

Amendments to Cannabinoid Hemp Regulations: Part 114

ASSESSMENT OF PUBLIC COMMENT

OVERVIEW

The New York State Cannabis Control Board (the “Board”) and the Office of Cannabis Management (the “Office”), collectively, received approximately 218 distinct comments in response to the proposed regulations amending Title 9 of the New York Codes, Rules and Regulations (NYCRR), Part 114 (Cannabinoid Hemp) relating to the processing and retail sale of cannabinoid hemp products in New York State. Notice of emergency adoption and proposed rulemaking was filed for publication on the State Register on July 27, 2023. Public comments were received from August 9 through October 10, 2023. The Office received an approximate total of 218 distinct comments submitted from 86 individuals and organizations on the proposed regulations during this period. Commenters included a state government official, hemp industry advocacy organization, hemp industry stakeholders, local health departments, public health associations, public health partner organizations as well as members of the public offering their own expertise on the proposed regulations.

ACCESS TO CANNABINOID HEMP PRODUCTS CONTAINING THC

COMMENT: Several commenters expressed concerns about losing access to purchase cannabinoid hemp products and hemp-derived products in New York. Some of those comments concerning loss of access included:

- Concern that the proposed regulations limit their access and infringe on their rights to access cannabinoid hemp products containing CBD and THC.
- Some commenters interpreted the proposed regulations as a ban on purchasing any cannabinoid hemp products and that cannabinoid hemp is no longer legal in the state.
- Commenters noted that proposed regulations prevent them from accessing cannabinoid hemp products that provide people and animals such as canines, relief from various medical conditions and help individuals avoid the use of pharmaceuticals such as opioids.
- Commenters noted concern about customers losing access to affordable and effective cannabinoid hemp products that help them manage their health and well-being due to the CBD and THC limits in the proposed regulations. Commenters stated that cannabinoid hemp products as they are currently formulated are beneficial for health and wellness purposes. Commenters mentioned several specific hemp product brands and hemp product forms including non-intoxicating full-spectrum cannabinoid hemp products, hemp beverages, and hemp gummies, which would no longer be permissible for retail sale or distribution under the proposed regulations due to the THC limits.

- Commenters stated they are concerned the proposed regulations will result in increased pricing of cannabinoid hemp products containing THC which will limit consumers from accessing and purchasing these products. Commenters explained the proposed regulations on hemp-derived products does not promote public safety and instead pushes consumers to the unregulated market and other state markets to access and purchase cannabinoid hemp products. One commenter recommended allowing licensed retailers to sell lower-potency hemp edibles containing 5 milligrams or less of delta-9 THC per serving and allowing only licensed adult-use dispensaries to sell hemp-derived products containing more than 5 milligrams of delta-9 THC.

RESPONSE: The proposed regulations are not intended to prevent access to cannabinoid hemp products but rather to limit intoxicating products that are better suited for the Office’s Adult-Use Cannabis Program, where additional safeguards are in place to prevent youth and adolescent use and protect public health, safety, and welfare of consumers in New York State to ensure consumers do not consume intoxicating levels unwittingly. In addition, the Office’s Medical Cannabis Program is designed to support and provide access to patients in need of medical cannabis. More information on how to become a certified patient can be found on the Office’s website to ensure that medical needs are being met. Finally, the proposed regulations do not limit access to cannabinoid hemp products that meet the regulatory requirements. No changes were made to the proposed regulations as a result of these comments.

SUPPORT FOR FEDERAL GUIDANCE

COMMENT: Commenters expressed their support for the proposed regulations and provided general suggestions for consideration. Some commenters noted the need for guidance on the federal level regarding the classification of hemp derived products. One commenter requested that THC in cannabinoid hemp products be limited to 0.3% of the total dosage of cannabinoids in the entire package. Some commenters suggested there is an urgent need for uniform federal regulation, in light of interstate commerce and the online sales of cannabinoid hemp products, including CBD beverages. Commenters advocated for the reclassification of cannabinoid hemp products with high-THC levels as cannabis products. Commenters remarked that all psychoactive and intoxicating cannabis and hemp-derived products should meet the regulatory requirements and be regulated under the adult-use structure in New York to protect public health and prevent loopholes that put consumers and populations at risk of unintentional or accidental product exposures. Commenters expressed concerns about the availability of hemp-derived intoxicating products and urged that they are regulated to a higher standard than non-altered hemp or CBD products.

RESPONSE: The proposed regulations ensure hemp-derived products containing intoxicating levels of THC are regulated and sold solely through the Office's Adult-Use Cannabis and Medical Cannabis Programs. Neither the Cannabis Law nor applicable regulations allow for sale of high THC hemp-derived products in the Cannabinoid Hemp Program. While neither the Board nor Office authority extends beyond New York's jurisdiction, the Board and Office agree that there needs to be guidance at a federal level regarding the classification of hemp-derived products and acknowledge these comments. No changes were made to the proposed regulations as a result of these comments.

CBD TO THC RATIO FOR CANNABINOID HEMP PRODUCTS

COMMENT: Commenters stated their concern regarding the proposed CBD to THC ratio of 15:1, while proposing an assortment of differing suggested changes, including:

- Specific cannabinoid hemp products containing higher concentrations of THC such as 1:1 and 1:5 help consumers manage several different medical conditions.
- Suggesting a 2-3 milligram maximum per gummies and a maximum 80-100 milligrams per package, with a minimum 12.5:1 ratio or a 25:1 ratio to help customers manage their health conditions.
- Removing the 15:1 CBD to THC ratio stating that:
 - it does not effectively distinguish between intoxicating and non-intoxicating cannabinoid hemp products; or
 - 2.5 milligrams THC per serving is not economical for adult-use companies and are better suited for the cannabinoid hemp marketplace as they are not overly intoxicating but rather promote general wellness, and therefore to limit cannabinoid hemp products to no more than 2.5 milligrams THC per serving and 50 milligrams THC per package, except for flower products or topical products.
 - the proposed CBD to THC ratio does not allow consumers to access micro doses of CBD with a low risk of psycho-activity and can negate or change the micro-dosing effects that consumers may be looking for.
 - consumers demand more formulations and ratioed cannabinoid hemp products.

RESPONSE: The Office acknowledges these comments; however, there was insufficient and inconsistent information provided by these comments with respect to this topic to warrant making the recommended changes. In drafting the hemp regulations, the Office completed a regulatory analysis of the eight (8) states with THC limits imposed on cannabinoid hemp products, the available peer reviewed literature, and task force recommendations from three (3) states that convened task forces, as well as analyzed numerous studies to determine an appropriate level of THC in cannabinoid hemp products. The Office will continue to monitor safety data concerning CBD, with a commitment to improving our regulatory framework. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Commenters stated they are unaware of adverse events related to full-spectrum hemp products, or incidents of abuse or misuse or other safety concerns, including intoxication. Other commenters noted the potency limits per package will not prevent consumers looking to become intoxicated from consuming more.

RESPONSE: The Office acknowledges these comments; however, as no specific changes were requested, no changes were made to the proposed regulations as a result of these comments.

CANNABINOID LIMITS IN CANNABINOID HEMP PRODUCTS

COMMENT: Commenters proposed increasing the total cannabinoid content limit in individually packaged product from 25 milligrams to a minimum of 100 milligrams and a 5 milligram THC per serving limit. Commenters stated that some consumers require higher cannabinoid dosages for effective relief.

RESPONSE: The Office acknowledges these comments; however, there was insufficient and inconsistent information provided by commentors with respect to this topic to warrant making the recommended changes. The proposed regulations limit orally consumed cannabinoid hemp products to 3,000 milligrams of total cannabinoids per package, with no more than 100 milligrams of total cannabinoids per individual serving, provided however, if the orally consumed product is in the form of a tincture it is limited to 4,000 milligrams of cannabinoids per package. In drafting the hemp regulations, the Office completed a regulatory analysis of the eight (8) states with THC limits imposed on cannabinoid hemp products, the available peer reviewed literature, and task force recommendations from three (3) states that convened task forces, as well as analyzed numerous studies to determine an appropriate level of THC in cannabinoid hemp products. The Office will continue to monitor safety data concerning CBD, with a commitment to improving our regulatory framework. No changes were made to the proposed regulations as a result of these comments.

PACKAGING AND LABELING OF CANNABINOID HEMP PRODUCTS

COMMENT: Various comments were received regarding the packaging and labeling of cannabinoid hemp products. Commenters suggested the presence of THC should be prominently displayed on the principal display panel label on cannabinoid hemp products containing 5 milligrams of THC per serving or less. Commenters stated the product requirements set forth in the proposed regulations will negatively impact hemp manufacturers and retailers. Commenters noted the proposed regulations will lead to burdensome costs and environmental waste due to repackaging and relabeling. Some commenters articulated that packaging does not prevent accidental and underage consumption events that occur after purchase. Some commenters expressed doubt that repackaging and relabeling of hemp product benefits public health. Some commenters recommended the use of alternative child-proof containers including child safety bags, black opaque plastic wrapping to prevent accidental consumption, similar to packaging used in other states.

RESPONSE: The cannabinoid hemp packaging, labeling, marketing, and advertising requirements are intended to be reasonably consistent across the cannabinoid hemp, adult-use, and medical programs. There was insufficient and inconsistent information provided with respect to this topic to warrant making the recommended change, therefore no changes were made to the proposed regulations as a result of these comment.

TESTING REQUIREMENTS FOR CANNABINOID HEMP PRODUCTS

COMMENT: Commenters advocated for comprehensive testing requirements to ensure that consumers have access to accurately dosed and safe hemp beverages containing THC. One commenter stated keeping cannabinoid hemp products legal for retail sale allows for scientific testing to be completed with less stringent rules. Some commenters stated it will be financially burdensome to incorporate the additional required testing on cannabinoid hemp products that have already completed third party lab testing.

RESPONSE: The Office acknowledges this comment; however, there was insufficient and inconsistent recommendations and comments provided with respect to this topic to warrant making any changes. No changes were made to the proposed regulations as a result of this comment.

AGE REQUIREMENTS FOR CANNABINOID HEMP PRODUCT PURCHASES

COMMENT: One commenter suggested establishing the minimum age to purchase cannabinoid hemp products at either 18 or 21 years old. Commenters agreed with the minimum age requirement to purchase cannabinoid hemp products however did not agree with the 0.5 milligrams total THC per serving or more as the appropriate limit. Commenters suggested that along with an appropriate THC limit, regulatory requirements such as, mandatory licensing, product labeling requirements, packaging and retail sale age restrictions, can help to ensure potentially intoxicating products are not appealing or accessible to minors. One commenter stated limiting cannabinoid hemp products containing 0.5 milligrams or more of total THC per serving to those 21 and older acknowledges and contemplates that the regulated cannabinoid hemp space may contain intoxicating products similar to those offered for sale in adult-use dispensaries and rely on consumer maturity and ability to make rational, well-informed decisions about products and their consumption.

RESPONSE: The Office acknowledges these comments; however, there was insufficient and inconsistent recommendations and comments provided with respect to this topic to warrant making any changes. No changes were made to the proposed regulations as a result of these comments.

COMPLIANCE PERIOD

COMMENT: Commenters emphasized the importance of a sell-through period to ensure an orderly transition for businesses. Commenters suggested allowing retailers to continue selling cannabinoid hemp products that are part of their existing inventory prior to the effective date of the regulation and/or establishing a minimum 180-day effective date for the THC limits to allow the industry reasonable time to come into compliance with the new packaging and formulation requirements for hemp product sold in New York. Some commenters expressed their businesses cannot financially afford to change their product formulas and packaging by the January 1, 2024 effective date and request an extension of 180 days or the latest end of 2024 for the sale of non-compliant cannabinoid hemp products. These commenters stated the additional time will allow businesses to adapt to the proposed regulations and meet label and market requirements effectively. Some commenters noted their agreement with the effective date of January 1, 2024 for business to come into compliance with the revised packaging, labeling, and advertising requirements.

RESPONSE: These proposed regulations were necessary to immediately allow the Office to address several challenges with the processing and retail sale of cannabinoid hemp products in New York State, and to protect public health and safety by, among other things, limiting the THC content of these products to prevent retail sale of intoxicating cannabinoid hemp products and ensuring consumers are not misled by these products' marketing. No changes were made to the proposed regulations as a result of this comment.

CANNABINOID HEMP SALES AT ALCOHOL RETAIL ESTABLISHMENTS

COMMENT: Commenters suggested allowing business such as bars and liquor stores to obtain a license to sell cannabinoid hemp products. One commenter noted it has been proposed in other states to allow liquor stores to sell lower-potency edible cannabinoid hemp products containing no more than 5 milligrams THC per serving. Several commenters noted low-potency THC beverages can serve as an alcohol alternative and benefit public health.

RESPONSE: These comment are out of scope as this recommendation would require the collaborative efforts of the State Liquor Authority that has not previously been contemplated by the MRTA nor these regulations. No changes were made to the proposed regulations as a result of these comments.

IMPACT ON BUSINESSES

COMMENT: Commenters are concerned the proposed regulations negatively impact businesses and place undue burdens on businesses operating in New York. Comments included concerns such as:

- the proposed regulations inadvertently allow out-of-state and online entities to operate with minimal oversight;
- the CBD and THC requirements prevent businesses from selling many of their current cannabinoid hemp products and decreases their ability to provide a diverse range of products;
- concerns about the compliance challenges cannabinoid hemp licensees are facing due to the proposed regulations;

- the impact of the proposed regulations on cannabinoid hemp product inventory, noting that portions of licensee inventory did not align with the proposed regulations;
- the negative impact of the proposed regulations on their production, sales, and revenue;
- concern that the proposed regulations will negatively impact small businesses, women and minority owned businesses, local farmers, retail stores, distributors, and manufacturers that sell hemp and CBD products in New York and will force them to take their businesses out of state; and
- concern that the proposed regulations impact on profits will result in a reduction in the number of jobs available in hemp retail stores and career opportunities for younger, low-income New Yorkers.

RESPONSE: Cannabinoid hemp licensees and permittees distributing or offering cannabinoid hemp retail sale, including online retail sale of cannabinoid hemp products to consumers in New York State must meet all of the requirements set forth in Part 114. While there would be an immediate initial impact on businesses, the Office considered a number of mitigating factors when developing the regulations including, among others: the compelling state interest in making sure to limit intoxicating products that are better suited for the Office’s Adult-Use Cannabis Program, where additional safeguards are in place to prevent youth and adolescent use and protect public health, safety, and welfare of consumers in New York State; following the effective date of the regulations, producers and licensees will not be prevented from selling those products that they are no longer authorized to sell in New York State to out-of-state consumers and vendors in states that authorize the legal sale of those products. No changes were made to the proposed regulations as a result of this comment.

MAIL ORDER CANNABINOID HEMP PRODUCTS

COMMENT: One commenter requested the continued legality of mail order cannabinoid hemp products.

RESPONSE: There were no changes to the regulation that would prohibit the continued legality of mail order cannabinoid hemp products. No changes were made to the proposed regulations as a result of this comment.

ENFORCEMENT

COMMENT: Comments were received regarding the importance of enforcement in the cannabinoid hemp product industry. Commenters suggested the implementation of robust regulatory frameworks to enforce hemp-based THC limits, ensuring accurate product labeling, standardized testing protocols, and strict compliance measures. Commenters urged that collaboration with industry stakeholders, regulatory agencies, and law enforcement authorities is crucial to ensure effective enforcement and monitoring of THC levels in cannabinoid hemp products. One commenter suggested lawmakers assess the practicality of implementing regulations around THC limits and the resources required for effective monitoring and enforcement of these limits.

RESPONSE: The Office appreciates these comments. Enforcement actions continue for any unlicensed or noncompliant activity by a cannabinoid hemp licensee or permittee. No changes were made to the proposed regulations as a result of this comment.

PUBLIC EDUCATION

COMMENT: Commenters recommended the development of comprehensive education and awareness campaigns focused on promoting responsible use, the importance of adhering to serving sizes, and the implications of impaired driving.

RESPONSE: The Office has developed public education campaigns and supplemental educational materials around cannabis to inform New Yorkers about safer and responsible consumption for adults 21 years of age and older. Educational materials are available on the Office's website at: <https://cannabis.ny.gov/adult-use-information>. No changes were made to the proposed regulations as a result of these comments.

SOCIAL EQUITY

COMMENT: One commenter urged for conformity when enforcing laws on individuals possessing or distributing federally legal substances – such as hemp. Several commenters expressed that the proposed regulations governing cannabinoid hemp products demonstrate the Office’s misunderstanding of cannabinoid products and contradicts efforts to decriminalize cannabis, noting that the prosecution of individuals for possessing or distributing hemp products further contributes to unjust law enforcement against marginalized groups. One commenter noted the proposed regulations would result in their stores closing in New York and loss of jobs for BIPOC employees. One commenter stated the availability of cannabinoid hemp products at numerous, widely available hemp retailers promotes equity and access to cannabinoid hemp products in disadvantaged communities—aligning with the equity goals established in statute.

RESPONSE: The Office acknowledges these comments; however, there were insufficient recommendations provided with respect to this topic to warrant making any changes. No changes were made to the proposed regulations as a result of these comments.

CANNABINOID HEMP FLOWER

COMMENT: Some commenters advocated for the inclusion of smokable hemp flower products in cannabinoid hemp retail spaces, including pre-rolls. Commenters noted that several minor cannabinoids are absorbed best via inhalation or combustion. Commenters stated the lack of hemp flower pre-rolls limits their business product lines.

RESPONSE: The Office acknowledges these comments; however; the recommended changes would require a change in the statute by the Legislature and therefore these comments is out of scope. No changes were made to the proposed regulations as a result of these comments.

COMMENT: Some commenters recommended an increase in total THC allowance for hemp flower products from 0.3% to 1%. Commenters stated the proposed regulations for hemp flowers to be tested below 0.3% total THC after decarboxylation would eliminate most hemp cannabinoid flowers from the market both in and out of New York State.

RESPONSE: The Office acknowledges these comments however they would require a change in the definition of hemp in federal law and therefore the comments are out of scope. No changes were made to the proposed regulations as a result of these comments.

MULTIPLE SERVINGS IN CANNABINOID HEMP BEVERAGES

COMMENT: Commenters stated they do not agree with the product packaging requirements for cannabinoid hemp beverages because they believed the measuring device requirement for multiple servings applies to cannabinoid hemp beverages. Other commenters expressed that the single serving packaging requirement for cannabinoid hemp beverages imposes a higher standard and unfairly burdens the cannabinoid hemp beverage market in several material ways.

Commenters requested the removal of the single serving limit and others provided recommendations to increase the THC limits for cannabinoid hemp beverages. Commenters expressed concerns about the cost of reformulation and repackaging of cannabinoid hemp products containing multiple servings and cannabinoid hemp products in the form of a beverages for businesses and manufacturers. Several commenters suggested allowing multiple servings per product without restricting how they are divided up in the package. Commenters stated the new packaging requirements for hemp beverages are wasteful and raised concerns about the impact on the environment. Commenters expressed concern that the packaging requirements will result in increased prices for consumers.

RESPONSE: The Office acknowledges these comments; however there was insufficient and inconsistent information provided with respect to this topic to warrant making the recommended changes. In drafting the hemp regulations, the Office completed a regulatory analysis of the eight (8) states with THC limits imposed on cannabinoid hemp products, the available peer reviewed literature, and task force recommendations from three (3) states that convened task forces, as well as analyzed numerous studies to determine an appropriate level of THC in cannabinoid hemp products. The Office will continue to monitor safety data concerning CBD, with a commitment to improving our regulatory framework. No changes were made to the proposed regulations as a result of these comments.

IMPACT ON INTERSTATE COMMERCE

COMMENT: Comments were received stating that the proposed regulations may unduly affect interstate commerce and hinder the free flow of cannabinoid hemp products across state lines. Commenters proposed amendments to the regulation to clearly allow for the sale of federally legal hemp-derived products prohibited in New York, outside of the state. Commenters expressed concern that the proposed regulations will reduce economic activity in New York.

RESPONSE: The proposed amendments were never intended to prevent hemp-derived products that are prohibited in New York from being sold out of state. The Office will consider developing guidance to clarify any discrepancies in the regulation and continue to monitor safety data to improve the proposed regulatory framework. No changes were made to the proposed regulations as a result of these comments.

RECOMMENDATIONS ON THC LIMITS PER SERVING SIZE OR PER PACKAGE

COMMENT: Comments were received which suggested various ways to limit or restrict the amount of THC per serving and per package. Some examples include:

- allowing up to 5 milligrams of THC per serving in all cannabinoid hemp products based on scientific-based studies. Commenters submitted a white paper summarizing scientific studies as evidence in support of instituting an upper limit of 5 milligrams of THC per serving;
- to establish THC potency standards using a more uniform approach through federal legislation, such as the Farm Bill;
- a comprehensive approach that takes into account factors such as tolerance, individual dosage, metabolism, and the endocannabinoid system. Commenters stated further research and study is needed on CBD to create regulations that maintain consumer safety and support cannabinoid hemp businesses.

RESPONSE: The Office acknowledges these comments; however, there was insufficient and inconsistent information provided with respect to this topic to warrant making the recommended changes. In drafting the hemp regulations, the Office completed a regulatory analysis of the eight (8) states with THC limits imposed on cannabinoid hemp products, the available peer reviewed literature, and task force recommendations from three (3) states that convened task forces, as well as analyzed numerous studies to determine an appropriate level of THC in cannabinoid hemp products. The Office will continue to monitor safety data concerning CBD, with a commitment to improving our regulatory framework. No changes were made to the proposed regulations as a result of these comments.

SALES TAX ON CANNABINOID HEMP PRODUCT

COMMENT: Commenters remarked that increased availability of lower potency cannabinoid hemp products outside the dispensary setting has the potential to significantly increase sales tax revenue in the state. Other commenters proposed that hemp retailers be subject to reasonable sales tax on cannabinoid hemp products containing over 1 milligram of THC similar to models proposed by other states. Commenters stated funds from sales taxes can be used towards social equity programs for hemp and cannabis entrepreneurs in an effort to support small and medium-sized businesses and entrepreneurs.

RESPONSE: The Office acknowledges these comments; however, there was insufficient and inconsistent information provided with respect to this topic to warrant making the recommended changes. No changes were made to the proposed regulation as a result of these comments.

SYNTHETIC CANNABINOID PRODUCTS

COMMENT: One commenter expressed that the proposed regulations would restrict the retail sale of synthetic products to consumers.

RESPONSE: The Office acknowledges this comment; however, there was insufficient information provided with respect to this topic to warrant making a change to the proposed regulation. Accordingly, no changes were made to the proposed regulations as a result of this comment.