

CDPHE Summary – August 24, 2016 - MEETING

On Wednesday, August 24th Bob Hoban (Hoban & Feola) and Samantha Walsh (National Hemp Association) participated in a meeting with the Colorado Department of Public Health and the Environment (CDPHE) at its headquarters in Denver. This meeting was a scheduled follow up to their July 19th meeting with the Colorado Department of Agriculture (CDA), the CDPHE, and the Governor's Office.

The meeting on July 19th specifically addressed the CDPHE's recent policy position regarding Colorado-produced food and products containing hemp (see prior meeting summary below). The August 25th meeting was a prescheduled follow up to discuss the perceived status of hemp extracts and hemp food products as "adulterants" and to carve a path forward.

At the August 25th meeting, Hoban and Walsh provided the CDPHE with a legal memorandum (attached) concerning the "adulterant" issue, in which it was determined that 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.

The CDPHE expressed its concerns regarding the FDA's positions, including but not limited to the recent FDA Q&A update (found here: <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm>), which states, in pertinent, that cannabinoids-rich hemp extracts cannot be used in food products. And the issue of hemp extract (from other than the nonviable seeds of a hemp plant) as an adulterant was discussed at length. It was noted by the CDPHE that its internal investigation into the FDA's enforcement practices on this issue did not yield any evidence that the FDA had been pursuing the "adulterant" issue, but rather had been focused on claims regarding dietary supplements. It was noted that the FDA had been exercising restraint and discretion in its enforcement on the issue of food adulterants and hemp.

Simply put, the CDPHE seeks clarity. And given the fact that it works closely with the DEA, is in part funded by the FDA, and is statutorily required to follow the FDA's lead in a variety of matters, clarity is needed in this scenario. Thus, a variety of legislative solutions were discussed, including but not limited to the policies in place in Oregon and the State of Washington (see attached H&F Memorandum).

Hoban and Walsh agreed to work together, along with other Colorado-based industrial hemp groups including but not limited to Grow Hemp Colorado, to craft a legislative solution on this matter which would provide the industry with guidance and clarity to allow the production of cannabinoid-rich hemp-based foods in Colorado. CDPHE is very interested in reviewing this proposal.

The meeting can be characterized generally as very promising, and the attendees exhibited a profound spirit of cooperation and productivity.

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July 19th Summary (from Hoban & Feola Facebook Page):

As most of you know, current regulations allow for industrial hemp seed with .3% THC content, or lower, and related products are acceptable to use in production. What many of you are wondering, and we are trying to get an answer to, is whether oil from other hemp plant parts or micro-greens can be used as well. The CDA and CDPHE are working with federal agencies to understand the status of hemp extracts from non-seed parts of the plant and whether or not that fits under the definition of "food." Other definitions they are trying to clarify are "adulterant" and "deleterious."

It is my understanding that the Federal Department of Agriculture (FDA) considers CBD and other cannabinoids to be "adulterants" under the Controlled Substances Act (CSA). Most in our industry feel that categorizing CBD under the CSA is a mistake and misunderstanding of the law as previously decided by the 9th Circuit District Court of the United States. Although Colorado has exempted itself from the CSA, we are seeking for clarification from the federal government as to Colorado's lack of regulatory enforcement as to CBD, which we believe follows the federal government's lack of regulation under the "adulterant" language.

It is the position of many in our industry that as long as hemp food companies continue to comply with general food safety guidelines, get a GMP, labeling regs they are operating lawfully under Colorado's regulatory guidelines. Until there is a legislative and/or statutory fix, we are seeking a position of discretionary enforcement from CDPHE.

Representatives from the National Hemp Association (NHA) were also present at this meeting. The NHA is continuing its work on industry food standards, manufacturing and processing standards, cultivation and agricultural standards..etc as CDPHE acknowledged that would be most helpful and beneficial to them as well as the industry.