



Council for Responsible Nutrition

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275 East Main Street 5 W-A
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RE: 902 KAR 45:190, Hemp-derived cannabidiol products and labeling requirements.

The Council for Responsible Nutrition (CRN)¹ submits these comments, along with our position paper, *Hemp-Derived CBD Dietary Supplement Position*, attached, in consideration of the Proposed Kentucky Administrative Regulation 902 KAR 45:190, hemp-derived cannabidiol products and labeling requirements. Our position paper details CRN's commitment to ultimately a federal regulatory scheme for hemp-derived CBD dietary supplements, and while we await clarity at the federal level for the application of federal requirements for dietary supplements to CBD, the promotion of state laws and regulations regulating hemp-derived CBD dietary supplements in a manner consistent with federal requirements for these products.

CRN continues to work with Congressional leaders to support passage of federal legislation, H.R. 8179, the [Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020](#). This legislation, if enacted, will direct that CBD be recognized as a lawful dietary ingredient irrespective of any other definitional hurdles in the federal Food, Drug & Cosmetic Act and will require that these CBD-containing products adhere to the same legal requirements for manufacturing, labeling, promotion and usage as any other dietary supplement. It provides a clear legal pathway to market for dietary supplements containing hemp-derived CBD and will help protect the health and safety of consumers by addressing many of the concerns that currently exist from an untamed market. We expect Congress to entertain this legislation early

¹The Council for Responsible Nutrition (CRN), founded in 1973, is a Washington, D.C.-based trade association representing 190+ dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN's Code of Ethics. Visit, www.crnusa.org. Follow us on: Twitter [@CRN_Supplements](#), [Facebook](#), and [LinkedIn](#).

in the 117th session and strongly encourage states looking to adopt their own hemp-related regulatory structures to fashion ones that would be consistent with that federal framework. In anticipation of Congress's rapid consideration and enactment of this legislation, we would like to encourage the following edits to the proposed Kentucky regulation.

Section 1: Definitions

CRN recommends the Kentucky Department of Public Health to incorporate a definition of hemp that mirrors the Agriculture Improvement Act of 2018 (commonly referred to as the 2018 Farm Bill)—namely that “hemp” is defined as:

“the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis” in the definition section of this proposed regulation. Cannabis is a plant of the Cannabaceae family and contains more than eighty biologically active chemical compounds. The most commonly known compounds are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD).”

Cannabidiol or CBD means the naturally occurring phytocannabinoid cannabidiol found in hemp and can be utilized as the definition of CBD for this proposed regulation as well.

Section 2: Permits

CRN suggests a clarification to this section and re-write as follows.

Original language: (1) A person seeking to manufacture, market, sell, or distribute a hemp-derived CBD ingestible or cosmetic product shall submit an Application for Permit to Operate a Food Plant or Cosmetic Manufacturing Plant, incorporated by reference in 902 KAR 45:160, to the department

New language proposal: (1) If a person seeks to operate a food, dietary supplement or cosmetic manufacturing plant in the state that manufactures a product containing hemp-derived CBD, they must apply for a permit from the Kentucky Department of Public Health.

The purpose of CRN's proposed revisions is to provide for better clarity, in that this language would distinctly authorize the state to require persons who manufacture hemp-derived CBD products in the state of Kentucky to register their manufacturing facilities with the state, while excluding from the registration and permit requirement those persons who are only selling or marketing a hemp-derived CBD product in the state of Kentucky, but manufacture their products in another state.

Section 3: Product Labeling

Original language with proposed strikethroughs and additional language:

(1) Each hemp-derived CBD product manufactured, marketed, sold, or distributed in the Commonwealth shall be labeled in accordance with KRS 217.037 ~~and this administrative regulation~~ **or federal regulations related to food, cosmetics and dietary supplements.**

(c) The ingredients of the hemp-derived CBD product, in descending order of predominance by weight **listed in the ingredients statement;**

(j) **If the hemp or hemp product is manufactured in the state of Kentucky, the product can denote,** ~~The~~ “Kentucky Hemp” or “Kentucky Proud” logo or a similar marking that denotes the product was produced in Kentucky.

~~(3) Each container of ingestible or cosmetic hemp-derived CBD product shall bear either a foil seal on the inside or a plastic sealant on the outside.~~

The purpose of CRN’s proposed revisions is to provide for better clarity and consistency with current Federal Food and Drug Administration (FDA) labeling and packaging requirements and regulation of dietary supplements overall.

Specifically, adding “or federal regulations related to food, cosmetics and dietary supplements” captures how food, cosmetics and dietary supplements are currently and extensively regulated by FDA under the federal Food, Drug and Cosmetic Act.² Without this language included, inconsistency and conflict arise because there are additional and specific labeling requirements for dietary supplements that are not covered in this proposed regulation.

Moreover, section (3)(c), as proposed, is inconsistent with current federal requirements as not all of the ingredients in a dietary supplement are listed together in descending order of predominance by weight, as some are listed separately per federal nutrition labeling requirements. Under federal regulations for dietary supplements there is a category of ingredients called “dietary ingredients” that may include vitamins and minerals that are required to be listed in a prescribed order not related to predominance by weight in the Supplement Facts panel. However, source ingredients for “dietary ingredients” and other ingredients in a supplement product, such as excipients or flavors, are listed in an “ingredients statement” below the Supplement Facts panel in descending order of predominance by weight. In the promotion of better consistency between state and federal regulation of dietary supplement products CRN proposes the above inclusion in section (3)(1) and section (3)(c). Please note that the inclusion of CRN’s proposed language to section (3)(1) would preclude any additional edits to “Section 3: Product Labeling” as varying product categories, including dietary supplement, manufacturers

² See, 21 CFR 101.

and suppliers could (and are already required by federal law) choose to comply with current federal regulations for their respective products.

Additionally, for better clarity of language that reflects the intent of the state to set out the specific labeling requirement of hemp-derived CBD products manufactured in the state to capture the marketability and prestige of Kentucky hemp to be labelled and marketed as “Kentucky Hemp” or “Kentucky Proud”, CRN has proposed the above revision to section (j).

Moreover, the purpose of CRN’s proposed strikethrough of section (3)(3) reflects CRN’s commitment to maintaining consistency with dietary supplement packaging requirements and overall regulation by FDA, detailed in the federal Food, Drug and Cosmetic Act, which sets out packaging requirements for dietary supplements that do not include the language in section (3)(3).³

Section 4. Hemp-derived ingestible CBD product as a food additive.

Original language with proposed strikethroughs and additional language:

Section 4. Hemp-derived ingestible CBD product. ~~as a food additive.~~

(1) Hemp-derived CBD may be added to an ingestible product during the manufacturing process, **and manufactured, marketed, sold, and distributed in this state by out of state producers if the product meets this state’s or another states hemp product quality requirements**, or prior to ~~retail~~ sale at a food service establishment.

The purpose of CRN’s proposed revisions provide for better clarity. Specifically, the state’s intent to regulate state-based manufacturers of food, dietary supplements and cosmetics that contain hemp-derived CBD, not solely as a “food additive” is better understood with the strikethrough of “as a food additive” in the title of section 4.

Moreover, the state’s intent to regulate state-based manufacturers of food, dietary supplements and cosmetics that contain hemp-derived CBD is better understood and creates opportunities for a diversified marketplace with language, in section 4(1) that includes the ability of ‘out of state producers’ to “manufacture, market, sell, and distribute” hemp-derived CBD products in the state, as long as the person complies with Kentucky or another states’ “quality requirements”. The testing of hemp products is important for quality control and meeting the threshold requirements of the 2018 Farm Bill definition of “hemp”.⁴

³ See, 21 CFR 174-178.

⁴ See, [Florida Statute 581.217\(7\)\(a\)](#) Distribution and Retail Sale of Hemp Extract, Colorado Department of Public Health & Environment [Industrial Hemp Policy](#).

Should you have any further questions about our position or CRN's efforts at the federal level with respect to hemp-derived CBD, please do not hesitate to contact me. Thank you for your time and consideration.

Sincerely,

Amanda Darlington,
Director, Government Relations
Council for Responsible Nutrition