

Pursuant to the authority vested in the Cannabis Control Board by Sections 13 and 91 of the Cannabis Law, 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 publication of a Notice of Adoption in the New York State Register, to read as follows:

Section 114.1 is amended to add subdivisions (f) and (k) to read as follows:

(f) *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 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 (l) of this Section.

[(f)] (g) *Cannabinoid hemp processor* means a person licensed by the office to extract hemp extract and/or manufacture cannabinoid hemp products in New York State, whether in intermediate or final form, to be used for human consumption.

[(g)] (h) *Certificate of analysis* means a certified report from an independent third-party laboratory meeting all of the requirements of section 114.10 of this Part, describing its analytical testing and results.

[(h)] (i) *Corrective action plan* means a plan submitted by a licensee and approved by the office under this Part for the licensee to correct a violation or non-compliance with this Part.

[(i)] (j) *Cosmetic* means a cosmetic meeting the requirements of section 321 of Title 21 of the United States Code and recognized as such by the office.

(k) *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 annually and the hemp is hand trimmed, hang dried and if a cannabinoid hemp flower product hand packaged.

[(j)] (l) *Distillate* means hemp extract where a segment of one or more cannabinoids from an initial extraction are selectively concentrated through heating and cooling, with all impurities removed.

[(k)] (m) *Distribute* means to offer or sell cannabinoid hemp products to a cannabinoid hemp retailer, for retail sale to consumers within New York state.

[(l)] (n) *Extract* or *Extraction* means the process of concentrating or isolating one or more cannabinoids from hemp or cannabinoid hemp.

[(m)] (o) *Flower product* means any form of cannabinoid hemp product consisting of the flower, buds, leaves, or stems of the hemp plant, including trimmings thereof, intended for retail sale to consumers with minimal processing. Provided, however that flower product shall not include:

- (1) any food, food ingredient, food additive, or items that are generally recognized as safe, pursuant to state or federal law; or
- (2) any other product, including microgreens, sprouts or certain hemp leaf products, as determined by the office.

[(n)] (p) *Full spectrum* means hemp extract or cannabinoid hemp product containing multiple hemp-derived cannabinoids, terpenes, and other naturally occurring compounds, processed without intentional complete removal of any compound and without the addition of isolated cannabinoids, with a final Δ9-Tetrahydrocannabinol concentration of not greater than 0.3%.

[(o)] (q) *Hemp* means the plant *Cannabis sativa L.* and any part of such plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Δ9-Tetrahydrocannabinol concentration of not more than 0.3% on a dry weight basis.

(p) (r) *Hemp extract* means all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers derived from hemp and used for human consumption, with a Δ9-Tetrahydrocannabinol concentration of not more than an amount determined by the office pursuant to this Part. Hemp extract shall not include:

- (1) any food, food ingredient or food additive that is generally recognized as safe pursuant to federal law; or
- (2) any extract derived from hemp that is not used for human consumption.

[(q)] (s) *Isolate* means hemp extract or cannabinoid hemp product comprised of 95 percent or more of a single cannabinoid compound.

[(r)] (t) *Lot* or *batch* means any cannabinoid hemp product produced during a period of time under similar conditions and identified by a specific code that allows traceability.

[(s)] (u) *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) of this Section.

[(t)] (v) *New York Hemp Product* means a cannabinoid hemp product that is derived from hemp exclusively grown, extracted and manufactured in New York, in compliance with section 114.13 of this Part.

[(u)] (w) *Person* means an individual, partnership, corporation, limited liability company, association, or any business entity or institution of higher education, by whatever name designated and whether or not incorporated.

[(v)] (x) *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.

*[(w)] (y) Total Δ9-Tetrahydrocannabinol concentration* means [ $\Delta 9$ -Tetrahydrocannabinol] + (0.877 x [tetrahydrocannabinolic acid]).

*[(x)] (z) 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.

Section 114.2 is amended to add a new subdivision (c) and modify subdivision (d) to read as follows:

(c) The information required by subparagraph (b)(9) of this Section shall not be required for cannabinoid hemp farm processor applicants.

*[(c)] (d) Applications under this section shall be accompanied by a non-refundable application fee of \$1,000 for extraction and manufacturing, [and] \$500 for manufacturing only and \$100 for cannabinoid hemp farm processors.*

*[(d)] (e) Applicants shall verify the truth and accuracy of the information contained in the application. The office, in its discretion, may reject or deny an application if it determines that information contained therein is false, inaccurate or omits a material fact.*

Subdivision (f) of section 114.4 is amended to read as follows:

(1) [a copy of a certificate of occupancy, or its equivalent, demonstrating compliance with all local building codes;] if for Extracting and Manufacturing or Manufacturing Only:

(i) a copy of a certificate of occupancy, or its equivalent, demonstrating compliance with all local building codes; and

(ii) a copy of the approved applicant's qualified third-party GMP certification.

[(3)] (2) payment of licensure fee as follows:

(i) Cannabinoid Hemp Processor – Extraction and Manufacturing: \$3,500 [per location]; [or]

(ii) Cannabinoid Hemp Processor – Manufacturing Only: \$1,000 [per location]; or

(iii) Cannabinoid Hemp Farm Processor: \$300.

[(4)] (3) proof of sufficient product liability insurance for all manufactured cannabinoid hemp products; and

[(5)] (4) evidence, to the office's satisfaction, that the applicant will be able to comply with this Part, which may include an onsite inspection.

Subdivision (b) of section 114.5 is amended to read as follows:

(3) Cannabinoid Hemp Farm Processor: \$100 application fee, \$300 license fee;

[(3)] [(4)] Cannabinoid Hemp Retailer: \$300 license fee per retail location;

[(4)] [(5)] the license fee shall be returned if the licensee's renewal application is not granted.

Subdivisions (a) and (b) of section 114.7 are amended to read as follows:

(1) extract hemp extract and/or manufacture cannabinoid hemp products to GMP standards and if applicable for the type of processor license, maintain a qualified third-party certification, to the satisfaction of the office, for the applicable GMP standard(s) for the duration of the license;

\* \* \*

(b) Possession and the intermediate sale of hemp extract by and between licensed cannabinoid hemp processors, is permitted, provided when such extract leaves the licensed premises it is accompanied by a certificate of analysis certifying that the extract is less than [three (3)] five (5) percent THC and a copy of the cannabinoid hemp processor's license, and further provided such hemp extract is only transported intra-state.

Subdivisions (a), (b) and (c) of section 114.8 are amended to read as follows:

[(9) be shelf stable]

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

[(11)] (10) not contain synthetic cannabinoids, or cannabinoids created through isomerization, including  $\Delta 8$ -tetrahydrocannabinol and  $\Delta 10$ -tetrahydrocannabinol.

(b) If the cannabinoid hemp product is a 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 [75] 100 milligrams per individual serving.

(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.

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

(1) if the cannabinoid hemp product is consumed through ingestion, [including sublingual or oral absorption] 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) the number of servings per package or container, including the milligrams per serving [and the milligrams per package] of:

(i) CBD;

(ii) "Total THC" or "THC" which for the purposes of product labeling may be rounded and shall include detectable levels of total Δ9-Tetrahydrocannabinol, Δ8-Tetrahydrocannabinol and Δ10-Tetrahydrocannabinol; and

\* \* \*

(8) the state(s) [country] or if outside of the United States of America, country [countries] of origin from which hemp used in the product was sourced;

\* \* \*

(e) All cannabinoid hemp products claiming to be "craft," "isolate," "full spectrum," "broad spectrum," or "distillate" shall comply with the applicable definition contained in this Part.

\* \* \*

(2) that the 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 [derived entirely from hemp grown, extracted, and manufactured in New York State];

\* \* \*

(g) No information required to be listed on cannabinoid hemp product labeling or packaging in accordance with this section shall be smaller than 4.5-point font [and the information required by subparagraphs (a)(3)(i) through (iii) and paragraph (f)(2) of this section shall be bolded and at least one font sized larger than other text required to be listed on the product label].

Subdivision (i) and (k) of section 114.10 are amended to read as follows:

(i) Biological Limits.

1. Shiga toxin-producing Escherichia coli (STEC E. coli) and other pathogenic E. coli, none [present] detected in 1 gram.

2. Salmonella, none [present] detected in 1 gram.

\* \* \*

(k) Cannabinoid Limits. The total Δ9-Tetrahydrocannabinol concentration for cannabinoid hemp products shall not exceed three-tenths of a percent (0.3%). If a cannabinoid hemp product fails, the processor may elect to [re-extract] re-formulate the failing batch to reduce the total Δ9-

Tetrahydrocannabinol of the batch to not more than three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol. If the [re-extract] re-formulated batch still exceeds the three-tenths of a percent (0.3%) total Δ9-Tetrahydrocannabinol the processor shall destroy the batch in compliance with subdivision (d) of section 114.7 of this Part.

Subdivision (a) of section 114.12 is amended to read as follows:

(iii) lead a reasonable person to believe that a cannabinoid hemp product is adult-use cannabis, marihuana, medical cannabis, or medical marihuana, or that a licensee is authorized to sell or dispense adult-use cannabis, marihuana, 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;