products shall remain in effect until the adoption of regulations pursuant to the federal law that authorizes industrial hemp products. At that time, the department shall adopt new regulations ***either*** as necessary pursuant to the federal law ***or deemed necessary to protect consumers***.

REGISTERED SUPPORT / OPPOSITION:

Support

California Cannabis Industry Association
California Hemp Council
Canopy Growth Corporation
Charlotte's Web
CMG/Caliva
Eden Enterprises Inc.
Imperial County Board of Supervisors
The Chronos Group
US Hemp Roundtable

Opposition

Getting It Right From the Start

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