

Date of Hearing: March 19, 2019

ASSEMBLY COMMITTEE ON HEALTH

Jim Wood, Chair

AB 228

(Aguiar-Curry) – As Amended March 13, 2019

SUBJECT: Food, beverage, and cosmetic adulterants: industrial hemp products.

SUMMARY: Declares that food, beverage, or cosmetics that include hemp-derived cannabinoids, are not considered adulterated products. Prohibits imposing restrictions on selling products based solely on the inclusion of industrial hemp. Specifically, **this bill:**

- 1) Specifies that a food, beverage, and/or cosmetic is not adulterated by the inclusion of industrial hemp-derived cannabinoids.
- 2) Prohibits restricting the sale of food, beverage, and cosmetic based solely on the inclusion of industrial hemp-derived cannabinoids.
- 3) Subjects products containing industrial-hemp-derived tetrahydrocannabinol (THC) in concentrations above 0.3% by product weight is be subject to the Medicinal and Adult-Use Cannabis Regulation and Safety Act (MAUCRSA).
- 4) Declares that any food or beverage product containing industrial hemp, or derivatives as safe for human and animal consumption.
- 5) Authorizes any entity licensed under MAUCRSA to cultivate, manufacture, distribute, or sell products containing industrial hemp or derivatives from industrial hemp.

EXISTING LAW:

- 1) Establishes the Department of Public Health (DPH) to among other functions administer and enforce the Sherman Food, Drug, and Cosmetic Law (Sherman Law) which among other provisions, regulates food and food additives.
- 2) Establishes the Department of Food and Agriculture to among other functions administer and enforce laws governing the growing, cultivating, and distributing of industrial hemp.
- 3) Defines in the Sherman Law:
 - a) “Food” as any article or component of an article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.
 - b) “Cosmetic” as any article, or its components (excluding soap), intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to, the human body, or any part of the human body, for cleansing, beautifying, promoting attractiveness, or altering the appearance.
- 4) States that any food is adulterated if it contains any poisonous or deleterious substance that may render it injurious to health of man or any other animal that may consume it.

- 5) Defines “Industrial hemp” as a fiber or oilseed crop, or both, that is limited to types of the plant *Cannabis sativa L.*, having no more than three-tenths of 1% THC.
- 6) Excludes, under MAUCRSA, industrial hemp from the definition of “Cannabis.”

- 7) Regulates, under Sherman Law, the packaging and labeling to contain accurate declaration of contents in food, beverages, and cosmetic products.

- 8) Requires cannabis products, including food containing cannabinoids, to include warning labels for children, pregnant and breastfeeding women.

- 9) Defines in federal law "industrial hemp" as the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a THC concentration of not more than 0.3% on a dry weight basis.

- 10) Establishes the federal Controlled Substances Act (CSA) which regulates the manufacture, importation, possession, use, and distribution of controlled substances such as hallucinogens, narcotics, depressants, and stimulants. Categorizes drugs into five schedules based on their potential for abuse, status in international treaties, and any medical benefits they may provide. Specifies that Schedule I drugs, including marijuana, are considered the most harmful and have no medical benefits and Schedule V substances are the least restricted.

- 11) Prohibits under federal law the introduction of Cannabidiol (CBD) to products unless approved by the Food and Drug Administration (FDA).

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

COMMENTS:

- 1) **PURPOSE OF THIS BILL.** According to the author, the use of industrial hemp as the source of CBD is still prohibited and this bill clarifies that food, drinks, and cosmetics that contain hemp-derived CBD are legal for sale in California. The author states that many people have been purchasing hemp-derived CBD products at their local natural food shops, fitness centers, and health stores for some time. Additionally, seniors are a significant portion of the people choosing to use hemp CBD. The author concludes that for many reasons, consumers want legal access to these products and this bill is an opportunity to make it easier for citizens to access these non-intoxicating, alternative products.

- 2) **BACKGROUND.** Industrial hemp is a distinct variety of the plant species *Cannabis Sativa L* (*Cannabis*). In California, this plant is considered an agricultural plant and has historically been used for products such as paper, textiles, cosmetics, and fabric. Industrial hemp is often mistaken for marijuana. However, the two plants chemically are distinctly different. Both industrial hemp and marijuana contain the two cannabinoids THC and CBD. Cannabinoids can be ingested, inhaled, or sprayed under the tongue. THC is a psychoactive compound that is responsible for the ‘high’ associated with marijuana. By scientific and legal definition, industrial hemp contains less than 0.3% THC which is considered trace amounts compared to marijuana (15-40% THC) rendering CBD as a non-psychoactive and non-intoxicating substance. The food, beverage, and

cosmetic products containing industrial hemp derived CBD are primarily sold at small, independently owned natural product retailers and in online markets.

- a) **State and Federal Law.** In California, industrial hemp is regulated as an agricultural product and the growing and cultivation of hemp is overseen and regulated by the California Department of Food and Agriculture. The medicinal uses of industrial hemp cannabinoids, including its use in food, beverages and cosmetics, in particular, however, is still a grey area in California law.

The U.S. Agriculture Improvement Act of 2018 (known as the Farm Bill) federally legalized the growing, cultivating, and the transporting of industrial hemp between states. But the Farm Bill resulted in CBD containing products that have been approved by the FDA to be removed from the list of Schedule I substances under the CSA and reclassified as a Schedule V drug. This policy was enacted because of the findings that it does not contain any psychoactive or addictive properties and has a very low abuse potential. This separates industrial hemp from marijuana specific cannabis products, which remains a Schedule I drug on the federal level. The Farm Bill also classifies CBD as a food product. Importantly, the Farm Bill also requires states to devise their own sale restrictions and regulations, of which the U.S. Department of Agriculture is responsible for overseeing.

- b) **DPH Oversight.** The DPH Food and Drug Branch (DPH-FDB) published frequently asked questions (FAQs) in July 2018 stating “unless 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.”

According to DPH, industrial hemp derivatives, excluding hemp seed oil, hemp seed protein, and hull hemp seed are deemed unapproved food additives and unapproved dietary supplements. Thus, the DPH-FDB is currently authorized to take enforcement action against food and beverages that contain industrial hemp derivatives, namely CBD. In response to about 50 complaints concerning hemp derived CBD foods and beverages, DPH-FDB has issued 13 notices of violations, seven voluntary condemnation and destruction regulatory letters, and nine embargoes regarding prohibited industrial hemp derived CBD products since releasing the published FAQs regarding CBD in these products. Because the Sherman Law does not currently recognize industrial hemp cannabinoids as a non-poisonous ingredient in food, beverages, and cosmetics, the enforcement actions against these products appear legal.

- c) **Health Considerations for Hemp CBD and Consumers.** According to a review article published in the journal *Cannabis and Cannabinoid Research* in 2017 entitled “An Updated on Safety and Side Effects of Cannabidiol: A Review of Clinical Data and Relevant Animal Studies,” CBD has been shown to be effective at promoting overall health wellness by relieving anxiety, mild psychosis, and some neurological disorders including but not limited to epilepsy, multiple sclerosis, and reducing inflammation in the brain that can be associated with neurodegenerative diseases. This evidence is the

culmination of research in animal models of disease as well as in human patients. The most comprehensively studied medical use for CBD has been in treating children and adults with epilepsy. Currently, the only FDA approved therapeutic drug containing CBD is Epidolex, which is prescribed for patients 2 years of age and older with two rare forms of epilepsy (Dravet syndrome and Lennox-Gastaut syndrome). According to the World Health Organization (WHO) Expert Committee on Drug Dependence (ECDD), CBD is well tolerated, has a good safety profile, and any adverse side effects are rare and likely due to interactions with other medications a patient may be on. Additionally, WHO has published no findings that industrial hemp-derived CBD leads to abuse or substance dependence. Thus, the WHO does not foresee any public health problems with industrial hemp CBD when consumed. It is important to note, however, that the evidence for efficacy of CBD to treat conditions outside of epilepsy, for both adults and children, is lacking. Among the epilepsy research, however, the safety profile of CBD for both adults and children has been consistently good. To date, there have been no serious adverse events or fatalities associated with consumption or use of industrial hemp derived cannabinoids.

Another consideration is there currently is no approved dosage information for hemp-derived CBD products. Dosages that have been assessed in scientific studies for safety and efficacy range from 100-800 mg/day in a variety of preparations including capsule and oil solutions, according to the WHO ECDD report. Epidolex is prescribed at a dosage of up to 20 mg/kg/day, which is notably higher than the amount of CBD included in consumer products (~5-10 mg per serving or application on average).

- 3) **SUPPORT.** According to the Consortium Management Group (CMG), the FAQs published by DPH last spring has nearly frozen the hemp CBD market in California. CMG states that “California, having already charted its own course on cannabis, has the opportunity again to get ahead of the federal government and craft its own law on hemp products.”
 - 4) **OPPOSITION.** The American College of Obstetricians and Gynecologist (ACOG) opposes this bill unless there is an amendment adopted to warn consumers of the risk of consuming CBD for women who are pregnant, considering pregnancy or breastfeeding. ACOG recommends that women who are pregnant or contemplating pregnancy should be discouraged from using cannabis, including CBD. ACOG also states that studies have shown that cannabis use during pregnancy may result in lower birth weight or other undesirable outcomes. The author has agreed to amend the bill to add this warning on the label.
- 5) **COMMITTEE AMENDMENTS.**
- a) The Committee suggested and the author has agreed to amend this bill to delete on page 3 lines 9-11: “(c) A food or beverage containing industrial hemp or one or more derivatives thereof is safe for human consumption.”
 - b) Additionally, to protect children from inadvertent or accidental ingestion of products that contain cannabinoids, the Committee also suggested and the author has agreed to amend this bill to include the following in the label: “KEEP OUT OF REACH OF CHILDREN.”
- 6) **URGENCY AMENDMENTS.** The author wishes to amend this bill to add an urgency clause. According to the author, the urgency is necessary to protect the expanding industry relating to industrial hemp and derivatives of hemp in California and that this will reduce

inconsistency in implementation of state and federal law.

7) PREVIOUS LEGISLATION.

- a) SB 566 (Leno) Chapter 398, Statutes of 2013, allows hemp to be grown in California, upon federal approval, by defining “industrial hemp” to be excluded from the definition of “marijuana”, a Schedule I controlled substance.
- b) SB 94 (Committee on Budget and Fiscal Review) Chapter 27, Statutes of 2017, established the MAUCRSA which provides comprehensive control and regulation over cannabis.

REGISTERED SUPPORT / OPPOSITION:

Support

California Grocers Association
Consortium Management Group
Townsend Public Affairs, Inc.
U.S. Hemp Roundtable

Opposition

None on file.

Analysis Prepared by: Marissa Kraynak / HEALTH / (916) 319-2097