

EMERGENCY REGULATION – Part 114 Cannabinoid Hemp Regulations

Pursuant to the authority vested in the Cannabis Control Board by sections 13 and 91 of the Cannabis, Chapter II of Subtitle B Part 114 of Title 9 of the Official Compilation of Codes Rules and Regulations of the State of New York is hereby amended, to be effective upon filing of a Notice of Emergency Adoption in the New York State Register, to read as follows:

Subdivisions (a) through (h) of section 114.1 are renumbered to subdivisions (b) through (i) and a new subdivision (a) is added to read as follows:

(a) Attractive to individuals under twenty-one means attractive to individuals under twenty-one as defined in Part 128 of this Title.

Newly renumbered subdivision (g) of section 114.1 is amended to read as follows:

(g) Cannabinoid hemp farm processor means a cannabinoid hemp processor that is licensed to cultivate hemp by the New York State Department of Agriculture & Markets and is permitted to manufacture [cannabinoid hemp] flower products. A cannabinoid hemp farm processor shall not:

(1) produce more than 1,000 pounds of dried hemp flower annually;

(2) purchase or sell hemp or hemp extract other than those produced from hemp grown on their own farm; or

(3) perform extraction as defined in [subdivision (1)] section 114.1 of this [Section]Part.

Subdivisions (i) through (m) of section 114.1 are renumbered as subdivisions (k) through (o) and a new subdivision (j) is added to read as follows:

(j) Concentrated cannabinoid hemp product means:

(1) the separated resin, whether crude or purified, obtained from cannabinoid hemp; or

(2) a material, preparation, mixture, compound or other substance which contains no more than three-tenths of a percent (0.3%) by weight or by volume of total THC.

Newly renumbered subdivision (m) of section 114.1 is amended to read as follows:

(m) *Craft* means a cannabinoid hemp product manufactured from hemp grown by a licensed hemp grower who grows less than 1,000 pounds of dried hemp flower annually and the hemp is hand trimmed, hang dried if a [cannabinoid hemp] flower product hand packaged.

Subdivisions (n) through (p) of section 114.1 are renumbered as subdivisions (q) through (s) and a new subdivision (p) of section 114.1 is amended read as follows:

(p) *Exit package* means exit package as defined in Part 128 of this Title.

Subdivision (t) of section 114.1 is added to read as follows:

(t) *Health claim* means health claim as defined in Part 128 of this Title.

Subdivisions (q) through (v) are renumbered as subdivisions (u) through (z) and newly renumbered subdivision (y) is amended to read as follows:

([u]y) *Manufacture* means to prepare, treat, modify, compound, process, package or otherwise manipulate hemp or hemp extract into a cannabinoid hemp product. Manufacturing shall not include:

(1) growing, cultivating, cloning, harvesting, drying, curing, grinding or trimming when authorized pursuant to article 29-A of the Agriculture and Markets Law; or

(2) extraction as defined in [subdivision (l)] section 114.1 of this [section] Part.

Subdivisions (w) through (z) of section 114.1 are renumbered as subdivisions (ac), (ae), (ag) and (ai) and new subdivisions (aa), (ab), (ad), (af), and (ah) of section 114.1 are added and newly renumbered subdivision (ac) and (ag) are amended to read as follows:

(aa) Orally consumed product means any cannabinoid hemp product intended for use or consumption through ingestion, including sublingual or oral absorption.

(ab) Package means a sealed, hard or soft-bodied, receptacle in which the cannabinoid hemp product shall be placed before retail sale. Retail package does not mean: (1) inner wrapping or lining; (2) an exit package; or (3) a non-consumer package used to transfer cannabinoid hemp from one licensee to another.

([w]ac) Person means person as defined in article 1 of the Cannabis Law.

(ad) Resealable means a package that preserves the integrity of cannabinoid hemp products contained within, for multiple servings.

([x]ae) Serious adverse event means a medical occurrence associated with the use of a cannabinoid hemp product in a human that results in one or more of the following outcomes: death, a life- threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.

(af) Tincture means a non-potable edible cannabinoid hemp product that is a cannabinoid hemp extract solution, intended for human consumption or ingestion, dissolved in alcohol, glycerin, or plant-based oil.

([y]ag) Total Δ 9-Tetrahydrocannabinol concentration means Δ 9-Tetrahydrocannabinol + (0.877 x tetrahydrocannabinolic acid).

(ah) Total THC means as defined in article 1 of the Cannabis Law.

([z]ai) Used for human consumption means intended by the manufacturer or distributor to be:

(1) used for human consumption for its cannabinoid content; or

(2) used in, on or by the human body for its cannabinoid content.

Paragraph (5) of subdivision (b) of section 114.3 is amended to read as follows:

(5) a statement attesting that the applicant will not sell [inhalable]the following cannabinoid hemp products [or flower products] to consumers under twenty-one (21) years of age[;];

(i) flower product;

(ii) concentrated cannabinoid hemp product including, but not limited to, oil cartridges, pre-filled vape devices, shatter, crumble, wax, resin, or any form intended for inhalation or vaporization;

(iii) any cannabinoid hemp product containing more than 0.5 milligrams of total THC per serving; and

(iv) any other disallowed product as determined by the office.

Section 114.8 is amended to read as follows:

(a) All cannabinoid hemp products distributed or offered for retail sale in New York State shall:

(1) be manufactured in accordance with Parts 101, 111 or 117 of Title 21 of the Code of Federal Regulations, as appropriate for the type of product being manufactured and as otherwise determined appropriate by the office in guidance or future regulation;

(2) contain no more than three-tenths of a percent (0.3%) total Δ 9-Tetrahydrocannabinol concentration[. The office may through future regulation impose a total THC cap for the purpose of protecting public health, which shall include detectable levels of total Δ 9-

Tetrahydrocannabinol, Δ 8-Tetrahydrocannabinol and Δ 10-Tetrahydrocannabinol in milligrams

per serving and milligrams per package for cannabinoid hemp products based on the product form, volume, number of servings, and ratio of CBD to THC];

(3) except for flower products or topical products, contain a ratio of CBD to THC that is 15:1 or higher, provided however, if CBD is not the primary marketed cannabinoid, the sum of cannabinoids excluding THC must have a ratio of 15:1 THC;

([3]4) not contain liquor, wine, beer, cider or meet the definition of an alcoholic beverage as defined in section 3 of the Alcohol Beverage Control Law;

([4]5) not contain tobacco or nicotine in the product;

([5]6) not be in the form of an injectable, inhaler, product including cigarette, cigar, pre-roll, or any other disallowed form as determined by the office;

([6]7) accurately reflect testing results and not contain less than 80 percent or more than 120 percent of the concentration of total cannabinoid content as listed on the product label;

([7]8) comply with packaging and labeling standards in section 114.9 of this Part;

([8]9) be prepackaged and not added to food or any other consumable products at the point of sale;

(9]10) comply with product testing standards in section 114.10 of this Part; and

(1[0]1) not contain synthetic cannabinoids, or cannabinoids created through isomerization, including, but not limited to, Δ 8-tetrahydrocannabinol and Δ 10-tetrahydrocannabinol.

(b) All cannabinoid hemp products distributed or offered for retail sale in New York State shall meet the following additional requirements:

(b]1) [I]f the cannabinoid hemp product is an orally consumed product [food or beverage manufactured under Part 117 of Title 21 Code of Federal Regulations,]it shall not contain more than:[25 milligrams of total cannabinoids per individually packaged product. If the cannabinoid hemp product is a supplement manufactured under Part 111 of Title 21 Code of Federal Regulations, it shall not contain more than 3,000 milligram of total cannabinoids per product, with no more than 100 milligrams per individual serving.]

(i) 10 milligrams total THC per package, with no more than 1 milligram total THC per serving; and

(ii) 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 shall not contain more than:

(a) 100 milligrams of total THC per package; and

(b) 4,000 milligrams of cannabinoids per package.

(2) for cannabinoid hemp products other than flower products, topical products, orally consumed products, or concentrated cannabinoid hemp products, cannabinoid hemp product information must be submitted for review and approval to the office prior to making the product available for sale to retailers and consumers.

(c) If the cannabinoid hemp product contains multiple servings which are not individually wrapped, premeasured, separated or delineated, it shall include a measuring device such as a measuring cap, cup or dropper with the product packaging. Hash marks on the package shall not qualify as a measuring device. This provision shall not apply to flower products, topical products, or concentrated cannabinoid hemp products intended for inhalation or vaporization.

Products that consist of more than a single serving shall be:

(1) packaged in a manner such that a single serving is readily identifiable;

(2) packaged in resealable packaging; and

(3) if an orally consumed product in the form of a beverage, packaged in a manner that shall not have more than a single serving per package, provided however, multiple packages of beverage products can be sold together.

(d) All [~~inhalable~~]concentrated cannabinoid hemp products intended for inhalation or vaporization shall meet the following additional requirements:

* * *

Paragraphs (1), (3) and (10) of subdivision (a) of section 114.9 are amended to read as follows:

(1) if the cannabinoid hemp product is [~~consumed through ingestion~~]an orally consumed product, comply with the requirements in Title 21 Code of Federal Regulations Part 101 and include a nutritional or supplement fact panel that is based on the number of servings within the container;

* * *

(3) except for flower products, topical products, and concentrated cannabinoid hemp products intended for inhalation or vaporization, the number of servings per package or container, including the milligrams per serving of:

* * *

(10) any other marking, statement or symbol as required by the office[in regulation].

Subdivisions (b), (d) (f), and (g) of section 114.9 are amended to read as follows:

(b) No cannabinoid hemp products [packaging] offered for retail sale shall be made attractive to individuals under twenty-one (21) years of age, imitate a candy label, or use cartoons or other images popularly used to advertise to children or otherwise be marketed to individuals[anyone] under twenty-one (21)[18] years of age, or for [inhalable] concentrated cannabinoid hemp products intended for inhalation or vaporization and flower products, to anyone under twenty-one[21] years of age.

* * *

(d) All cannabinoid hemp products shall be accompanied by the following:

(1) recommended size of a serving except for flower products, topical products, and concentrated cannabinoid hemp product intended for inhalation or vaporization; and

(2) clear usage instructions.

* * *

(f) All cannabinoid hemp products offered for retail sale shall include the following warnings on the product label or packaging, in a manner that is clear and conspicuous that:

(1) must be kept out of the reach of children and pets;

(2) [that the]this product is derived from hemp and may contain THC which could result in a failed drug test. Provided however, this warning may be omitted for cannabinoid hemp products that are: topically applied; made exclusively using an “isolate;” or made from “broad spectrum” hemp extract;

(3) [that the]this product has not been evaluated by the Food and Drug Administration for safety or efficacy;

(4) [those who] if you are pregnant or nursing you should consult your[their] healthcare provider before use; [and]

(5) [if the product is an inhalable]for cannabinoid hemp products intended to be inhaled or vaporized, a warning stating that smoking or vap[oriz]ing is hazardous to your health[.]; and

(6) any other warning required by the office.

(g) All [No]information required to be listed on cannabinoid hemp product labeling or packaging in accordance with this section shall be displayed:

(1) in the English language; and

(2) in text no smaller than 4.5 point font.

Subdivision (h) of section 114.9 is added to read as follows:

(h) No cannabinoid hemp product packaging shall display any content, or be labeled in any manner that:

(1) is attractive to individuals under twenty-one;

(2) includes any false or misleading statements, images, or other content including, but not limited to, any health claims;

(3) includes the term “organic” unless describing the product’s ingredients and in compliance with section 128.6 of Part 128 of this Title;

(4) includes the term “gluten-free” unless the product meets the term as defined in Title 21, as it relates to Food and Drugs, of the Codes of Federal Regulations section 101.91;

(5) includes the term “vegan” unless the product contains no animal products;

(6) includes the term “kosher” unless the product is packaged and labeled in compliance with section 128.6 of Part 128 of this Title;

(7) causes a reasonable consumer confusion as to whether the cannabinoid hemp product is trademarked, marked or labeled in a manner that violates any federal trademark law or regulation;

(8) causes a reasonable consumer to believe that a cannabinoid hemp product is cannabis, or medical cannabis, or that a licensee is authorized to sell or dispense cannabis, or medical cannabis, as those terms are defined in article 1 of the Cannabis Law;

(9) depicts cannabis products or paraphernalia;

(10) promotes overconsumption; or

(11) violates any other prohibitions as set out by the office.

Paragraphs (1) and (2) of subdivision (b), of section 114.10 are amended to read as follows:

(b) To be recognized as a testing laboratory for purposes of testing cannabinoid hemp products as required by this Part, a laboratory must either be approved to test [medical marijuana] cannabis pursuant to [Section 55-2.15] Part 130 of this Title[10 of the Official Compilation of Codes, Rules and Regulations of the State of New York], article 6 of the Cannabis Law, or meet all of the following minimum requirements:

(1) maintain ISO/IEC 17025 accreditation for the premises and for the testing of one or more of the analytes determined by the office, pursuant to section 130.22(d) of this Title

[the following:

- (i) Cannabinoids;
- (ii) Heavy metals;
- (iii) Microbial impurities;
- (iv) Mycotoxins;
- (v) Residual pesticides;
- (vi) Residual solvents and processing chemicals; or
- (vii) If tested, terpenoids].

(2) maintain a valid scope of accreditation, issued by an accreditation body, that attests to the laboratory's competence to perform testing of one or more analytes [listed]in subdivision (b)(1) of this section.

Subdivision (f) through (j) of section 114.10 are repealed and a new subdivision (f) is added to read as follows:

(f) Testing limits. Pursuant to section 130.22(d) of this Title, the office shall make available a list of required analytes, their acceptable limits and approved testing methods on the office's website and in any other manner as determined by the Board.

Subdivision (k) and (l) of section 114.10 is renumbered as subdivision (g) and (h).

Subdivision (b) of section 114.11 is amended to read as follows:

(b) Cannabinoid hemp retailers shall not offer or sell any cannabinoid hemp product clearly labeled or advertised for the purpose of smoking, or in the form of a cigarette, cigar, or pre-roll, or packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes. Retailers shall have sufficient safeguards in place to verify that an individual presenting or submitting proof of age matches the identification and is twenty-one (21) years of age or older in order to purchase [for an inhalable] any cannabinoid hemp product containing more than 0.5 milligrams of total THC per serving, concentrated cannabinoid hemp product intended for inhalation or vaporization, or flower product [matches the identification and is 21 years of age or older].

Paragraphs (i) through (iv) of subdivision (a) of section 114.12 are renumbered as (1) through (4) and are amended to read as follows:

([i]1) [make] include any false or misleading [claims or] statements[;], images, or other content including, but not limited to, any health claims;

(ii)2) contain claims that cannabinoid hemp or a cannabinoid hemp product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease;

(iii)3) lead a reasonable consumer to believe that a cannabinoid hemp product is cannabis, [marihuana] or medical cannabis[, or medical marihuana], or that a licensee is authorized to sell or dispense cannabis[, marihuana,]or medical cannabis[, or medical marihuana], as those terms are defined in section 3 of the Cannabis Law[and Article 33 of the Public Health Law];

(iv)4) have the purpose or effect of targeting or [appealing to anyone]being attractive to individuals under twenty-one (21) years of age[for inhalable cannabinoid hemp products or flower product]. The use of images of children or minors consuming [the] cannabinoid hemp products and the use of words, [a] designs, or brands that resemble[s a] products [that is] commonly associated with children, [or] minors, or marketed to children or minors, is prohibited.

Subdivision (b) of section 114.14 is amended to read as follows:

(b) No person shall extract hemp extract or manufacture cannabinoid hemp products in New York State unless licensed to engage in such activity by the office or otherwise authorized by the United States F[f]ood and D[d]rug A[a]dministration.

Subdivision (f) of section 114.15 is added to read as follows::

(f) No cannabinoid hemp processor shall process any final cannabinoid hemp products for retail sale which exceeds the maximum total THC limits per serving and per package as set forth in this Part.

Subdivision (a) of section 114.16 is amended to read as follows:

(a) No cannabinoid hemp retailer shall offer or sell any cannabinoid hemp product containing more than 0.5 milligrams of total THC per serving, concentrated cannabinoid hemp product [in the form of an inhalable cannabinoid hemp product]or flower product to anyone under twenty-one (21) years of age.

Subdivisions (a) and (b) of section 114.21 are amended to read as follows:

(a) The provisions of this Part are effective upon filing for publication in the State Register[; provided, however, that sections 114.9 and 114.10 shall not become effective until April 25, 2021].

(b) Notwithstanding subdivision (a) of this section, [a licensed cannabinoid hemp retailer] cannabinoid hemp products sold in New York must meet the requirements set forth in sections [possess, transport, and sell cannabinoid hemp products in the retailer's inventory before the effective date of this Part] 114.9(a), 114.9(b), 114.9(d), 114.9(f), 114.9(g), 114.9(h) and 114.12(a) by January 1, 2024], unless the cannabinoid hemp product:

- (1) is unsafe for consumption based on the presence or quantity of heavy metals, pesticides, harmful microorganisms, or residual solvents;
- (2) has a Δ -9 tetrahydrocannabinol concentration of more than 0.3 percent;
- (3) is a flower product clearly labeled or advertised for the purpose of smoking or in the form of a cigarette, cigar or pre-roll or otherwise packaged or combined with other items designed to facilitate smoking such as rolling papers or pipes; or
- (4) contains or was manufactured with Δ 8-tetrahydrocannabinol or Δ 10-tetrahydrocannabinol created through isomerization].