

Industrial Hemp Advisory Board (IHAB) Meeting
California Department of Food and Agriculture (CDFA)

1220 N Street, Auditorium
Sacramento, CA 95814

Wednesday, July 25, 2018
10:00 AM – 12:00 PM

Board Members

Van Butsic
Joshua Chase
Rick Gurrola
Allison Justice
Matt McClain
Valerie Mellano (Absent)
Tom Pires
David Robinson (Absent)
John Roulac (Absent)
Lawrence Serbin
Richard Soria

CDFA & Guests

Chris Boucher
Colin Coltrane
Paul Correa
Thomas McDonagh
Justin Eve
James Glang
Ian Grymes
Enquan He
John Heaton
Chris Hewes
David Holey
Rick Jahnke
Jean Johnson
Janice Jurado
Joshua Kress
Pat Leathers
Xiaozhou Mai

Alicia Madsen
Lora Madsen
Yashmi Malik
Alex Mkandawire
Lauren Murphy
Aaron Olague
Michelle Phillips
Wayne Richman
Taylor Roschen
Robin Sanchez
Jennie Tedlos
Cathy Vue
David Wales
Brian Webster
Brian Wermund
Luke Wilson
Joe Worrell
Marie Ziegel

1. Roll Call and Opening Remarks

Meeting called to order at 10:04 AM by Lawrence Serbin, Board Chair. Board members and Program staff provided self-introductions. Serbin welcomed new Board Member Joshua Chase.

Serbin briefly reviewed the meeting's agenda. Michelle Phillips, Senior Environmental Scientist of the CDFA Nursery, Seed, and Cotton Program, reviewed general housekeeping information. Phillips also reminded board members of the procedures for making travel arrangements and filing travel expense claims. Phillips noted that Chase signed an Oath of Office form.

2. Review of Minutes from April 24, 2018 and May 30, 2018 Board Meetings

The draft minutes from the April 24, 2018 Board Meeting were presented to the Board. No changes were requested.

Board Motion #1: Lawrence Serbin moved to accept the minutes for the April 24, 2018 Board Meeting as presented. Richard Soria seconded the motion.

There were no further discussions or comments.

The Board voted on Motion #1 as follows:

Yes: Van Butsic, Joshua Chase, Rick Gurrola, Allison Justice, Matt McClain, Tom Pires, Lawrence Serbin, and Richard Soria
No: None
Abstained: None
Absent: Valerie Mellano, David Robinson, John Roulac

Motion carried.

The draft minutes from May 30, 2018 Board Meeting were presented to the Board. No changes were suggested.

Board Motion #2: Lawrence Serbin moved to accept the minutes for the May 30, 2018 Board Meeting as presented. Richard Soria seconded the motion.

There were no further discussions or comments.

The Board voted on Motion #2 as follows:

Yes: Van Butsic, Joshua Chase, Rick Gurrola, Allison Justice, Matt McClain, Tom Pires, Lawrence Serbin, and Richard Soria
No: None
Abstained: None
Absent: Valerie Mellano, David Robinson, John Roulac

Motion carried.

There were no public comments regarding this item.

3. Brief Update on Proposed Federal and State Legislation for Industrial Hemp

Jean Johnson, Vote Hemp, provided an update on the proposed federal and state legislation for industrial hemp.

Johnson explained that the federal Hemp Farming Act (S.2667) had secured 29 cosponsors in the U.S. Senate before its full inclusion into the federal 2018 Farm Bill in June 2018. Johnson noted that Senator Grassley's proposed amendment to remove language legalizing CBD was unsuccessful. In late June, the Senate passed the 2018 Farm Bill that included S.2667's language without any modifications by a vote of 87 to 11.

Johnson stated a conference committee was formed with representatives from the U.S. Senate and U.S. House of Representatives to reconcile the Farm Bill versions from each chamber. Johnson noted the Farm Bill originating from the U.S. House of Representatives did not include language from S.2667 and was likely done so to give precedence to U.S. Senate's version.

Johnson explained that U.S. Representative James Comer was included in the conference committee to reconcile the two Farm Bill versions. Johnson noted that Comer was the original author of the U.S. House of Representatives version of federal Hemp Farming Act (H.R. 5485) and he legalized industrial hemp in Kentucky during his tenure as the Agriculture Commissioner of Kentucky.

Johnson explained that the proposed state legislation, Senate Bill 1409, had unanimously passed through various State Senate committees including Public Safety, Agriculture, and

Appropriations. Johnson noted that SB 1409 moved to State Assembly after receiving a unanimous vote in the State Senate in late May 2018. SB 1409 was unanimously passed in the State Assembly's Committee on Public Safety and Committee on Agriculture in June 2018. Johnson noted that SB 1409 was to be heard by the State Assembly's Committee on Appropriations in August 2018. SB 1409 had since received new cosponsors and been amended to include language for counties to retain fees. She expected SB 1409 to be on the Governor's desk in September 2018.

Johnson noted that Vote Hemp submitted a letter to the California Department of Public Health (CDPH) to seek an open dialogue and explain the inconsistencies in the Department's FAQ document regarding CBD in food products to the state definition of industrial hemp.

Serbin asked if the federal Farm Bill would impact CDPH's stance on CBD in food products. Johnson replied that she believed the federal Farm Bill would change CDPH's stance on CBD in food products.

Serbin asked about the expected timeframe for the passage of the federal Farm Bill and the SB 1409. Johnson replied that she could not provide a timeline but was optimistic of the passage of both the federal Farm Bill and SB 1409.

Wayne Richman, California Hemp Association, noted the Federal Farm Bill included a provision to restrict individuals with a drug-related felony from cultivating industrial hemp.

Richman noted that SB 1409 included a provision to restrict on hemp cultivation due to pollen drift concerns with relation to licensed cannabis plantings. He noted that it was his opinion that the provision turned SB 1409 into a cannabis bill and recommended it to be removed.

Richman requested that the Board to acknowledge CHA as the successor organization to HIA for the purposes of allowing membership to the Board, as outlined in Section 81001(a)(5).

Richman noted that CHA was working with the sponsors of SB 1409, and hoped to support the final version of the bill.

Serbin asked about status of the provision that allowed restrictions to industrial hemp cultivation due pollen drift concerns. Johnson responded that the provision remained unchanged in SB 1409 and was proposed to protect industrial hemp from arbitrary bans by cities and counties.

4. Review of Draft Guidelines for Sampling and Testing for THC Content

Joshua Kress presented draft guidelines on sampling and testing for THC based on the recommendations presented by the Sampling and Testing Task Force at the April 24, 2018 meeting. Kress noted that comments on the draft guidelines included items that have yet to be determined by the task force and items that conflicted with current law. Kress stated that the Department determined the sampling and testing guidelines will require the Program to undergo the rulemaking process.

Kress noted the following items on the draft guidelines for sampling for THC content:

- Notification of the harvest date was not addressed by the task force.
- The sampler was not identified by the task force.
- The recommendation to conduct the sampling no more than 30 days prior to harvesting conflicted with current law.
- The recommendation of random collection of samples must be further defined or specified.

- The recommendation to sample specific portions of the plant conflicted with current law.
- The recommendation of cool storage of the samples must be further defined or specified.
- Delivery timeframe was not addressed by the task force.
- Confirmation of harvest was not addressed by the task force.

Serbin asked if the recommended sampling and testing guidelines would be impacted by the proposed changes in SB 1409. Kress replied that recommendations on the sampling timeframe and plant parts for sampling conflicted with existing law but may not if SB 1409 passed.

Serbin asked about the timeframe for the sampling and testing guidelines to be in place. Kress replied that the Department would initiate a rulemaking package for the sampling and testing guidelines once SB 1409 is signed. Kress noted that he was uncertain about the timeline but stressed the need to be proactive. He explained the difficulties of having farmers planting prior to guidelines being developed and in place.

Chase asked about the expected timeline after the Board provided the recommendations on the guidelines for sampling and testing for THC content. Kress explained that any recommended guidelines would proceed through the regular rulemaking process.

Soria asked if the Board should hold off on making any recommendations on sampling and testing guidelines until the outcome of SB 1409 is known. Kress replied that the Board could wait but recommended the discussions continue to assist in the regulation development.

Kress noted the following items on the draft guidelines for testing for THC content:

- Moisture content of samples was not addressed by the task force.
- The recommendation for homogenous powder-like consistency must be further defined or specified.
- Cross-contamination prevention, identity maintenance of the samples, size of the material to be tested, storage and disposal were not addressed by the task force. Kress noted that these items may fall under the laboratories' standard operating procedures, but were noted for the Board's consideration.
- The recommendation to allow harvesting prior to receiving test results conflicted with current law. Kress explained that this recommendation would require adequate authority in the future to allow marketing, comingling, and submitting secondary samples for resampling.

Allison Justice noted that some of the items listed required additional research. Justice suggested for a task force to further investigate and provide recommendations.

Serbin asked Rick Gurrola if it would be feasible for the counties to be responsible for sampling. Gurrola replied that a comprehensive scope of work was needed to determine the feasibility for counties to conduct sampling activities. Serbin noted that it could potentially be a significant workload. Gurrola agreed and explained that counties may need to hire additional staff to handle the workload.

Soria reiterated his recommendation from the April 24, 2018 meeting that sampling should be completed by private laboratories to relieve the burden of the counties.

Chase recommended that the Board made recommendations today specifically on sample size to be tested. Chase explained that the regulations can be amended later and establishing a recommendation today would continue the progress made.

Kress explained the task force originally provided the recommendation to use at least five samples of the same variety for composite sample, however, the Department was open to other suggestions. Kress explained that during the previous investigation, the Department found that no state was consistent in defining an adequate sample size.

Kress asked Justice and Soria if they found more information through their investigation. Justice replied she learned that different labs did conducted sampling differently. Justice explained that the sample size for testing cannabis is 2 grams using protocols from ISO and other various entities, but she was not sure if it was consistent with all laboratories.

Kress explained that future changes to established regulations would require the rulemaking process. Kress noted that the rulemaking process would be less complicated than creating an entire regulation, but it would also depend on the change and how controversial it would be. Kress stated that regardless of the complexity, it would be additional work for the Department.

Serbin asked Justice and Soria if they felt they needed more time to review and address the items presented by Kress. Justice replied that she felt more comfortable investigating the items further in a task force setting.

Chase asked about the process for the Board to make a recommendation. Kress explained that it must be done during a board meeting and allow for public commenting prior to voting. Kress explained that the board meetings required a minimum 10-day notice. Kress clarified that task forces assigned to two individuals by the board chair would not be subject to the public notice rules of the Bagley-Keene Open Meeting Act.

Richman asked how the federal law would impact the testing requirements in state law. Kress replied that a legislative change would be required to change testing requirements at the state level.

Justin Eve, 7 Generations, stated that he was aware of a recommended moisture content of 12% or less for mold. He also noted that Nevada sampled every five acres. He believed that the use of certified seed should not require testing. He stated that it should be the farmer's discretion to use certified laboratories for testing. Eve recommended further discussion be held with laboratory representatives since California did not have a standardized testing methodology. Eve expressed concerns regarding not allowing growers to harvest prior to test results.

Thomas McDonagh recommended that testing be completed within 24 hours.

Carson Pettit, Broken Box Ranch, asked about post-harvest testing and expressed issues with farmers delivering the samples to the laboratory.

Serbin acknowledged the complexities of the concerns brought up and recommended further investigation by the task force. Serbin asked Justice and Soria to investigate the issues identified on the draft guidelines.

Serbin requested two sets of recommendations from the task force: one based on current law, and one based on pending legislation.

5. Discussion of Adoption of Methodology and Procedures to Amend List of Approved Seed Cultivars (Per FAC Section 81002)

McClain explained that the current approved seed cultivars list was too restrictive and needed to be addressed by the Board. McClain reviewed FAC Section 81002 and noted the majority of approved cultivars were of international origin except for one. McClain also noted possible seed importation issues.

McClain expressed concerns with the lengthy process for seed certification. Alex Mkandawire, CCIA, confirmed that the seed certification progress can be lengthy. McClain also noted that commercial growers' access to certified seed would be further limited due to requirements for a DEA permit and Section 7606 Farm Bill compliance.

McClain reviewed 81002(c) and suggested expanding the list of approved seed cultivars. Mkandawire stated that expansion of the list was one way to address McClain's concerns of limited access to certified seed. Mkandawire introduced the concept of a quality assurance (QA) program that provided a uniform and unbiased control system and marketing tool for crop seed that cannot be verified and sold as certified seed. Mkandawire explained that seeds are referred as germplasm entities or heritage cultivars in a QA program due to their ineligibility for traditional certification. However, seeds in a QA program would be recognized by seed certifying agencies.

Mkandawire reported that AOSCA established a variety review board at the national level in June 2018. Mkandawire noted that efforts were made to simplify the seed certification application and CCIA requested that clones were included as part of the certification process. Mkandawire stated that he now is part of a subcommittee to work on simplifying the seed certification process.

Mkandawire explained that the requirement for certified seeds was not unique to hemp. He noted the requirements for the use of certified seeds for cotton production in the San Joaquin Valley and the California Rice Commission recently required the use of certified seeds.

McClain requested a task force to be formed to further investigate amending the list of approved seed cultivars.

Kress reviewed FAC Section 81002 and noted that the rulemaking process to establish a methodology to amend the list and well as amendments to the list required public commenting and review, but was not subjected the Administrative Procedures Act.

Serbin requested further clarification from McClain on why the Board should consider amending the approved seed cultivars list. McClain explained that the Board should consider amending the list of approved seed cultivars because of the limited resources for seed and the lengthy process for seed certification. McClain explained that the quality assurance program was one way to expand the list of approved seed cultivars.

Mkandawire explained that most states implemented a three-strike rule where varieties are identified as a variety of concern after receiving three test results that exceed the THC limit.

Chase suggested repealing the list as an option to address the concerns of the limited availability of seeds.

Serbin asked about the Board's authority regarding amending the approved seed cultivars list. Kress explained that the Board can make recommendations pertaining to this section, including repealing the list. Kress noted that further investigation would be necessary to see if the approved seed cultivars list can be repealed or it must be repealed and replaced.

Serbin summarized Chase's suggestion to repeal the list and allow the use of any seed. Chase confirmed that he was suggesting allowing open source seed. McClain stated that he did not think Chase's suggestion would be ideal and suggested forming a task force to explore the issue further. McClain explained the QA program would be a good compromise between certified seed and open source seed.

Justice asked how quickly a QA program can be developed and implemented. Mkandawire replied that a QA program would only take a couple months to establish. Mkandawire noted the rice industry already has one in place after approving a QA program last year. Mkandawire stated that California had one of the most exhaustive list of approved seed cultivars. He explained that other states continued to have hemp production despite allowing farmers to grow using 10 or less approved seed cultivars.

McClain asked if the law would still require the use of approved seed cultivars if the list was repealed, therefore restricting cultivation all together since there would be no approved seed cultivars. Kress replied that impact of repealing the list would need to be explored.

Pires expressed concerns regarding the use of varieties that do not produce great results. McClain explained that his intention was to expand the list but through a vetted process like a QA program to decrease the risks for the farmer.

Chase asked if clarification on the repeal language can be provided to the Board. Kress replied that the questions would be asked internally at CDFA and the information can be provided to the task force or the Board.

McClain requested that a task force be formed to further investigate amending the approved seed cultivars list.

Richman thanked Mkandawire for providing another avenue for seed certification and supported the use of a QA program.

Eve asked about the definition of a seed breeder. Kress explained that current law provided a definition for a seed breeder in FAC Section 81000(f). Kress noted that seed breeding activities can also be conducted by an established agricultural research institution (EARI).

Eve asked about the seed certification from AOSCA. Mkandawire explained if a cultivar was approved by another state and/or AOSCA, CCIA included the variety on the approved seed cultivars list for California.

Chris Boucher, Farmtiva, expressed concerns regarding seed importation and asked if EARIs were exempted from using approved seed cultivars. Kress noted that California did not have state specific importation requirements for industrial hemp, and could not comment on federal rules regarding importation. Kress explained that EARIs are exempt from the requirements in FAC Section 81002(a) to use approved seed cultivars.

Boucher asked about seed cultivars approved in other states that are not certified. Mkandawire explained that the list of approved seed cultivars is specifically for certified seed and would not include non-certified seeds. However, non-certified seeds could be vetted and included in a QA program.

McClain asked if a cultivar in the QA program can also be a certified seed. Mkandawire replied that the seed certification program and QA program are two separate programs and a cultivar can only be in one program. Mkandawire explained that cultivars in the QA program can exchange material with other states. He noted that the QA program used the term genetic entities rather than cultivars.

Serbin asked if a cultivar in the QA program could become certified seed in the future. Mkandawire replied no because the QA program catered to varieties that may not otherwise be certified, unless if the cultivar can be described at the certification level as required.

Serbin asked McClain and Chase if they would participate in a task force to further investigate amending the approved seed cultivars list. McClain and Chase agreed. Chase suggested holding a meeting prior to the next board meeting for public input. Kress recommended McClain and Chase to meet and determine how they would like to proceed.

6. Brief Update on CDFA Program Activities

Kress briefly provided a general update on program activities:

- The Program established the Industrial Hemp Advisory Board. Since June 2017, the Program held six meetings and one task force meeting and filled one mid-term vacancy.
- The Program had extensive communication and meetings with other agencies including the UC system, CACASA, commissioners, and local agencies. Kress reported that the Program responded to approximately 30-50 public inquiries each week.
- Carl Pfeiffer visited Colorado in 2017 to learn more about Colorado's industrial hemp program.
- Phillips attended the National Industrial Hemp Regulatory Conference in 2018.
- The Program recently updated the FAQ online.
- The Program conducted analyses on pending legislation.
- The Program provided briefings to the CDFA's executive office.
- The Program required extensive assistance from CDFA's executive and administrative offices, including Legal and Information Technology.
- The Program developed a registration application which was reviewed by the Board in January 2018.

Kress briefly reviewed the status of each board recommendation:

- The Board recommended CDFA provide guidance on the legal status of EARIs in June 2017. The Program posted the guidance on the CDFA website in January 2018.
- The Board recommended CDFA develop regulations related to the interactions between commissioners and EARIs. The Program developed and routed guidelines for internal review. CDFA determined that regulations were required, and the regulations were currently under development.
- The Board recommended CDFA increase the budget to hire a full-time employee in October 2017. The Program hired Phillips in February 2018.
- The Board created a task force in January 2018 to further investigate sampling and testing protocols for THC content. The task force held a meeting in February 2018 and provided recommendations to the Board in April 2018. The Program drafted and presented the guidelines as requested by the Board at this meeting.
- The Board initially recommended a fee structure that required the commissioners to set additional fees beyond \$1,000 to cover the counties' cost. CDFA determined that it did not have adequate statutory authority to implement the recommendation. The Board assigned a task force to determine the county fees in April 2018. The Board recommended CDFA to establish registration fees at \$1,800 for a two-year registration in May 2018. The Program

was working on the rulemaking package as well as developing a memorandum of understanding for county reimbursement.

Serbin asked about the status of the registration fee regulation. Kress replied that the regulations was still under internal review. Kress explained that under the Administrative Procedures Act, the Department must address different areas related to the impacts of the proposed regulations. Kress reported that the Program was finalizing the support documents. Once completed the rulemaking package is completed and reviewed internally, the Office of Administrative Law (OAL) would have one to two weeks for review. The proposed rulemaking would be posted for at least 45 days for public commenting. The Program would be required to respond to each public comment received.

Serbin asked about the public commenting process. Kress explained that the Department was required to develop an Initial Statement of Reasons to support the proposed rulemaking. Once the public commenting period is completed, the Department must include a response to all public comments in the Final Statement of Reasons. The Department must take into consideration all comments and determine if adjustments are necessary. The OAL would ensure the Department followed the Administrative Procedures Act.

Richman ask about the status of the application form template. Kress noted that the application form template was presented to the Board and the Board did not request any additional changes to the form template.

Eve asked about the timeframe of the rulemaking process. Kress explained that the Department still needed to develop and review the regulations internally. He stated that OAL had two weeks to review before posting the proposed regulations for a 45-day commenting period.

Eve asked if there was an expected timeframe for internal development and review. Kress replied that ideally it would be a few more weeks but he did not know when it would be completed. Kress explained that although the Department was actively working on the regulation, the regulation may be delayed due to the Department's workload.

Serbin raised concerns that CDFA's webpage did not fully reflect current federal law. He noted the webpage still stated that hemp was considered a controlled substance and did not take into consideration the 2014 federal Farm Bill and the 2018 Appropriations Act. Kress clarified that the language Serbin was referring to was a disclaimer for the public regarding federal law. Kress recommended interested parties to provide suggested changes to the website, and the Department would review.

Boucher suggested the Program to review an internal directive from Drug Enforcement Administration, dated May 22, 2018. Kress requested that Boucher forwarded the directive to the Program for review.

7. Public Comments

Richman requested the Program to provide future meeting notices three to four week in advance. Richman explained that it would allow more time for the public to make arrangements to attend and participate in the board meetings.

Serbin noted that there were several requests from the public for the Board to recommend an amendment in SB 1409 to include language that designated industrial hemp as an agricultural crop. Serbin requested Brian Webster to clarify to the Board the reasoning behind his request.

Webster explained that at the last board meeting that there was a proposed provision in SB 1409 to allow counties and cities to ban industrial hemp cultivation. Webster expressed concerns that industrial hemp would be continuously subjected to proposals to ban cultivation from local authorities.

Webster recalled that the right to farm agricultural crops was brought up at the May 30, 2018 meeting. Webster also recalled that Kress explained the notion of right to farm did not apply to industrial hemp because was not recognized as an agricultural crop at the meeting and discussion concluded that the designation would need to be included in proposed legislation.

Webster explained the designation was not included in pending legislation. Webster requested that the Board recommend inclusion of a resolution declaring industrial hemp as an agricultural crop to establish the right to farm.

Kress clarified that he stated that he was not familiar with the term the right to farm at the May 30, 2018 meeting. He also clarified that he stated the law did not specifically state that industrial hemp as an agricultural crop but it also did not state that industrial hemp was not an agricultural crop.

Kress explained that, based on the discussion at the May meeting, the Department was currently investigating the term right to farm and the impacts of designating industrial hemp as an agricultural crop.

Serbin asked if any board member was familiar with the term right to farm. Pires replied he was not aware of the term. Gurrola clarified that he was familiar with the term on a local level but noted that he learned of Civil Code Section 3482.5 after the May 30, 2018 meeting. Gurrola explained that the state law protected agricultural operations that were in operation for more than three years from nuisance claims. Gurrola noted that Tehama County also had a local ordinance that protected farming activities from various nuisance claims.

Soria noted that the farm bill legalizes industrial hemp.

Richman noted that SB 94 identified industrial hemp as an agricultural crop. Webster contended that the language in SB 94 did not identify industrial hemp as an agricultural crop but instead only stated that industrial hemp was legal. Webster stated that he did not believe that there would be any harm including the designation in SB 1409.

Thomas McDonagh, stressed the need for clarity to avoid creating more issues.

Serbin stated that he did not foresee any harm for the Board to make a recommendation to include language that designated industrial hemp as an agricultural crop.

Board Motion #3: Serbin moved to recommend that language to designate industrial hemp as an agricultural crop be included in SB 1409. Soria seconded the motion.

Gurrola expressed concerns regarding voting on motion without knowing the full impact of the designation of industrial hemp as an agricultural crop.

Chase asked if a task force was created to review and provide recommendations on SB 1409. Kress explained that the legislation task force presented at the May 30, 2018 meeting. Kress noted that there was a discussion on task force's recommendations, but the Board did not make a formal motion.

Chase asked if those suggestions reached Senator Wilk's office. Kress replied that he believed it did. Serbin discussed the difficulties with SB 1409's language continuously changing. Kress explained that the Board could make recommendations regarding pending legislation. However, the Board did not have authority to advise the Legislature. Kress explained he was not aware of a pathway for the Department to act on the Board's recommendation since the Department's role was to administer and enforce the law, not advise the Legislature.

Serbin retracted the motion and requested CDFA to further investigate of the impacts of the designation of industrial hemp as an agricultural crop.

Serbin invited David Holey, Carbone Green Energy Partners, to address the Board regarding his letter to the Board. Holey proposed that industrial hemp that tested above the THC content limits should be taken to an approved extraction facility to remove the THC material to allow the use of non-THC material for other purposes. Holey recommended implementing a track and trace system to provide oversight of the process. Holey explained that the proposal would mitigate current statutory destruction requirements as well as minimize the risk to farmers by preserving the crop.

Serbin noted that Holey's proposal may require legislative change. Kress agreed with Serbin. Serbin recommended Holey to present his proposal to the members of the Legislature.

An unknown member of the public asked if there were a list of people working on the SB 1409. Kress explained that SB 1409 was introduced by Senator Wilk's office and sponsored by VoteHemp and Ojai Entergetics.

Kress recommended Holey to contact his local legislative members and/or industrial hemp associations such as Hemp Industries Association or California Hemp Association (CHA).

Richman stated that the U.S. Hemp Roundtable and CHA submitted a joint statement to CDPH regarding their advisory on CBD in food products. Richman provided a copy for the Board.

Kress noted that the Board was also provided with a letter form Hoban Law addressed to CHPH regarding their advisory on CBD in food products.

Webster expressed concerns with the productivity of the meeting. Webster compared the progress made for the industrial hemp industry to the cannabis industry in California. Webster noted that hemp was currently be grown in California without registration and local authorities were allowing the cultivation. Webster requested CDFA and the Board to provide timelines for the progress of the development the Program.

Pires reiterated his request for the list of items that needed to be addressed by the Board. Serbin explained the main milestone for the Program was the registration fee. Kress explained the Program was currently working on three regulations: registration fee, sampling and testing guidelines, and interaction between counties and EARIs.

Kress explained that the sampling and testing guidelines needed more work from the Board as discussed earlier during the meeting. Kress noted the other two regulations needed to be developed internally by CDFA and did not need further action by the Board. Kress stated that there was nothing else statutorily required to be addressed through regulations except for amending the approved seed cultivars list.

Kress explained that the Board could provide additional clarification regarding the law. He noted that pending legislation may add additional work for the Board. Kress stated that the Board may need to address approved laboratories if SB 1409 passed. Pires requested the list of pending items to be address by the Board in print.

Soria requested to adjust the start time of future meetings.

8. Next Meeting/Agenda Items

Serbin noted that there may be changes occurring in September due to federal and state legislation. Serbin suggested the Board met at the end of September.

Chase suggested in meeting in two to four weeks to address the sampling and testing guidelines. Kress asked the sampling and testing task force how much time they would need for their investigation. Soria replied that they would need two weeks.

Kress asked if the next meeting will be specific for the laboratory task force. Chase recommended also including the approved seed cultivars list and a status update on the registration fee regulation.

Kress explained CDFA will check the availability of the auditorium in three to four weeks.

The Board tentatively set the next board meeting for the end of August 2018, pending confirmation.

9. Adjournment

Meeting adjourned by Serbin at 1:05 PM.

Respectfully submitted by:

Michelle Phillips
Senior Environmental Scientist (Specialist)
CDFA Nursery, Seed and Cotton Program

DRAFT Industrial Hemp Sampling Guidelines for Testing for THC Content

A. Notification of Harvest Date –

1. Registrants should inform the [SAMPLER TBD] of the following information:
 - i. Harvest date
 - ii. Variety
 - iii. Location
 - iv. Authorized representative
2. Registrants should inform the [SAMPLER TBD] of any changes to the above information no less than 5 days prior to scheduled sampling.

Commented [KJ1]: Sampling entity needs to be determined (i.e., laboratory staff or county inspectors)

B. Sampling Timeframe – Sampling should occur no more than 30 days prior to harvesting.

Samples should be collected prior to any harvest or destruction of plants. The registrant should coordinate with the [SAMPLER TBD] on a date and time for the collection of the samples. Any changes to the harvest date may require additional testing prior to harvest.

Commented [KJ2]: Conflicts with existing statute: FAC § 81006 (f)(1)

C. Site Verification – [SAMPLER TBD] should verify collection site corresponds to registered location using GPS coordinates prior to the collection of samples.

D. Collection of Samples – Samples should be randomly collected by [SAMPLER TBD]. The registrant or an authorized representative should be present during the collection of samples and allow [SAMPLER TBD] access to all industrial hemp plants within the registered land area and all areas and facilities used for cultivation.

Commented [KJ3]: Definition or methodology for random selection should be specified

E. Sample Volume and Composition –

1. A separate composite sample should be taken for each plant variety.
2. A separate composite sample should be taken for the same plant variety grown both indoors and outdoors.
3. A separate composite sample should be taken for each non-contiguous field.
4. Each composite sample should consist of at least five samples from different plants of the same plant variety.
 - i. Samples should include the plant's stem, stalks, flowers, leaves, seeds, and buds (all parts intended to be included in the extraction process).
 - ii. Samples should not be taken from male plants.
 - iii. [SAMPLER TBD] should avoid collecting samples near field edges.
5. Any abnormal plants should be sampled individually.

Commented [KJ4]: Conflicts with existing statute: FAC § 81006 (f)(2)

F. Sample Handling –

1. Samples should be placed in a breathable bag (e.g. brown paper bag) and kept in a cool storage in a manner not conducive to mold.
2. Samples should be sealed in a manner to show evidence of tampering and labeled to show chain of custody. The chain of custody label should be signed by both the registrant or authorized representative and the inspector.
3. Samples should be labeled with identifying information
4. [DELIVERY TIMEFRAME]

Commented [KJ5]: A temperature or temperature range should be specified

Commented [KJ6]: Requirement for timeframe for delivery of sample to laboratory should be specified

G. [CONFIRMATION OF HARVEST]

Commented [KJ7]: Method for confirmation that harvest occurs within 30 days should be specified

DRAFT Industrial Hemp Testing Guidelines for THC Content

- A. **Sample Preparation** – Each composite sample should be dried and milled to a homogenous powder-like consistency. No plant parts should be removed during the sample preparation process.
- B. **Sample Storage** –
- C. **Testing** – Each composite sample should be tested separately for THC content by [APPROVED TESTING ENTITY].
- D. **THC Testing Method** – Samples should be tested for THC content using gas chromatography with a flame ionization detector.
- E. **Sample Retention** – Samples with THC levels less than 0.3% should be retained by the laboratory for 30 days. Samples with THC levels more than 0.3% but less than 1.0% should be retained for 60 days.
- F. **Sample Disposal** –
- G. **Notification of Test Results** – Registrants should be notified of test results within 10 days of sampling.
- H. **Retesting of Harvested Material** – Plantings harvested prior to notification of the test results could retest if registrant kept each variety in properly identified separate lots throughout the drying, milling, and storage process. Co-mingling with other plantings or varieties will result in [ACTION TBD]. Registrants should be able to submit new samples from the harvested material for retesting.

Commented [KJ8]: Should moisture content be addressed further, either here or in sampling guidelines?

Commented [KJ9]: Does particle size need to be further defined?

Commented [KJ10]: Conflicts with existing statute: FAC § 81006 (f)

Commented [KJ11]: Can the harvested crop be marketed/sold prior to receiving test results?

Commented [KJ12]: What action should be taken if harvested crops are co-mingled prior to receiving test results?

Commented [KJ13]: What is the process and what are the requirements for this?

[Note: In addition to the above, are specific requirements necessary for other laboratory SOP's regarding: cross-contamination, identification of samples, sample size, sample storage, sample disposal, etc.?)

State of California

FOOD AND AGRICULTURAL CODE

Section 81002

81002. (a) Except when grown by an established agricultural research institution or by a registered seed breeder developing a new California seed cultivar, industrial hemp shall only be grown if it is on the list of approved seed cultivars.

(b) The list of approved seed cultivars shall include all of the following:

(1) Industrial hemp seed cultivars that have been certified on or before January 1, 2013, by member organizations of the Association of Official Seed Certifying Agencies, including, but not limited to, the Canadian Seed Growers' Association.

(2) Industrial hemp seed cultivars that have been certified on or before January 1, 2013, by the Organization of Economic Cooperation and Development.

(3) California varieties of industrial hemp seed cultivars that have been certified by a seed-certifying agency pursuant to Article 6.5 (commencing with Section 52401) of Chapter 2 of Division 18.

(c) Upon recommendation by the board or the department, the secretary may update the list of approved seed cultivars by adding, amending, or removing seed cultivars.

(1) The adoption, amendment, or repeal of the list of approved seed cultivars, and the adoption of a methodology and procedure to add, amend, or remove a seed cultivar from the list of approved seed cultivars, pursuant to this section shall not be subject to the requirements of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(2) The department, in consultation with the board, shall hold at least one public hearing with public comment to determine the methodology and procedure by which a seed cultivar is added, amended, or removed from the list of approved seed cultivars.

(3) The department shall finalize the methodology and procedure to add, amend, or remove a seed cultivar from the list of approved seed cultivars and send the methodology and procedure to the Office of Administrative Law. The Office of Administrative Law shall file the methodology and procedure promptly with the Secretary of State without further review pursuant to Article 6 (commencing with Section 11349) of Chapter 3.5 of Part 1 of Division 3 of Title 2 of the Government Code. The methodology and procedure shall do all of the following:

(A) Indicate that the methodology and procedure are adopted pursuant to this division.

(B) State that the methodology and procedure are being transmitted for filing.

(C) Request that the Office of Administrative Law publish a notice of the filing of the methodology and procedure and print an appropriate reference in Title 3 of the California Code of Regulations.

(d) The department, in consultation with the board, may determine the manner in which the public is given notice of the list of approved seed cultivars, and any addition, amendment, or removal from that list.

(Added by Stats. 2013, Ch. 398, Sec. 4. (SB 566) Effective January 1, 2014. Section operative January 1, 2017, pursuant to Section 81010.)

Industrial Hemp Seed Certification Standards



GENERAL STANDARDS -- The standards on this sheet are in part condensed and apply to Industrial Hemp. For greater detail and additional provisions, see the General Standards. All production of industrial hemp is subject to registration, license application and approval by the California Department of Food and Agriculture (CDFA) and the County Agricultural Commissioner in whose county the crop is grown. Only varieties of industrial hemp that are approved by the CDFA and California Crop Improvement Association (CCIA) are eligible for certification. The size of an industrial hemp research area or production field may be determined by the regulatory authorities in California.

PLANTING STOCK -- In most varieties Breeder seed must be planted to produce Foundation seed, Foundation seed must be planted to produce Registered seed, and Registered seed must be planted to produce Certified seed. Nursery propagation for plants intended for cannabidiol (CBD) production and processing in California will be certified by generations instead of seed classes.

APPLICATION -- Applications should be submitted electronically on CCIA's website (Application to grow and certify seed) as soon as possible and no later than four (4) weeks after planting. New applicants should contact the CCIA office for instructions on obtaining access to the online application system. Applicants must attach to the application the tetrahydrocannabinol (THC) test results of the crop that produced the planting stock or propagules.

FIELD ELIGIBILITY -- Crops should not be grown on land where remnant seed from a previous crop may germinate and produce volunteers that may cause contamination. Crops for Foundation and Registered classes of industrial hemp seed must not be grown on land that produced another crop of industrial hemp in the previous 5 years. Crops for Certified class seed must not be grown on land that had an industrial hemp crop in the preceding 3 years.

ISOLATION -- There shall not be any Cannabis sativa plants within 330 ft of the inspected crop. However, not more than 4 plants per acre of harmful contaminants (including species other than Cannabis sativa that can cross pollinate with the inspected crop) shall be permitted beyond 330 ft within the isolation distance of the inspected crop (see Table 1).

The minimum isolation distances between a field of industrial hemp and fields of other crops prior to flowering and field inspection are presented in Table 1. If Dioecious male plants within the seed

production field start flowering before removal from field, all plants around them should be destroyed for a radius of 10 feet for Foundation and 6 feet for Registered seed crops. All fields or portions of fields intended for certification must have a definite boundary such as a fence, ditch, roadway, levee, or barren strip at least ten (10) feet wide.

Table 1. Minimum Isolation Distances between Inspected Industrial Hemp and Other Crops

Inspected Crop	Other Crops	Isolation Distance (feet)
Dioecious type - Foundation Class Registered Class	-Different varieties of Industrial Hemp -Non-certified crops of same kind	16,150
	-Lower certified class seed crop of same variety	6,460
	-Same class of certified seed of same variety	3
Dioecious type - Certified Class	-Different varieties of Industrial Hemp -Non-certified crops of same kind	3,230
	-Lower certified class seed crop of same variety	646
	-Same class of certified seed of same variety	3
Monoecious and Hybrid types - Foundation Class Registered Class	-Dioecious varieties of Industrial Hemp -Non-certified crops of same kind	16,150
	-Different varieties of same type of IndustrialHemp [Monoecious or female hybrid]	6,460
	-Lower certified class seed crop of same variety	3,230
	-Same class of certified seed of same variety	3
Monoecious and Hybrid types - Certified Class	-Dioecious varieties of Industrial Hemp -Non-certified crops of same kind	3,230
	-Different varieties of same type of IndustrialHemp [Monoecious or female hybrid] -Lower certified class seed crop of same variety	646
	-Same class of certified seed of same variety	3

FIELD INSPECTION -- It is the grower’s responsibility to ensure that the field is inspected by the CCIA field inspector at least twice prior to swathing or harvesting, except in the case of Foundation and Registered monoecious types and unisexual female hybrids, in which three inspections are required. Seed from a field that is cut, swathed or harvested prior to field inspection is not eligible for certification. Fields must be inspected at a stage of growth when varietal purity

is best determined. Fields not inspected at the proper stage for best determination of varietal purity may be rejected. The presence of Broomrape (*Orobanche* spp.) in an industrial hemp field may be cause for rejection.

The first inspection will be made before female (pistillate) flowers of the inspected crop are receptive and after the formation of male (staminate) flowers, preferably before pollen is shed. The second inspection will be made during the receptive stage of the female plants in the inspected field, normally within 3 weeks of first inspection. If a third inspection is necessary or required, it will be made when off-type female flowers can be identified. Isolation areas will be inspected for volunteer industrial hemp plants and harmful contaminants at each inspection.

Off-Types -- Impurities and off-types should be rogued prior to field inspection. Any combination of impurities may be cause for rejection. An industrial hemp crop for Certified Class, unless otherwise specified by the Breeder, must not exceed the limits of harmful contaminants (species that can cross pollinate with the inspected crop), plants of other varieties or distinct types foreign to the variety being inspected, weeds or other crops with seeds that are difficult to separate from industrial hemp seed (e.g. Hemp Nettle) as outlined in Table 2. The table indicates the maximum number of impurities and off-types permitted by CCIA in approximately 10,000 plants of the inspected crop. A field inspector will make at least 6 counts (10,000 plants each) or the equivalent to determine the number of impurities. The average of these counts must not exceed the maximum impurity standards presented in Table 2.

Table 2. Maximum Impurity and Off-type Standards.

Inspected Crop	Maximum impurities per 10,000 plants in Registered and Certified Class Industrial Hemp seed crops		
	Maximum number of 'Too Male' Monoecious plants	Maximum number of Dioecious male plants shedding pollen	Maximum number of other impurities
Dioecious type - Foundation	-	-	3
Dioecious type - Registered and Certified	-	-	10
Monoecious type – Foundation	500	1	3
Monoecious type – Registered	1,000	2	10

Monoecious type and Hybrids – Certified	-	100	10
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Weeds -- Fields must be free of any **prohibited noxious** weeds. **Restricted noxious** weeds and common weeds difficult to separate must be controlled. Prohibited and Restricted noxious weeds are listed in the California Seed Law/CA Code of Regulations/Sections 3854 and 3855. See California Seed Law - Prohibited and Restricted Noxious Weed List. Fields may be rejected due to unsatisfactory appearance caused by weeds, poor growth, poor stand, disease, insect damage, and any other condition that prevents accurate inspection or creates doubt as to identity of the variety. A field inspection report will be available online for the applicant. If the field is approved, a certification number will be assigned. This number must be on all containers of seed before they leave the field. It is the responsibility of the applicant to make sure their field has been inspected before it is harvested.

HARVESTING -- Harvesting is subject to the supervision of the County Agricultural Commissioner who must be contacted prior to harvest. Any seed moved out of the county for conditioning must be accompanied by an Inter-County or Inter-State Seed Transfer Certificate issued by the Commissioner.

CONDITIONING AND SAMPLING -- Conditioning of seed for certification may be done only in facilities approved for this purpose by the CCIA. It is the responsibility of the applicant to determine if the plant is eligible before delivering seed for conditioning. Conditioning, sampling, reconditioning, and blending will be conducted under the supervision of the County Agricultural Commissioner. Conditioning equipment must be free from contaminating seed to the satisfaction of the supervising inspector.

SEED INSPECTION -- All seed must be sampled and tested after conditioning and the seed lot must meet or exceed seed certification standards for that crop. A seed lab using the Association of Official Seed Analysts (AOSA) “Rules for Testing Seeds” must test the sample. A Registered Seed Technologist must sign each lab analysis. In addition to AOSA rules, specific seed testing may be required to meet CCIA seed certification standards. Applicants must also submit THC test results of the seed crop to CCIA before the Seed Inspection Report is issued.

The conditioner is required to submit a 450 gram sample to the laboratory for analysis. (Submitted Sample Sizes for Certification). In some instances, varietal identity cannot be determined by visual seed inspections. Seed must be well screened and graded, bright in color, of good appearance and meet the following standards:

Pure seed	98.00% (Minimum)
Inert Matter*	2.00% (Maximum)

Other Crop Seed		
-	Foundation	0.10% (Maximum)
-	Registered	0.03% (Maximum)
-	Certified	0.08% (Maximum)
Other Varieties		
-	Foundation	0.005% (Maximum)
-	Registered	0.01% (Maximum)
-	Certified	0.05% (Maximum)
Other Kinds**		
-	Foundation	0.01% (Maximum)
-	Registered	0.03% (Maximum)
-	Certified	0.07% (Maximum)
Weed Seed		0.10% (Maximum)
Germination		80.00% (Minimum)

*Inert matter shall not include more than 0.5 per cent of material other than seed fragments of the variety under consideration.

**Other kinds shall not exceed 2 per lb. (454 grams) for Foundation, 6 for Registered, 10 for Certified.

The CCIA requires Reports of Analysis for initial certification to be dated no more than a maximum of six (6) months prior to the request for seed certification. The 'Purity Analysis' and 'Germination' must be conducted on the same laboratory seed sample and those results must be presented in a single Report of Analysis.

FINAL CERTIFICATION AND TAGGING -- If the seed sample meets all standards a seed inspection report is issued. Before certification is complete, however, each container must have an official tag or label attached. Certified seed may be sold to a grower in bulk without tagging if a properly filled out Bulk Sale Certificate accompanies the shipment. The tags and Bulk Sale Certificates are issued by the CCIA to the County Agricultural Commissioner who supervises their attachment.

Date: February 2018

List of Approved Industrial Hemp Varieties for California

<i>Variety Name</i>	<i>Origin</i>	<i>Certification</i> ¹	<i>Purpose</i> ²	<i>Flowering</i> ³	<i>Approval</i> ⁴
Alyssa	Canada	AOSCA	D	H; Fep	02.22.18
Anka	Canada	AOSCA	D	M	02.22.18
Beniko	Poland	OECD	F	M	02.22.18
Bialobrzeskie	Poland	OECD	F	M	02.22.18
Canda	Canada	AOSCA	D	M	02.22.18
CanMa	Canada	AOSCA	G	D	02.22.18
Carmagnola	Italy	OECD	F	D	02.22.18
Carmen	Canada	AOSCA	G	D	02.22.18
CFX-1	Canada	AOSCA	G	D	02.22.18
CFX-2	Canada	AOSCA	G	D	02.22.18
Crag	Canada	AOSCA	D	D	02.22.18
CRS-1	Canada	AOSCA	G	D	02.22.18
CS	Italy	AOSCA	F	D	02.22.18
Delores	Canada	AOSCA	D	M	02.22.18
Deni	Canada	AOSCA	D	M	02.22.18
Eletta Campana	Italy	OECD	F	D	02.22.18
Elite	U.S.	AOSCA	G	D	02.22.18
ESTA-1	Canada	AOSCA	G	D	02.22.18
Fasamo	Germany	AOSCA	D	M	02.22.18
Fedrina 74	France	AOSCA	F	M; Fep	02.22.18
Felina 34	France	OECD	F	M; Fep	02.22.18
Ferimon	France	OECD	D	M	02.22.18
Fibranova	Italy	OECD	D	D	02.22.18
Fibriko	Hungary	AOSCA	F	D; Fep	02.22.18
Fibrimon 24	France	AOSCA	F	M	02.22.18
Fibrimon 56	France	OECD	F	M	02.22.18
Georgina	Canada	AOSCA	D	D	02.22.18
GranMa	Canada	AOSCA	G	D	02.22.18
Grandi	Canada	AOSCA	G	D	02.22.18
Helena	Serbia	OECD	D	M	02.22.18
Joey	Canada	AOSCA	D	M	02.22.18
Jutta	Canada	AOSCA	D	M	02.22.18
Katani	Canada	AOSCA	G	D	02.22.18
Kompolti	Hungary	OECD	F	D	02.22.18
Kompolti Hibrid TC	Hungary	OECD	F	H; Fep	02.22.18
Kompolti Sargaszaru	Hungary	AOSCA	F	H	02.22.18
Lovrin 110	Romania	OECD	F	D	02.22.18
Martha	Canada	AOSCA	G	D	02.22.18
MS77	Australia	AOSCA	D	D	02.22.18
Petera	Canada	AOSCA	F	D	02.22.18
Piccolo	Canada	AOSCA	G	D	02.22.18
Silesia	Canada	AOSCA	F	M	02.22.18

<i>Variety Name</i>	<i>Origin</i>	<i>Certification</i> ¹	<i>Purpose</i> ²	<i>Flowering</i> ³	<i>Approval</i> ⁴
Tygra	Poland	OECD	D	M	02.22.18
UC-RGM	Canada	AOSCA	F	M	02.22.18
Uniko B	Hungary	OECD	F	H; Fep	02.22.18
USO 14	Ukraine	AOSCA	F	M	02.22.18
USO 31	Ukraine	AOSCA	D	M	02.22.18
Victoria	Canada	AOSCA	G	D	02.22.18
X-59 (Hemp Nut)	Canada	AOSCA	G	D	02.22.18
Yvonne	Canada	AOSCA	F	M	02.22.18
Zolotonosha 11	Ukraine	AOSCA	F	M	02.22.18
Zolotonosha 15	Ukraine	AOSCA	F	M	02.22.18

Notes:

1. **Certification:** AOSCA = Association of Official Seed Certification Agencies. OECD = Organization for Economic Co-operation and Development.
2. **Purpose:** F = Fiber; G = Grain; and D = Dual (Fiber and Grain).
3. **Flowering:** M = Monoecious; D = Dioecious; H = Hybrid; Fep = Female predominant.
4. **Approval:** by California Crop Improvement Association (CCIA) Board of Directors' Meeting.

Date: June 6, 2018



July 24, 2018

Karen L. Smith, MD, MPH
Director
California Department of Public Health
Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899

RE: FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products

Dear Dr. Smith:

We write to express our concerns regarding the California Department of Public Health's (CDPH) recent issued statement titled FAQ- Industrial Hemp and Cannabidiol (CBD) in Food Products.¹ The California Hemp Association is the state's leading industrial hemp trade group and serves as a voice for the California farmers and businesses involved in the industrial hemp trade.

As discussed in detail below, the CDPH's suggestion that CBD extracts from industrial hemp differ in legal status from the plant itself is a flawed argument and an incorrect interpretation of the plain text of California's industrial hemp laws. Furthermore, we urge the CDPH to uphold California law and not to rely upon statements issued by federal authorities, especially given the CDPH's current stance on cannabis more generally, which is in complete contradiction to the same federal authorities cited with respect to CBD.²

We encourage the CDPH to re-evaluate its current position and to work with the California industrial hemp community to ensure the public is well informed regarding all aspects of industrial hemp and its various chemical compounds and byproducts.

CBD Is Not a Controlled Substance Pursuant to California Law

¹ California Department of Public Health, *FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products*. Available at <https://www.cdph.ca.gov/Programs/CI/HI/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/HEMP/Web%20template%20for%20FSS%20Rounded%20-%20Final.pdf> (Revised 7/6/2018) (last visited July 22, 2018).

² California Cannabis Health Information Initiative, *Let's Talk Cannabis: What is Legal for Adult Use?* Available at <https://www.cdph.ca.gov/Programs/DO/letstalkcannabis/CDPH%20Document%20Library/October%202017%20Update/CDPH1-Legal.pdf> (last visited July 22, 2018).

Industrial hemp belongs to the genus *cannabis* and as such, contains many cannabinoids. Cannabinoids are chemical compounds produced in the flower of all cannabis plants, including industrial hemp. The California Industrial Hemp Farming Act³ distinguishes industrial hemp from *Cannabis sativa* L. generally on the basis of a single cannabinoid, tetrahydrocannabinol (“THC”). The lack of this compound is the distinguishing feature of industrial hemp under both federal and California law.⁴

Accordingly, California 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 percent tetrahydrocannabinol (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.*

Industrial hemp *shall not be* subject to the provisions of the [California Uniform Controlled Substances Act], *but instead shall be regulated by the Department of Food and Agriculture.*”⁵

In deciding to define industrial hemp on the basis of THC content, the legislature deliberately recognized “every compound” and “derivative” from the *Cannabis sativa* L. plant could be used for production purposes, so long as the plant was cultivated to be below the established 0.3% THC threshold. This definition expressly ensured the production of industrial hemp and all of its various chemical compounds could proceed unencumbered by California’s controlled substances laws.

With the exception of THC, the California Uniform Controlled Substances Act expressly regulates no other cannabinoids, including CBD. The CDPH’s assertion that CBD products produced from industrial hemp should be governed differently from hemp seed oils is in direct contradiction to the express language used to define industrial hemp.

Pursuant to the statutory language cited above, the CDPH’s current position established through the FAQ document is unsupported by California law and will likely do little more than create confusion amongst other regulatory agencies and local law enforcement officials.

The CDPH’s Reliance On Federal Authorities Is Unfounded And We Urge The Department To Evaluate CBD Using Science Based Evidence

The CDPH’s FAQ document appears to rely in part on statements released by the U.S. Food and Drug

³ Senate Bill 566, Chapter 398, Statutes of 2013.

⁴ See California Health and Safety Code §11018.5 and Agricultural Act of 2014, Pub. L. 113-79, title VII, § 7606 (codified at 7 U.S.C. § 5940 (2014)).

⁵ See California Health and Safety Code §11018.5 (emphasis added).

Administration (FDA).⁶ As noted in detail in the recent correspondence issued by the U.S. Hemp Roundtable, a copy of which is enclosed for your further review, the FDA’s current position regarding CBD in dietary supplements and conventional food is unsettled and unsupported by law. Furthermore, the FDA has stated its current opinions regarding CBD may change as additional science based evidence becomes available.

We encourage the CDPH to respect California law first and foremost and suggest its approach towards industrial hemp and CBD should mirror the department’s approach towards cannabis generally. The CDPH currently acknowledges California’s cannabis regulations are in direct contradiction to federal law,⁷ yet it works in conjunction with a host of other state regulatory agencies to ensure California’s cannabis industry is maintained in a manner, which promotes public health and safety.

Pursuant to this more inclusive approach, we encourage the CDPH to engage with the California Department of Food and Agricultural (CDFA) and more specifically the CDFA’s Industrial Hemp Advisory Board. In working with all California agencies appointed to regulate industrial hemp, the CDPH is assured to create an environment in which public information regarding industrial hemp and its byproducts, such as CBD, is rooted in fact based scientific analysis.

Given the abundance of misinformation surrounding industrial hemp and CBD, we encourage the CDPH and all other California agencies charged with overseeing industrial hemp, to work with those currently engaging in industrial hemp research to ensure public information available on the topic is rooted in scientific principals. This science based approach will ensure the CDPH fulfills its vision of being a transparent, evolving and data driven organization that provides leading edge public health knowledge and services to all Californian’s.

In closing, we respectfully urge the Department of Public Health to withdraw or revise the FAQ document in order to ensure public information relating to industrial hemp-derived CBD is grounded in California law and established scientific principles.

Sincerely



Wayne Richman
Executive Director, and on behalf of, the California Hemp Association

Enclosure

⁶ See FAQ document at p. 2, “Until the FDA rules that industrial hemp-derived CBD oil and CBD products can be used as a food... CBD products are not an approved food, food ingredient, food additive, or dietary supplement.” and FAQ 4, “CBD is an unapproved food additive... per the FDA”

⁷ California Cannabis Health Information Initiative, *Let’s Talk Cannabis: What is Legal for Adult Use?*



ROBERT HOBAN, MANAGING PARTNER
303-674-7000

July 20, 2018

Karen L. Smith, MD, MPH
Director
California Department of Public Health
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Via US Certified Mail and Email

Dr. Smith:

Our firm represents numerous clients engaged in the cultivation, processing, manufacture, distribution, and use of products which contain derivatives of industrial hemp (the “Products”) across the United States. This letter is in response to a certain *FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products* (the “FAQ”) issued by the California Department of Public Health (“CDPH”) on July 6, 2018.

In short, the FAQ mischaracterizes relevant federal and state law and regulation and is fundamentally flawed for many reasons including, without limitation, the following:

1. The FAQ neither acknowledges or addresses all relevant provisions of California law, legislation which indicates the intent to provide for the Products;
2. The FAQ mischaracterizes the scope of Section 7606 of the Agricultural Act of 2014 (the “Farm Bill”) and corresponding legislation more narrowly than Congress intended;
3. CDPH mistakenly asserts “CBD derived from hemp . . . is a federally-regulated controlled substance” and gives inappropriate deference to the (erroneous) interpretations of law proffered by the Drug Enforcement Agency (“DEA”) and other agencies, in contradiction of guidance provided explicitly and directly by Congress; and
4. CDPH inappropriately mischaracterizes cannabidiol (“CBD”) as a prohibited food additive or dietary ingredient.

Correspondingly, we implore the CDPH to seriously reconsider the implementation of the FAQ and thereby rescind it. We request a meeting with CDPH at its earliest convenience to engage in further discussion with appropriate stakeholders to sensibly regulate the Products without implementing the FAQ. For years, California has been at or near the forefront of policy reform, having first enacted hemp legislation years ago. However, the FAQ stands to threaten an entire

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newly emerging industry, causing California to fall far behind the rest of the nation for years to come in its treatment and regulation of these Products. Simply put, the adverse impact of this FAQ would be devastating and irreparable.

Factual Background

“Industrial hemp,” as defined by the Farm Bill, is a variety of *Cannabis sativa L.* which contains less than 0.3% tetrahydrocannabinol (“THC”), the psychoactive compound typically associated with “marihuana.” The Farm Bill legalizes industrial hemp including, but not limited to, the cultivation, transport, processing, sale and use thereof.¹

Moreover, the intent of Congress – as described by 29 bipartisan members of Congress in a congressional amicus brief – in enacting the Farm Bill was to confirm that industrial hemp, or cannabinoids derived from industrial hemp, are not to be treated as controlled substances.² Contrary to the treatment of controlled substances, the Farm Bill sought to specifically allow for many activities relating to industrial hemp, including but not limited to certain commercial activities, development of the Products, exploring the economic impact of hemp-derived cannabinoids including the Products and creating a retail marketplace for the Products.³

Cannabinoids – including THC and CBD – are compounds which naturally occur in *Cannabis*, both “marihuana” and “industrial hemp,” but also an array of non-*Cannabis* sources including cacao, human breast milk, and even other flower varieties, as DEA acknowledges.⁴ Naturally occurring cannabinoids, *per se*, are not controlled substances (with the exception of *synthetic* THC).⁵ DEA even recently issued an internal and external directive confirming the same.⁶

¹ See Pub. L. 113-79, §7606; see also Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729)).

² See *Amicus Brief of Members of United States Congress in Support of Petitioners with Consent of All Parties* at 3, 26, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (argued February 15, 2018), available at: https://polis.house.gov/uploadedfiles/amicus_brief.pdf.

³ *Id.* at 13-15.

⁴ See *Denial of Petition to Initiate Proceedings to Reschedule Marijuana*, 81 Fed. Reg. 83,688-765, 53,692, 53,698, 53,753 (Aug. 12, 2016) (citing Giovanni Appendino et al., *Cannabinoids: occurrence and medicinal chemistry*, 18 *Curr. Med. Chem.* 1085 (2011)); see also *Brief of Petitioners* at 7, fn 3, *Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

⁵ See *Hemp Indus. Ass'n. v. DEA*, 357 F.3d 1012, 1014 (9th Cir. 2004); *Hemp Indus. Ass'n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

⁶ DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant (May 22, 2018), available at:



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Discussion

Below, this letter addresses the flaws inherent within the FAQ. In light of these irreparable flaws, we respectfully request that CDPH not implement the FAQ, and instead engage in further dialogue with stakeholders, including our firm, to discuss California's regulatory scheme.

1. *FAQ Assertion: California law does not render the Products lawful under state law.*

Response:

California's legislature initially enacted the Industrial Hemp Farming Act in 2013 (the "Act") and subsequently Proposition 64, in 2016, which amended the Act. As amended, the Act specifically legalizes "industrial hemp," which is now defined in the Health and Safety Code, in relevant part, to include the flowering tops and leaves of the hemp plant, along with resins, manufacture, derivatives, mixtures and preparations thereof.⁷

Moreover, recently enacted AB 710 specifically indicates the intent that Section 11018.5 is intended to contemplate as lawful, and to preclude restriction of access to, the Products containing cannabidiol ("CBD").⁸

2. *FAQ Assertion: CBD derived from hemp is a federally-regulated controlled substance.*

Response:

*Congress knew what it was doing and its intent to exclude nonpsychoactive hemp from regulation is entirely clear.*⁹

Or, alternatively, in DEA's own words, "*DEA is not seeking to schedule cannabinoids.*"¹⁰ Further, DEA "*does not purport to override the [Farm Bill].*"¹¹ Perhaps even most convincingly, in DEA's own internal and external directive, which our firm was involved in penning, DEA again confirmed that cannabinoids are not controlled substances:

https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html.

⁷ California Health and Safety Code, Section 11018.5

⁸ California Assembly Bill 710 §§ 1; 3(c) (enacted July 9, 2018).

⁹ *Id.*

¹⁰ *See Brief for Respondents at 29, Hemp Indus. Ass'n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

¹¹ *Id.* at 32.

Products and materials that are made from the cannabis plant and which fall outside the CSA definition of marijuana . . . are not controlled under the CSA. Such products may accordingly be sold and otherwise distributed throughout the United States without restriction under the CSA or its implementing regulations. The mere presence of cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance falls within the CSA definition of marijuana.¹²

To expound on the above points, the federal Controlled Substances Act (“CSA”) does not illegalize the entire *Cannabis* plant. “Marihuana” only includes certain portions of the *Cannabis* plant, and neither includes “industrial hemp,” pursuant to the Farm Bill, nor the exempted stalk, stem, fiber and non-viable seeds of the plant. Those exempted portions and varieties of the *Cannabis* plant are still lawful, *even if they contain naturally occurring cannabinoids such as THC*.¹³ In these early 2000s cases, the Court found against DEA, and DEA did not appeal these decisions.

Relatedly, the Court also found that although the CSA lists “THC” as a controlled substance, this reference is merely to *synthetic* THC, and not THC which naturally occurs in lawful portions and varieties of *Cannabis* – such as industrial hemp.¹⁴

As noted above, in writing as well as during argument before the Ninth Circuit Court of Appeals, DEA itself has admitted that DEA is not seeking to control cannabinoids and that cannabinoids may be found in parts of the *Cannabis* plant, or other lawful sources, which DEA does not control.¹⁵ Importantly, DEA also admits that where the Farm Bill applies, the DEA has no jurisdiction.¹⁶ Accordingly, the Ninth Circuit Court of Appeals confirmed that the Farm Bill pre-empts the federal CSA and DEA’s authority or jurisdiction.¹⁷

As noted above, the Farm Bill specifically makes lawful “industrial hemp” which includes all derivatives therefrom. It would, in fact, be a perverse interpretation of the Farm Bill for

¹² DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant (May 22, 2018), available at: https://www.deadiversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html.

¹³ 357 F.3d at 1018; *Hemp Indus. Ass’n. v. DEA*, 333 F.3d 1082, 1089 (9th Cir. 2003).

¹⁴ *Id.*

¹⁵ See *Brief for Respondents* at 26-29, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).

¹⁶ *Id.* at 13-14, 32; see also Consolidated Appropriations Act, 2018 (Pub. L. No. 114-441 (Sec. 537, 729)).

¹⁷ See *Memorandum* at 4, *Hemp Indus. Ass’n. v. DEA*, Case No. 17-70162 (decided April 30, 2018).



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“industrial hemp” to be made lawful, but that the crop must then be destroyed because it contains alleged controlled substances.

For these reasons, the FAQ mischaracterizes CBD and hemp as controlled substances and far too narrowly interprets the scope of the Farm Bill. As a result, the FAQ fails to accurately reflect the law and fails to acknowledge that cannabinoids derived from “industrial hemp” are in fact lawful.

3. *FAQ Assertion: CBD is an unapproved food additive or dietary ingredient, or otherwise inappropriate for inclusion in products intended for human or animal consumption, as regulated by the U.S. Food and Drug Administration (“FDA”).*

Response: For the reasons noted above, including DEA’s own admissions, cannabinoids derived from “industrial hemp” are lawful. Thus, such cannabinoids cannot be deemed an “adulterant” or an unapproved food additive or dietary ingredient by virtue of alleged illegality. Further, there are no other sources of federal or state law which specifically classify “CBD” or other hemp derivatives as an “adulterant.”

The Products would, at minimum, be appropriately regulated as dietary supplements pursuant to the Dietary Supplement Health and Education Act of 1994,¹⁸ if not also as a conventional food pursuant to the Federal Food, Drug and Cosmetic Act.¹⁹ This treatment would be appropriate given the longstanding prevalence in the marketplace of products containing derivatives of industrial hemp, including various amounts of cannabinoids such as CBD. Such products were even the subject of above-referenced litigation in the early 2000s.²⁰

Moreover, the FAQ inappropriately defers to FDA’s position statements concerning CBD, which are unsettled and are not a *final* decision by FDA. FDA’s citation of certain provisions under the Federal Food, Drug and Cosmetic Act are in error, given that the prerequisite requirements for FDA to invoke those provisions do not appear to have been timely satisfied. Thus, the Department and the FAQ should not rely upon FDA’s positions in making definitive statements and conclusions.

FDA’s mission and underlying authority – as well as that of CDPH– is ensuring the safety of products intended for human consumption; given the FDA’s statutory positions are

¹⁸ See generally *Dietary Supplement Health and Education Act of 1994*, 108 Stat. 4325, Pub. L. No. 103-417 (1994).

¹⁹ See generally *Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. 301, *et seq.*

²⁰ See 357 F.3d at 1014; 333 F.3d at 1089.



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erroneous, CDPH and the FAQ should not preclude the Products unless there is a showing that the Products undermine that safety purpose.

To this end, evidence demonstrates the Products are safe. Studies, and even the World Health Organization, conclude CBD maintains a good safety profile and has not been shown to cause dependence, abuse or harm.²¹ Moreover, other publicly available studies confirm the safety of the Products.

Accordingly, the FAQ's determination that the Products do not comply with FDA regulations is both premature and in error. Thus, the FAQ should not be implemented to regulate upon these flawed determinations.

For the reasons set forth above, we implore CDPH to not implement the FAQ, and instead propose that CDPH engage in further dialogue with stakeholders to appropriately regulate hemp-derived products, such as the Products, in the State of California.

Thank you for your thoughtful consideration of the above commentary. Our firm also extends a standing offer to further discuss these sensitive issues to ensure that any policy considered and promulgated accurately reflects both the law and sensible policymaking regarding the Products. Please do not hesitate to contact myself or my colleagues, Garrett Graff or Patrick Goggin, with any questions. Thank you.

Very truly yours,

/s/ Robert T. Hoban
Robert T. Hoban

CC:

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²¹ See *Kerstin, Iffland and Grotenhermen Franjo*, AN UPDATE ON SAFETY AND SIDE EFFECTS OF CANNABIDIOL: A REVIEW OF CLINICAL DATA AND RELEVANT ANIMAL STUDIES, available at: <https://www.liebertpub.com/doi/10.1089/can.2016.0034> (June 1, 2017); *World Health Organization*, CANNABIDIOL (CBD) PRE-REVIEW REPORT, available at: http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf; 21 C.F.R. 53,693; *Researching Marijuana for Therapeutic Purposes: The Potential Promise of Cannabidiol (CBD)*, NATIONAL INSTITUTE OF DRUG ABUSE, available at: <https://www.drugabuse.gov/about-nida/noras-blog/2015/07/researching-marijuana-therapeutic-purposes-potential-promise-cannabidiol-cbd> (July 20, 2015).

U.S. Hemp Roundtable

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July 19, 2018

Karen L. Smith, MD, MPH
Director
California Department of Public Health
Food and Drug Branch
P.O. Box 997435, MS 7602
Sacramento, CA 95899

RE: FAQ – Industrial Hemp and Cannabidiol (CBD) in Food Products

Dear Dr. Smith:

The U.S. Hemp Roundtable writes to express significant concerns regarding a recent FAQ document issued by the California Department of Public Health (“CDPH”) that prohibits the use of industrial hemp-derived cannabidiol (“CBD”) oil or CBD products in food.¹ The Roundtable is the industry’s national business association that represents over forty firms from across the country – at each link of the hemp supply and sales chain – and includes the ex officio membership of the industry’s major grassroots and trade organizations.

As discussed further below, the FAQ document makes inaccurate statements about the status of industrial hemp-derived CBD under the Controlled Substances Act (“CSA”) and the Federal Food, Drug, and Cosmetic Act (“FD&C Act”). Further, the safety profile of industrial hemp-derived CBD is well-established. The World Health Organization (“WHO”) recently evaluated CBD and determined that “CBD is generally well tolerated with a good safety profile,” and furthermore that “there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD.”²

¹<https://www.cdph.ca.gov/Programs/CEH/DFDCS/CDPH%20Document%20Library/FDB/FoodSafetyProgram/HEMP/Web%20template%20for%20FSS%20Rounded%20-%20Final.pdf> (revised 07/06/2018).

² http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf.

Hemp-Derived CBD is not a Controlled Substance

The FAQ incorrectly states that “CBD derived from hemp and cannabis is a federally-regulated controlled substance” and makes repeated references to “industrial hemp,” suggesting that CBD derived from industrial hemp also falls within the scope of the CSA.

Industrial hemp that is grown and distributed pursuant to Section 7606 of the Agricultural Act of 2014 (also known as the “Farm Bill”) is exempted from the CSA. Section 7606 defines “industrial hemp” as the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.³ California’s own CSA likewise exempts “industrial hemp” from its list of controlled substances.⁴

In addition, under the CSA, “marihuana” (commonly referred to as “marijuana”) is a Schedule I controlled substance and is defined as follows:

all parts of the plant *Cannabis sativa L.*, whether growing or not; the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds or resin. *Such term does not include the mature stalks of such plant, fiber produced from such stalks, oil or cake made from the seeds of such plant, any other compound, manufacture, salt, derivative, mixture, or preparation of such mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of such plant which is incapable of germination* (emphasis added).⁵

Materials that are derived from the exempted plant parts –and any “compounds” thereof – are excluded from the definition of marijuana and are not considered a controlled substance. Therefore, CBD derived from either the exempted parts of the *Cannabis* plant or derived from lawfully grown and cultivated industrial hemp is not a federally-controlled substance.

This interpretation of the CSA is also supported by two cases decided by the United States Court of Appeals for the Ninth Circuit.⁶ In the first case, the Court found that “marihuana is defined so as to bring within its scope all parts of the plant having the harmful drug ingredient, but so as to exclude the parts of the plant in which the drug is not present” (including “hemp”).⁷ In a subsequent case a year later, the same Court considered a

³ Section 7606 of the Agricultural defines “industrial hemp” as the plant *Cannabis sativa L.* and any part of such plant, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

⁴ California Health and Safety Code, Section 11018.59(b).

⁵ 21 U.S.C. § 802(16).

⁶ In both cases, the conduct and products directly at issue were the importation and distribution of sterilized hemp seed and oil and cake derived from hemp seed for the manufacture and sale of food and cosmetic products containing hemp seed and oil.

⁷ *Hemp Industries Assn. v. Drug Enforcement Admin.*, 333 F.3d 1082, 1085 (9th Cir. 2003) (“Hemp I”).

challenge of two administrative rules established by the Drug Enforcement Agency (“DEA”) that sought to ban non-psychoactive hemp products that contained trace amounts of tetrahydrocannabinol (“THC”).⁸ The *Hemp II* Court reiterated its position from *Hemp I* and stated that “non-psychoactive hemp [that] is derived from the ‘mature stalks’ or is ‘oil and cake made from the seeds’ of the Cannabis plant...fits within the plainly stated exception to the CSA definition of marijuana.”⁹ The court further noted that “Congress knew what it was doing, and its intent to exclude non-psychoactive hemp from the regulation is entirely clear.”¹⁰

Thus, it is clear (as outlined by the Court in *Hemp I* and *Hemp II*) that CBD is not a Scheduled I controlled substance if it is derived exclusively from the excluded parts of *Cannabis Sativa L.* plant, as set forth in the CSA’s definition of marijuana.

A recent directive from the DEA is consistent with the above interpretation in that the source of cannabinoids such as CBD, rather than the presence, will determine whether a product falls within the scope of the CSA. It states:

Products and materials that are made from the cannabis plant and which fall outside the CSA definition of marijuana are not controlled under the CSA. Such products may accordingly be sold and otherwise distributed throughout the United States without restriction under the CSA or its implementing regulations. *The mere presence of cannabinoids is not itself dispositive as to whether a substance is within the scope of the CSA; the dispositive question is whether the substance falls within the CSA definition of marijuana* (emphasis added).¹¹

We also note the irony in that CDPH is making its decision based on federal law (CSA and FD&C Act) yet cannabis products are widely available to consumers for both recreational and medicinal purposes, despite being regulated as a Schedule I controlled substance at the federal level.

The Status of Hemp-Derived CBD Under the FD&C Act is Unsettled

The FAQ document also states that the U.S. Food and Drug Administration (“FDA”) “has concluded that it is a prohibited act to introduce or deliver for introduction into interstate commerce any food...to which [THC] or CBD has been added,” regardless of the source. However, the FDA’s current position regarding CBD in dietary supplements or conventional food is unsettled and unsupported by law or regulations. More importantly, the agency’s current position is *not* a final determination.

⁸ *Hemp Industries Assn. v. Drug Enforcement Admin.*, 357 F.3d 1012 (9th Cir. 2004) (“Hemp II”).

⁹ *Id.* at 1017.

¹⁰ *Id.* at 1018.

¹¹ *DEA Internal Directive Regarding the Presence of Cannabinoids in Products and Materials Made from the Cannabis Plant* (May 22, 2018),

https://www.dea diversion.usdoj.gov/schedules/marijuana/dea_internal_directive_cannabinoids_05222018.html.

As background, the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (“DSHEA”),¹² defines a “dietary supplement” as a product intended to supplement the diet that contains one or more of the following:

- (a) a vitamin;
- (b) a mineral;
- (c) an herb or other botanical;
- (d) an amino acid;
- (e) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- (f) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (a) through (e).¹³

Thus, it permits a wide range of dietary ingredients in dietary supplements, including CBD which is an extract of a botanical (*Cannabis sativa L.* plant). CBD also falls under clause (e) as it is a dietary substance for use by man to supplement the diet by increasing the total dietary intake.

The FDA has taken the position – via Warning Letters sent to hemp-CBD companies¹⁴ and an FDA Q&A document¹⁵ – that because substantial clinical trials studying CBD as a new drug were made public prior to the marketing of any food or dietary supplements containing CBD, dietary supplements or food are therefore precluded from containing this ingredient (“IND Preclusion”).¹⁶ However, we firmly disagree that the referenced clinical trials are in fact “substantial,” as the trials were extremely limited in scope, and funding and the publication of these trials were limited. The FDA also seems to misinterpret the IND Preclusion in that it believes the preclusion date is simply the date in which it authorized CBD as an IND, without giving deference to the remaining portion of the statute, which requires that substantial clinical investigation be commenced and that such substantial clinical investigation be made public. In addition, The FDA Q&A document does not have the effect of law but instead reflects FDA’s opinion, which the agency suggests may change as evidenced from the FDA’s own request for further input on the topic.

Rather, we believe that industrial hemp-CBD products were marketed as dietary supplements and/or foods prior to any *substantial* drug investigations being undertaken, or made public, and that based on the definition of “dietary supplement” under DSHEA, CBD is in fact a permissible dietary ingredient. Moreover, Warning Letters and agency Q&A documents are by no means final agency determinations. To date, the FDA has not taken any industrial hemp-CBD products off the market, prohibited the sale of such products, or ordered a

¹² Dietary Supplement Health and Education Act of 1994, Pub. L. No. 104-417.

¹³ 21 U.S.C. § 321(ff).

¹⁴ <https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm>.

¹⁵ FDA, *FDA and Marijuana: Questions and Answers*, https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm421168.htm#dietary_supplements.

¹⁶ 21 U.S.C. § 321(ff)(3)(B)(ii).

product recall. Further, the primary motivation for the Warning Letters issued in 2015, 2016, and 2017 concerned the improper use of disease-remediation claims by supplement/food companies.

Absent a clear safety issue, CDPH should not categorically prohibit the use of industrial hemp-derived CBD in food or dietary supplements.

Industrial Hemp-Derived CBD is Safe

Current scientific research confirms that industrial hemp-derived CBD is safe in food, supplements, and beverages and has provided health benefits to millions of Americans, including thousands of Californians. We are also not aware of any serious adverse events associated with the consumption of CBD. Indeed, the World Health Organization (“WHO”) recently evaluated CBD and determined that “CBD is generally well tolerated with a good safety profile,” and furthermore that “there is no evidence of recreational use of CBD or any public health-related problems associated with the use of pure CBD.”¹⁷ Because industrial hemp contains only a negligible amount of tetrahydrocannabinol (“THC”), the psychoactive component of cannabis, hemp-derived CBD products are non-psychoactive and safe. Further, hemp-derived CBD does not have the potential for abuse or addiction, and there is no potential for diversion.

Of note, the FAQ document indicates that California will continue to permit the sale of edible cannabis products and other cannabis products that contain CBD, which fall outside the statutory definition of “food” and are regulated by the Manufactured Cannabis Safety Branch (“MCSB”). However, there is no justification for making this distinction, especially from a health and safety perspective. MCSB must be reasonably certain that CBD does not pose a safety risk if it permits it to be sold in cannabis products. We also note that CDPH’s policy creates a situation whereby CBD products that may contain high levels of THC are readily available, but access to supplement and food products with zero THC that are both safe and non-addictive is now restricted.

Food and supplements that contain industrial hemp-derived CBD are subject to a comprehensive regulatory framework that addresses both the safety and quality of these products. In fact, the current Good Manufacturing Practices (“cGMPs”) for food and supplements (21 CFR Part 117 and Part 111, respectively) are equally if not more robust than the MCSB regulations governing the manufacture and production of cannabis products in California. Thus, as a result of the CDPH policy, California consumers will be denied access to safe, quality industrial hemp-derived CBD products at the retail level and will be limited to purchasing CBD only from licensed cannabis cultivators – absent a final determination from the FDA and without regard to the well-established safety record of industrial hemp-derived CBD.

In closing, we respectfully urge the Department of Public Health to withdraw or revise the FAQ document to permit the continued use of industrial hemp-derived CBD in dietary supplement and food products in California.

¹⁷ http://www.who.int/medicines/access/controlled-substances/5.2_CBD.pdf.

Thank you for your consideration.

Sincerely,

Brian Furnish
President
U.S. Hemp Roundtable

Jonathan Miller
Member-in-Charge
Frost Brown Todd, Lexington, KY

Rend Al-Mondhiry
Senior Counsel
Amin Talati Upadhye, Washington, DC

July 11, 2018

To the California Industrial Hemp Advisory Board,

For some time now, I have been developing a model for a small farm to grow 50 acres of hemp and have an extraction facility on the farm to process the crop. I have been working with hemp industry professionals, growers and processors in Washington, Oregon, and California. I have listened to the last two hemp board meetings. As I have been developing the model to grow and process industrial hemp I find one of the greatest risk points for the model is language in the May 25, 2018 draft of "SB-1409". It basically states: if the laboratory test reports indicate a percentage content of THC that is greater than three-tenths of 1 percent (0.003) then the crop must be destroyed.

SB-1409 (7) states that "a registrant that grows industrial hemp shall destroy by under-tilling or biochar gasification the industrial hemp grown".

This is totally absurd, destroying a total crop because of a small amount THC, considering the science, the value of the other non-THC properties of the plant, the economic risk to the farmer, risk to the investors, and loss of jobs to the local community.

I realize to change the three tenths of 1 percent rule would be very difficult considering it so entrenched in the rules in various states.

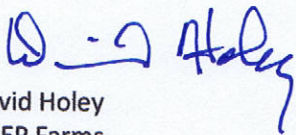
I would like to propose adding another alternative method to the destroy clause (7) which currently states, "by under-tilling or biochar gasification".

This alternative method is based on the science that is available to this industry today. If the crop of industrial hemp exceeds the current rules, then one of the destroy methods should be: allow the crop to be taken to an approved extraction facility. There the crop would follow the track and trace rules as it goes through the extraction separation process. The complete crop would be processed including the flower, leaves, seeds, stems and stalks. The extraction process would separate the plant's essential oils from the plant fiber. This full spectrum oil would contain all of the plant's THC. This full spectrum oil would then be distilled to separate the THC from the oil. The THC portion and only the THC portion could then be destroyed. The remaining oil and plant fiber could then be utilized for the various things the plant is known for.

It is only the destruction of the THC that is desired. The extraction process allows for methods of destroying the THC without the destruction of the total crop, and the destruction of the benefits of the crop to the community.

Please consider this beneficial addition to SB-1409 and the current destroy clause. I look forward to discussing this very positive option at the next Industrial Hemp Advisory Board meeting. As I noted above, this is the greatest risk factor in getting investment and starting the hemp farms in Californian. By mitigating this risk, the path to a successful Industrial Hemp industry will bloom and thrive in no time.

Sincerely,



David Holey
CGEP Farms
714-222-8929

Refer to David Holey's LinkedIn for information on his back ground.