



GARRETT O. GRAFF, ESQ., ASSOCIATE ATTORNEY  
303-674-7000 PHONE

# Memo

**From:** Robert Hoban, Garrett Graff  
**Date:** August 23, 2016  
**Re:** CDPHE Position Regarding Hemp Extracts as an Adulterated Substance in Foods

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This memorandum is a review and analysis of applicable legal aspects of the Colorado Department of Public Health and Environment's ("CDPHE") recent position which sets forth that the CDPHE considers cannabidiol ("CBD") to be an adulterated substance, which prohibits its inclusion in foods.

**Question:**

Are naturally occurring derivatives of industrial hemp, including extracts containing cannabinoids such as cannabidiol ("CBD"), even if from the flowering portions of the *Cannabis sativa L.* plant, appropriately considered "poisonous and deleterious substances" under CDPHE rules and applicable Colorado law?

**Short Answer:**

No, the treatment of naturally occurring hemp derivatives, as "poisonous and deleterious substances" is inappropriate, regardless of which portion of the *Cannabis* plant such derivatives are derived from, given the entire Cannabis plant is lawful in the State of Colorado if cultivated to contain less than 0.3% tetrahydrocannabinol ("THC"), the psychoactive cannabinoid.

Specifically, CBD and other hemp complexes and cannabinoids are naturally occurring in the *Cannabis* plant; further, CBD is a non-psychoactive cannabinoid, with no established basis to consider CBD, or the hemp complexes or cannabinoids therein, either "poisonous or deleterious substances" or "unsafe." Scientifically, there is no conclusive evidence indicating any substantive reason for which CBD should be deemed a "poisonous or deleterious substance" or "unsafe." Notably, there is also no structural or genetic distinction between CBD derived from the non-viable seeds, or other portions, of the *Cannabis* plant; thus, logically, if CBD from non-viable seeds is admittedly deemed safe for inclusion in foods, then so should CBD from other portions of the plant.

Importantly, other states such as Oregon and Washington corroborate this finding that hemp and hemp derivatives should not be treated as "adulterants." Further, the Colorado state legislature's specific restriction upon THC in its definition of industrial hemp is indicative that if the Colorado state legislature had intended for any other component, other than THC, to be restricted in any way, such as CBD, the

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**DENVER OFFICE**  
730 17TH STREET • SUITE 420 • DENVER, CO 80202  
303.674.7000 PHONE • 303.382.4685 FAX



GARRETT O. GRAFF, ESQ., ASSOCIATE ATTORNEY  
303-674-7000 PHONE

Colorado state legislature would have specifically provided for it. Correspondingly, existing Ninth Circuit case law paves the way for the import, manufacture and distribution of products derived from the *Cannabis sativa L.* plant and the naturally occurring components thereof. *See Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012 (9th Cir. 2004); *Hemp Indus. Ass'n v. DEA*, 333 F.3d 1082 (9th Cir. 2003).

Resultantly, as found in Oregon and other states, it is inappropriate to consider CBD or other naturally occurring components of industrial hemp to be a “poisonous or deleterious substances” or “unsafe” under Colorado law for purposes of inclusion in food products.

### **Factual Background:**

For years, product manufacturers and importers have either imported and/or manufactured products which contain derivatives (oils, powders and similar) from the *Cannabis sativa L.* plant, generally from the stalks, fibers, hurd and non-viable seeds of the plant. Such products are readily available in large natural grocery and wholesale retailers, such as Whole Foods, Costco and many others.

However, in recent years, manufacturing practices have extended to other parts of the plant as Colorado law provides for the cultivation of industrial hemp, in addition to the processing, manufacturing of products which contains derivatives of such hemp plants. *See* C.R.S. §§ 35-61-108(2); *see also* Colorado Constitution, Article XVIII, Section 16.

Recently, the Colorado Department of Public Health and Environment (“CDPHE”) has taken the position that cannabidiol (“CBD”), one of over eighty naturally occurring cannabinoids found in the *Cannabis sativa L.* plant, is a “poisonous and deleterious substance” which is “unsafe for human consumption,” and thus, unfit for incorporation into “food” products, when derived from the whole *Cannabis* plant. Despite this position towards CBD extracted from all other parts of the plant, the CDPHE’s appears not to disrupt the manufacturing of products from hemp seed and specific other parts of the plant.

Now, the question is presented as to whether derivatives of hemp, including CBD, regardless of what portion of the plant such derivatives come from, are “poisonous and deleterious substances” and/or “unsafe.”

### **Long Answer:**

#### Legal Standard

Colorado law defines “industrial hemp” as the “plant of the genus cannabis and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration that does not exceed three-tenths percent on a dry weight basis.” *See* C.R.S. § 35-61-101(7).

CDPHE rules and regulations set forth “adulterated” means as stated in C.R.S. § 25-5-401 *et seq.* *See* 6 CCR 1010-2(1-202)(A)(2). A “food” is a “raw, cooked, or processed edible substance, ice, beverage, or



GARRETT O. GRAFF, ESQ., ASSOCIATE ATTORNEY  
303-674-7000 PHONE

ingredient used or intended for use or for sale in whole or in part for human consumption. *See 6 CCR 1010-2(1-202)(A)(41).*<sup>1</sup> C.R.S. § 25-5-410 sets forth, in relevant part, a food is deemed “adulterated”:

*(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but, in case the substance is not an added substance, such food shall not be considered adulterated under this paragraph (a) if the quantity of such substance in such food does not ordinarily render it injurious to health;*

*(b) (I) If it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 25-5-413; except that a pesticide chemical in or on a raw agricultural commodity, a food additive, or a color additive shall not be deemed a poisonous or deleterious substance within the meaning of this paragraph (b);*

*(II) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 25-5-413 (1); but, if a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under section 25-5-413 (2) and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food, notwithstanding the provisions of section 25-5-413 (1) and this subparagraph (II), shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or*

*(III) If it is, or it bears or contains any food additive which is, unsafe within the meaning of section 25-5-413 (1);*

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*See. C.R.S. § 25-5-410.*

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<sup>1</sup> Note the distinction between this definition of “food” with that of a “drug,” pursuant to C.R.S. § 25-5-402(9), which includes articles recognized in a pharmacopoeia, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals, or other articles (other than food) intended to affect the structure or any function of the body of man or other animals. For purposes of this memorandum, we discuss only the issues as they relate to “food.”



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C.R.S. § 25-5-403 illegalizes, in relevant part: (a) the manufacture, sale, delivery or distribution of any food, drug or cosmetic that is adulterated or misbranded; (b) the adulteration or misbranding of the same; and, the receipt in commerce of, and/or payment or proffered payment for, any food, drug or cosmetic that is adulterated or misbranded. *See generally* C.R.S. § 25-5-403. Such offenses are potentially punishable with fines and/or imprisonment. *See* C.R.S. § 25-5-405(1). However, if a recipient of an adulterated product also receives a guaranty from the distributor that the product is not adulterated, the recipient shall not be subject to the penalties of this section. *See* C.R.S. § 25-5-405(1).

Importantly, C.R.S. § 25-5-413 provides the CDPHE the discretion with which to allow the inclusion of poisonous or deleterious substances, food additives and more into foods upon limitations and restrictions within certain ranges prescribed by the CDPHE. *See* C.R.S. § 25-5-413(1). If not in accordance with such limitations proscribed by the CDPHE, the substance shall be deemed “unsafe.” *Id.* Further, the CDPHE’s discretion includes, but also extends beyond, the regulations set forth in the Federal Food, Drug and Cosmetic Act (“FFDCA”), allowing the CDPHE to deviate from the guidance of the FFDCA and/or the Federal Drug Administration (“FDA”). *See* C.R.S. § 25-5-413(2).

#### Discussion

The CDPHE’s position regarding CBD appears to hone in on ambiguous preclusions of “poisonous or deleterious substance” and “unsafe”, as set forth in C.R.S. § 25-5-410(a-b) as it pertains to whole plant derivatives. Here, there is no apparent definition of “poisonous or deleterious substance,” impliedly leaving the CDPHE discretion to determine what substances are or are not “injurious to the public health” and/or are “unsafe.” Arguably, by default, in the absence of affirmative CDPHE approval, all additives to foods are initially deemed “unsafe” for purposes of inclusion in food products. *See* C.R.S. § 25-5-413(1).

Applied instantly, there is no affirmative evidence set forth by the Colorado legislature or any other applicable authority which indicates CBD is scientifically unsafe for consumption by humans. To the contrary, the Colorado legislature specifically noted elevated levels of THC are unfit as within the definition of “industrial hemp,” and could have acted similarly with respect to CBD, if desired, but the legislature opted not to. *See* C.R.S. § 35-61-101(7).

Additionally, CBD is inherently lawful as a non-psychoactive and naturally occurring derivative of the *Cannabis* plant, as set forth by the Ninth Circuit previously, which found naturally occurring substances within the *Cannabis* plant are not expressly scheduled as controlled substances. *See Hemp Indus. Ass’n v. DEA*, 357 F.3d 1012 (9th Cir. 2004); *Hemp Indus. Ass’n v. DEA*, 333 F.3d 1082 (9th Cir. 2003). There, the Court concluded: “[a]s in the case of poppy seeds commonly consumed on bagels and expressly exempted from the CSA, that come from a non-drug variety of, but the same species as, the opium poppy,” naturally occurring and non-psychoactive derivatives of the industrial hemp plant are not necessarily a controlled substance as defined by the CSA. *See* 357 F.2d at 1017. The Court further found that “Congress knew what it was doing and its intent to exclude non-psychoactive hemp from regulation is entirely clear.” *Id.* at 1018. Thus, to the extent the CDPHE relies upon the analysis that CBD is a controlled substance – as the Drug Enforcement



GARRETT O. GRAFF, ESQ., ASSOCIATE ATTORNEY  
303-674-7000 PHONE

Administration would suggest – in order to render CBD “unsafe” for purposes of inclusion in food products, such reliance is perhaps misplaced.

Remarkably, there is also no evidence to suggest any distinction related to the safety of such derivatives when such derivatives are derived from strictly the stalks and the seeds of the plant versus a whole plant extract. Despite this absence of distinction, it appears the CDPHE’s position relates to only whole plant extracts including CBD, but not those derivatives when strictly extracted from the stalks and seeds. Similar to the analysis of whether CBD is controlled substance above, it appears this distinction in the CDPHE’s position is perhaps based upon a misapplied distinction between the various sources of industrial hemp derivatives.

As a result of the above analysis, it appears there is no affirmative evidence upon which the CDPHE relies in its determination that CBD is “unsafe” and should not be incorporated into food products. Thus, it appears the CDPHE’s determination at issue here is arguably based upon a default provision for new food additives, rather than affirmative evidence that CBD is “unsafe,” leaving many industry actors and governmental and law enforcement officials seeking clarity and certainty on this issue given the discussion contained herein regarding the safe nature of CBD.

The simple answer is the CDPHE possesses the authority, upon its own accord whether or not in accordance with the FFDCA, with which to adopt and amend regulations which authorize the inclusion of CBD into food products. *See C.R.S. § 25-5-413(2)*. By utilizing its authority under this provision, CDPHE possesses the ability to provide the clarity and certainty sought by both industry actors and government and law enforcement officials within the State of Colorado, as it pertains to the inclusion of CBD into food products sold within Colorado. In light of the absence of affirmative evidence to the contrary, but with the Colorado legislature’s election to not expressly address CBD when the legislature could do so, in addition to the Ninth Circuit’s findings related to naturally occurring and non-psychoactive substances contained within industrial hemp, it appears appropriate to find CBD to be “safe” for inclusion in food products. Resultantly, it is respectfully requested the CDPHE affirmatively utilize such authority.

In support of this position for the inclusion of CBD in food products, regulatory agencies in other states recognize the safety of the inclusion of industrial hemp derivatives in food products. *See Oregon HB 4060-A, Sec. 4(2); see also Washington Department of Agriculture, Industrial Hemp Frequently Asked Questions*, website content available here: <http://agr.wa.gov/aginwa/i502/hempfaq.aspx>. Specifically, Oregon law provides its state regulatory agencies “may not consider industrial hemp or industrial hemp commodities or products to be an adulterant.” *See Oregon HB 4060-A, Sec. 4(2)*.

Further, to demonstrate the inappropriateness of the CDPHE’s designation of CBD as “unsafe”, there exist organizations such as the Hemp Food Association, which promulgate regulations, standards, guidance and education regarding the manufacturing and production of hemp food products. Such regulations, standards and guidance underlies the basis which the CDPHE and other similar organization can rely upon in comfortably providing for the inclusion of CBD in food products.