U.S. Hemp Roundtable

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Colorado Board of Health, ATTN: Board of Health Program Assistant
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As Colorado companies engaged in the hemp and hemp extract business in the state, we appreciate the opportunity to comment on the Colorado Department of Public Health and Environment's ("CDPHE") Proposed Industrial Hemp Regulations ("the Proposed Regulations").

While we applaud CDPHE's efforts to update and improve its current regulatory framework for industrial hemp products, we offer the following comments and recommended revisions to the Proposed Regulations, which we believe will provide clarity and promote compliance within the industry. In particular, in some instances the Proposed Regulations are not consistent with U.S. Food and Drug Administration ("FDA") regulations for dietary supplements, food, and cosmetics and create Colorado-specific requirements, further adding to the already significant burden on companies to navigate the growing patchwork of state testing and labeling requirements for hemp products – without adding significant value to consumers, or providing added consumer protection benefits.

Section 21.4 – Definitions.

- The definition of "broad spectrum" should be revised as to be specific to delta-9 tetrahydrocannabinol ("THC") and to better align with the industry's use of this term with respect to ingredients and finished products.

  ➔ Broad spectrum means industrial hemp products that contain multiple cannabinoids ~~and no more than 0.01% total THC~~ but where all Δ9- THC has been removed to non-detectable levels using a fit-for-purpose method with a limit of quantification of less than 0.01%.

- The definitions of "Certified Laboratory" and "Certificate of Analysis" indicate that only labs and testing facilities certified by the state may be used for purposes of compliance with the Proposed Regulation's testing requirements, even for companies located outside of Colorado and that use other highly qualified labs for testing. We therefore request that the definition of "Certified laboratory" be revised to allow the use of independent, accredited third-party labs for testing of hemp products, which the majority of states permit.

  ➔ Certified laboratory means a public or private laboratory or testing facility certified by the department to perform testing on industrial hemp and industrial hemp products, ~~or~~ a testing facility licensed by the Marijuana Enforcement Division~~.~~, or an independent laboratory with no direct interest in the manufacturer or distributor of the industrial hemp product that is accredited by an independent accreditation body in accordance with International Organization for Standardization ISO/IEC 17025 or a comparable or successor standard.

Alternatively, CDPHE could include a definition of "independent laboratory" using the same or a substantially similar definition to that above, and clarify that such labs may be used to comply with the testing requirement under Section F.1., as noted in our comments below.

- The definition of "dietary supplement" should be revised to remove "new dietary ingredient." New dietary ingredients are dietary ingredients regardless of their classification as "new." As such the current definition may cause confusion.

  ➔ Dietary supplement means a product taken by mouth that contains a dietary ingredient ~~or a new dietary ingredient~~ intended to supplement the diet.

- The definition of "industrial hemp or hemp" includes "extracts" and therefore overlaps with the definition of "industrial hemp extract." As a result, it is unclear whether the 0.3% delta-9 THC limit for "industrial hemp" also applies to "industrial hemp extract," as the latter definition does not include a THC limit.

  ➔ Industrial hemp product means finished products containing industrial hemp is for human or non-food producing animal use or consumption and includes a product that:
  a. Is a cosmetic as defined in 25-5-402(6) C.R.S.; or
  b. Is a dietary supplement as defined in 25-5-426(2)(b) C.R.S.; or
  c. Is a food as defined in 25-5-402(11) C.R.S.;
  d. Is a food additive as defined in 25-5-402(12) C.R.S.;
  e. Contains any part of the hemp plant, including naturally occurring cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives;
  f. Contains a Delta-9 THC concentration of no more than 0.3%, and
  g. Is not a drug as defined in 25-5-402(9) C.R.S.

- The definition of "industrial hemp product" should be revised to include products intended for pet consumption. In addition, either in this definition or elsewhere, the Proposed Regulations should exclude products that contain hemp seed derived ingredients from the testing and labeling requirements, provided such ingredients are the only hemp-derived ingredients in the product. These products contain only trace amounts of cannabinoids and THC.

- The definition of "labeling" is overly broad and would subject websites, promotional printed materials, and emails to the same regulatory requirements as product labels, and should be limited to product labels, packaging, or product inserts.
  - Labeling means a display of written, printed, or graphic matter upon a food, food ingredient container, or package and includes product inserts~~, and other promotional materials including digital communications~~.

- The definition of "unfinished hemp product" appears to limit the sale or transfer of such products to only those entities registered as an industrial hemp manufacturer in Colorado or laboratories certified by the state. We request that CDPHE delete "registered" as indicated below to permit the sale of unfinished hemp products to out-of-state industrial hemp manufacturers.

  ➔ Unfinished industrial hemp product means an oil, concentrate or other substance that has a total THC concentration above 0.3% and less than or equal to 5.0%, is not for consumer use or distribution, must be sold or transferred between ~~registered~~ industrial hemp manufacturers, or certified laboratories, and will undergo further refinement or processing into an industrial hemp product.

Section 21.7.F. – Industrial Hemp Processing and Manufacturing Requirements, Testing Requirements

- In general, it is unclear which of the requirements in this section apply to manufacturers or businesses located in Colorado, and which apply to out-of-state entities. In particular, Section B should be revised to clarify that only businesses located in Colorado must comply with the requirements outlined in subsections 1 through 4.

  ➔ B. Prior to manufacturing, packaging, or distributing an industrial hemp product or an unfinished industrial hemp product, a business in Colorado shall:

- Section D should be revised, as we are not aware of any "approved" or recommended standard operation procedures ("SOPs") developed by CDPHE, and therefore Colorado facilities involved in the production of hemp products should be able to utilize their own SOPs in accordance for federal requirements for current Good Manufacturing Practices ("cGMPs"), if applicable to the specific type of product being produced. Notably, the FDA does not require SOPs to be "approved" under its cGMP regulations.

  ➔ D. All standard operating procedures and scheduled processes for food and dietary supplements performed in the facility ~~are limited to those approved by the appropriate regulatory authority~~ should comply with applicable federal regulations under 21 CFR Parts 111 and Part 117.

- Section E.2 should be clarified to indicate where and how the required identifying information must be presented or displayed, e.g., on any outer packaging, or whether accompanying testing, paperwork, or other documentation would be sufficient.

- Further to our comments above regarding the definitions of "certified laboratory" and "Certificate of Analysis," Sections F.1 and F.4 appear to require all testing mandated under this section to be conducted only by CDPHE-certified labs, which would likely create a significant bottleneck in the industry and lead to delays in testing if all Colorado manufacturers (and possibly out-of-state manufacturers) are forced to use these labs, as well as increased costs if manufacturers must switch from their preferred lab(s) that are otherwise qualified to perform the testing. It is also unclear whether CDPHE would require out-of-state manufacturers or distributors to use certified labs for testing. A more reasonable approach, and one that most state hemp product regulations follow, is to permit the use of independent, accredited third-party labs that meet defined criteria, as provided in our comments above.

  ➔ 1. Effective July 1, 2021, analytical testing shall be performed by a certified laboratory in accordance with the department's State Public Health Laboratory, Disease Control and Public Health Response Division's, *Hemp Testing Laboratory Certification*, 5 CCR 1005-5, or by an independent laboratory using validated methods for all testing performed.

  ...

  4. All certificates of analysis provided as documentation of conformance with the established testing requirements shall be furnished from a certified industrial hemp testing laboratory, independent laboratory, or a licensed retail marijuana testing laboratory.

- Section F.4.a takes an extreme approach regarding potential exceedance of the contaminant limits outlined in the Proposed Regulations, and should be deleted or at the very least, be revised with a more reasonable time frame, e.g., three business days, to account for potentially inaccurate results and resolution of other testing discrepancies that may affect the accuracy of the results.

  ➔ a. Any exceedance of the contaminant action limits presented in section 21.7(F)(5)(a-e) shall be reported to the department by the industrial hemp manufacturer within ~~48 hours~~ three (3) business days of receipt of the analytical testing results.

- Section 5 should be revised as it is unclear how products that fail testing will be addressed under the Proposed Regulations, and it should permit remediation when possible.

    ➔ Permissible Levels of Contaminants: If an industrial hemp product is found to have a contaminant in levels exceeding those established as permissible under this regulation and cannot be remediated to compliant levels, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this regulation, the department reserves the right to determine, upon good cause and reasonable grounds that a particular product presents a risk to public health or safety and therefore shall be considered to have failed a contaminant test.

- Under Section 5.a, the sample amounts included in the limits for Salmonella and Shiga-toxin-producing Escherichia coli (STEC) Bacteria should be revised to 1 gram each, which is sufficient for both microbials. While some manufacturers use a larger sample, a 25-gram sample size can have a significant economic impact on small businesses that product hemp products.

    ➔ Salmonella spp. Absent in ~~25~~ 1 g
    Shiga-toxin producing Escherichia coli (STEC) – Bacteria Absent in ~~25~~ 1 g

- The pesticide limits under Section 5.c are unrealistic, difficult if not impossible for manufacturers to achieve, and require testing beyond the thirteen (13) pesticides required to be tested under Colorado's Marijuana Rules,[1] and there is no justification or rationale for this lack of parity. The list also includes numerous pesticides that many in the hemp industry are not testing for and for which validated methods may not be available. Thus, if the current limits in the Proposed Regulations are maintained, the majority of the hemp industry will be out of compliance even with an effective date of July 1, 2021, or will be forced to incur significant economic burdens to achieve compliance, assuming compliance is even possible. In addition, the statement "[t]he following pesticides are not allowed in finished hemp products or unfinished hemp products" may imply that products cannot contain any amount of the listed pesticides – including trace amounts up to or below the Limits of Quantification ("LOQ") provided in the table. Further, neither "Dried Hemp" nor "Hemp Oil" are defined making it unclear what products fall under each of these categories. At minimum, we request that CDPHE delay implementation of the pesticide contaminant limit requirements until the industry can work with the Department to develop more reasonable limits for dried hemp and hemp products. Alternatively, we ask that CDPHE revise the limits to reflect those currently used for cannabis products in other states, such as California.[2]

- The last row of the table in Section 5. for Residual Solvents states that "any other solvent not permitted" cannot be detected in the product, but fails to specify exactly which solvents are not permitted. We request that CDPHE include a reference or otherwise indicate which solvents cannot be used.

Section 21.7.G. – Industrial Hemp Processing and Manufacturing Requirements, Packaging and Labeling Requirements

- Section G.2 should be revised to include "direct contact" as suggested below.

    ➔ 2. Direct contact ~~P~~product packaging shall be food-grade or GRAS and labeling shall be performed in accordance with 21 C.F.R. 101, subparts A–G and the department's labeling requirements for hemp food products, which includes:

[1] 1 CCR 212-3, 4-115 – Regulated Marijuana Testing Program: Sampling and Testing Program, Section D.5., Pesticides.
[2] 16 CCR § 5719, Residual Pesticides Testing.

- Section G.2 should be revised to be consistent with FDA regulations concerning the statement of identity.[3]

  ➔ a. Product Identity Statement (in bold type) which indicates the common or usual name of the food ~~ingredient~~ or in the absence therefore, an appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food. Dietary supplements shall be identified by the term "dietary supplement" as a part of the statement of identity, except that the word "dietary" may be deleted and replaced by the name of the dietary ingredients in the product or an appropriately descriptive term indicating the type of dietary ingredients that are in the product.

- Section G.2.b should be deleted, or revised to clarify that a QR Code, other scannable code, or URL on the product label or packaging that links to a Certificate of Analysis ("COA") must provide information regarding the total THC content of the product. Including THC content on the label will require costly, continuous reprinting of packaging and labels given the natural variability of THC in hemp products, especially at low levels of 0.3% or less, creating significant supply chain and logistical challenges. In contrast, COAs available via scannable code or URL are live and can be updated for each batch, and the majority of hemp products already include a code or URL on the label or packaging. If this requirement is included in the final regulations, Colorado would be the only state other than West Virginia to require THC content on product packaging – adding to the growing patchwork of state-by-state requirements and placing significant burdens on the hemp industry without any meaningful consumer protection benefit.
  More importantly, responsible companies are not marketing hemp products for their THC content and not intentionally adding THC to hemp products as an ingredient on its own. Rather, companies using hemp-derived ingredients are calculating the concentration of THC for purposes of compliance with federal and state 0.3% concentration limits. Identifying the total THC content per serving and total THC content per finished individual product packaging could also consumer confusion and may encourage over-consumption of hemp products by drawing unnecessary attention to the THC content. For these reason, we request CDPHE delete this labeling requirement or

  ➔ b. Identify ~~in milligrams~~ the total THC content ~~per serving and total THC content~~ per individual finished product package which must be available through a Certificate of Analysis that can be accessed using a URL, QR code, or other scannable code on the product packaging;

  Although we maintain that information regarding THC can be accessed through the COA available via scannable code or URL, if CDPHE believes disclosure of THC content is necessary, we urge CDPHE to require disclosure only if total THC is present at a concentration greater than 0.05% per serving or if the product contains more than 2 milligrams of total THC per container or package, which should be disclosed in milligrams per serving only and may be rounded, rather than requiring both per serving and total milligrams per container or package. This approach is more feasible for manufacturers while also providing consumers with adequate information regarding the THC of the product. Regardless of the approach chosen by the CDPHE, the requirement to disclose THC in milligrams per serving will have a significant impact on all businesses, particularly small businesses, as it relates to labeling and packaging costs.

  Although we maintain that information regarding THC can be accessed through the COA available via scannable code or URL, if CDPHE believes disclosure of THC content is necessary, we urge CDPHE to require disclosure only if delta-9 THC is present at a concentration greater than 0.05% per serving or if the product contains more than 2 milligrams of delta-9 THC per container or package, which should be disclosed in milligrams per serving only and may be rounded, rather than requiring both per serving and total milligrams per container or package. This approach is more feasible

[3] *See* 21 CFR § 101.3 (b) and (g), Identity labeling of food in packaged form.

for manufacturers while also providing consumers with adequate information regarding the delta-9 THC content of the product. Regardless of the approach chosen by the CDPHE, the requirement to disclose THC in milligrams per serving will have a significant impact on all businesses, particularly small businesses, as it relates to labeling and packaging costs.

- Section G.2.d should be revised to accord with FDA regulations, which require a "Net Quantity of Contents" statement and not "Net Weight" specifically.[4] Further, to avoid any potential conflict with federal requirements, the Proposed Regulations should not be overly prescriptive with respect to the placement of this statement given variations in package size and shape. Similar to federal requirements, the Proposed Regulations should take a more flexible approach.

  ➔ d. Net ~~Weight~~ Quantity of Contents Statement placed as a distinct item parallel to the base of the package in the bottom third of the principal display panel, or otherwise in accordance with 21 CFR Part 101; and

- Section G.2.e(2) appears to require the total amount in milligram of each isolated cannabinoid and/or broad or full spectrum ingredients to be included in the ingredients list, which conflicts with FDA regulations concerning ingredient listings and would be preempted with respect to food and dietary supplement product labels.[5] Therefore, subsection (2) should be a stand-alone section and not included as a requirement for the list of ingredients.

- For the reasons stated above in our comments to Section G.2.b, the requirement to identify in milligrams the total THC content per product and per serving should be deleted or substantially revised. To the extent this requirement applies

[4] *See*, e.g., 21 CFR § 101.7, Declaration of net quantity of contents.

[5] *See* 21 USC 343-1. National uniform nutrition labeling. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—
(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,
(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,
(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,
(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or
(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.
Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.
(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—
(1) would not cause any food to be in violation of any applicable requirement under Federal law,
(2) would not unduly burden interstate commerce, and
(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

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to the ingredient listing, it also preempted with respect to food and dietary supplements, as noted in our previous comment.

- In Sections G.5 and G.6, the term "qualified" is unclear and should be deleted. Neither FDA nor FTC use the term "qualified" in such a broad context regarding health benefits claims and substantiation. In addition, because the term "health claim" is defined by FDA in regulation,[6] the term as used in this section should be revised to "health-related claim" to avoid confusion.

  ➔ 5. Health-related claims for hemp or hemp-derived ingredients ~~must be qualified~~ must follow Federal Trade Commission (FTC) and FDA regulations and guidance, including marketing materials and electronic communications.
  6. The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product. This applies to ~~qualified~~ claims on products and as well as ingredients, aerosol products, deodorant products, foaming detergent bath products, coal tar hair dyes, sun-tanning and sunscreen products.

- Section H.1 should be revised to specify that only facilities in Colorado that manufacture, process, pack, or hold food or dietary supplements must comply with the cGMP-related record keeping requirements, as cosmetic facilities are not required to do so under FDA regulations.[7]

  ➔ For all in-state facilities that manufacture, process, pack, or hold food or dietary supplements, the following records shall be maintained, as required herein:

- Section H.1.d should be revised to clarify that sourcing records only apply to hemp ingredients, given the limited scope of the Proposed Regulations which are not intended to apply to non-hemp ingredients.

  ➔ Source of ~~ingredients~~ industrial hemp ingredient.

- Similar to Section H.1, the records requirements under Section H.2. and H.3 should only apply to facilities in Colorado that manufacture, process, pack, or hold food or dietary supplements.

  ➔ For all in-state facilities that manufacture, process, pack, or hold food or dietary supplements, records shall:
  …
  3. Record retention for all food, and food additive~~, and cosmetic~~ manufacturing facilities

- Section I should also be revised to apply only to food and dietary ingredient facilities, as 21 CFR § 117.39 applies specifically to food with a hazard requiring a preventive control, and not cosmetics or finished dietary supplement products.[8] Further, 21 CFR Part 117 only applies to conventional food products and dietary ingredients, which are regulated as "food" under FDA regulations.

[6] *See*, e.g., 21 CFR § 101.14, Health claims: general requirements.
[7] However, FDA has issued non-binding guidance concerning Cosmetic Good Manufacturing Practices, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-cosmetic-good-manufacturing-practices.
[8] See 21 CFR § 117.39, requiring recall plans for "food with a hazard requiring a preventive control."

➔ Industrial hemp ~~product~~ food and dietary ingredient processing and manufacturing facilities shall establish a written recall plan in accordance with 21 C.F.R. 117.139, Recall Plan, that includes procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

* * *

In closing, we appreciate the opportunity to comment on the Proposed Regulations, and respectfully urge CDPHE to include the suggested modifications described above, which we believe will encourage compliance and protect both consumers and the industry.

Thank you for your consideration.

Sincerely,

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