

Division of Cannabis Control Proposed Rules Early Stakeholder Feedback – Rule Package 6B

OAC 1301:18-4-04 Requirements for Universal THC Symbol

- (A) Each licensee shall place the universal THC symbol in a form and manner prescribed by the division of cannabis control and as outlined by division 1301:18 of the Administrative Code.
 - o (1) The THC symbol must be a contrasting color to the surface or background upon which it is affixed or placed and be at least ¼ inch by ¼ inch in size.
- **(B)** The universal THC symbol shall be clearly visible and conspicuously placed on all of the following:
 - (1) In accordance with rule 1301:18-4-06 of the Administrative Code, each portion, serving size, or unit of a cannabis product;
 - o (2) Any portable, hand-held cannabis device used to administer cannabis;
 - (3) In accordance with rule 1301:18-3-16 of the Administrative Code, each package intended for bulk cannabis transfer to another licensed entity;
 - (4) In accordance with rule 1301:18-4-20 of the Administrative Code, each package intended for direct customer sale shall be affixed with the universal THC symbol; and
 - o (5) In accordance with rule 1301:18-4-22 of the Administrative Code, any advertisement

OAC 1301:18-4-06 Limitations on Packages of Cannabis for Direct Customer Sale

- (A) Prior to any transfer or sale, each licensee shall place all cannabis directly into a single cannabis container. A cannabis container by itself may constitute the package intended for direct customer sale.
 - **(1)** A cannabis container that is placed into secondary packaging, the secondary packaging would then constitute the **packaging intended for direct customer sale**.
 - o (2) Cannabis sold to customers within a device must be placed into a cannabis container.
- **(B)** Each **package of cannabis intended for direct customer sale** shall adhere to the following requirements:
 - o (1) Cannabis Plants:
 - (a) Cannabis clones and live plants must adhere to the requirements outlined under OAC 1301:18-1-01 and shall only be in a vegetative state. A clone or live plant that proceeds to the flowering stage, shall not be sold.
 - (b) Each package shall not exceed six (6) clones
 - (c) Each package shall not exceed six (6) live plants
 - (d) Each package shall not exceed six (6) seeds.
 - o (2) Cannabis Plant Material
 - (a) Each package shall not exceed one (1) ounce of cannabis plant material.
 - O (3) Raw single serving units:
 - (a) Each raw single-serving unit shall not exceed one (1) gram of cannabis plant material.
 - **(b)** Each package of raw single single-serving units shall not exceed five (5) single-serving units

- (4) Cannabis Vaporizers
 - (a) Each package is limited to one (1) vape device or one (1) vape cartridge, as applicable.
 - (b) The net weight of each vape device shall not exceed one (1) gram.
 - (c) The THC content per vape device shall not exceed 900mg.
 - (d) The serving size is one (1) inhalation lasting 2 seconds per serving.
- o (5) Cannabis Inhalers:
 - (a) Each package is limited to one (1) inhaler device.
 - **(b)** The net weight of each inhaler device shall not exceed one (1) gram
 - (c) The THC content per inhaler device shall not exceed 800mg
 - (d) The serving size is one (1) inhalation lasting 2 seconds per serving.
- o (6) Other Cannabis Extracts intended for vaporization or combustion:
 - (a) Each package is limited to one (1) container of cannabis extract.
 - **(b)** The net weight of each container of cannabis extracts shall not exceed one (1) gram.
 - (c) The THC content per container shall not exceed 900 mg
 - (d) The serving size is one (1) inhalation lasting 2 seconds per serving.
- (7) Infused single serving unit:
 - (a) The net weight for each infused single-serving unit shall not exceed one (1) gram.
 - **(b)** The THC content per package of infused single-serving units shall not exceed 500mg
 - (c) Each package of infused single-serving units shall not exceed five (5) single-serving units per package.
- (8) Other combination Inhalable Products
 - (a) The THC content per package shall not exceed 900mg
 - **(b)** Additionally, if the combination inhalable product is sold in portions, serving sizes, or units, the THC content per unit shall not exceed 100mg
- (9) For cannabis edibles, the following:
 - (a) For adult-use cannabis edibles:
 - (i) The THC content per portion or serving shall not exceed 10mg and
 - (ii) The THC content per package shall not exceed 100mg
 - **(b)** For medical cannabis edibles:
 - (i) The THC content per portion or serving shall not exceed 55mg and
 - (ii) The THC content per package shall not exceed 110mg
- o (10) Cannabis Beverages:
 - (a) The total THC content per container shall not exceed 10mg
 - (b) Each package is limited to six (6) containers per package
- (11) Oral pouches and oral strips
 - (a) The total THC content per unit shall not exceed 10mg
 - (b) The total THC content per package shall not exceed 100mg
- (12) Capsules and pills:
 - (a) The total THC content per capsule or pill shall not exceed 50mg
 - (b) The total THC content per package shall not exceed 500mg
- o (13) Oral Sprays
 - (a) Each package is limited to one (1) container.
 - **(b)** The net weight of each container shall not exceed one (1) gram
 - (c) The total THC content per container shall not exceed one (1) gram

- o (14) Drops for oral administration:
 - (a) The total THC content per serving shall not exceed 10mg
 - **(b)** The total THC content per package shall not exceed one 1 gram
- o (15) Topical sprays, salves, lotions, or other similar cosmetic products:
 - (a) The total THC content per package shall not exceed one (1) gram
- o (16) Patches for transdermal administration:
 - (a) The total THC content per patch shall not exceed 50mg
 - (b) The total THC content per package shall not exceed 500mg
- o (17) Suppositories for rectal administration:
 - (a) The total THC per suppository shall not exceed 100mg
 - **(b)** The total THC content per package shall not exceed one (1) gram

OAC 1301:18-4-19 Pre-Approval Requirements for Packaging and Labeling Intended for Direct Customer Sale

- (A) Prior to utilizing any packaging intended for direct customer sale, each cultivator and processor shall petition the division of cannabis control solely as outlined by this rule.
- **(B)** In accordance with paragraph A of this rule, each licensee shall evidence in a form and manner prescribed by the division each of the following for any package intended for direct customer sale:
 - (1) The package is tamper-evident;
 - o (2) The package is child resistant in accordance with 16 CFR 1700;
 - o (3) The package will maintain the integrity and stability of the cannabis contained within;
 - (4) A photograph of the entirety of the package;
 - (5) In accordance with rule 1301:18-4-04 of the Administrative Code, the universal THC symbol, which shall be affixed in a form and manner that clearly and immediately indicates to a reasonable person that the product contains cannabis;
 - o (6) The division of cannabis control seal, as prescribed by the division; and
 - o (7) Any other information deemed necessary by the division.
- **(B)** Upon receipt of an application, the division may:
 - o (1) Approve the application;
 - o (2) Approve the application, subject to certain mandates or limitations;
 - o (3) Advise the licensee in writing that further information is needed; or
 - (4) Deny the application.
- **(C)** Upon receipt of written approval by the division, a licensee may proceed and sell cannabis only within the associated packaging intended for direct customer sale.

OAC 1301:18-4-20: Packaging and Labeling Requirements for Cannabis Intended for Direct Customer Sale

- (A) Each cultivator and processor shall establish, maintain, and comply with written policies and
 procedures to ensure all cannabis intended for direct customer sale complies with the packaging
 and labeling requirements outlined under rule 1301:18-4-19 of the Administrative Code and this
 rule.
 - (1) Except as specified and required by rule 1301:18-4-19 of the Administrative Code, a licensee is not mandated to request approval prior to utilizing packaging and labeling intended for direct customer sale.
 - (2) However, licensees are mandated to adhere to all restrictions as further outlined in this rule. In the event the division determines that a licensee fails to comply with these rules, it may proceed with any action as outlined under chapter 1301:18-9 of the Administrative Code.

- **(B)** Each **package of cannabis intended for direct customer sale** shall prominently, conspicuously, clearly, and plainly display in an unobstructed manner when viewing the package the following in legible English:
 - (1) The net weight or volume of the contents contained within the package;
 - o (2) In accordance with rule 1301:18-4-09 of the Administrative Code, the name of the product as approved by and registered with the division;
 - o (3) In accordance with rules 1301:18-4-04 and 1301:18-4-19 of the Administrative Code, the universal THC symbol approved and registered with the division;
 - o (4) The division of cannabis control seal, as prescribed by the division;
 - (5) In accordance with rule 1301:18-4-07 of the Administrative Code, for cannabis plant material, the strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system; and
 - (6) For edible products, the phrase "cannabis-infused" or "marijuana-infused."
- **(C)** Labeling Requirements. In addition to the requirements outlined in paragraph (B) of this rule, each package of cannabis intended for direct customer sale shall be affixed with a label that includes the following information in legible English:

o (1) Cannabis Plant Material

- (a) The name and license number of the cultivator that cultivated and harvested the plant material;
- **(b)** If different than the entity outlined pursuant to paragraph (C)(1)(a) of this rule, the name and license number of the licensee that packaged the plant material;
- (c) The date the plant material was harvested;
- (d) The date the plant material was packaged for direct customer sale;
- **(e)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;
- **(f)** In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
- **(g)** The net weight in grams and ounces of the plant material contained within each package;
- **(h)** In accordance with rule 1301:18-4-05 of the Administrative Code, the approved range of THC content, as prescribed by the division;
- (i) The name and license number of the testing laboratory that conducted all state-required testing;
- (j) The date the associated batch of plant material was submitted to all state-required testing;
- **(k)** The state inventory tracking number associated with the specific batch of plant material submitted to all state-required testing as outlined under division 1301:18 of the Administrative Code;
- (I) The following as reflected on the associated certificate of analysis:
 - (i) The following cannabinoids, at a minimum:
 - (A) Cannabidiol (CBD);
 - o (B) Cannabidiolic acid (CBDA);
 - o (C) THCv; and
 - o **(D)** Any other cannabinoid deemed necessary by the division.
 - (ii) The top three terpenes by percentage
 - (iii) The label shall not include:

- (A) Results for THC content other than the approved range prescribed by the division;
- o **(B)** Any sum total of terpenes or cannabinoids;
- (C) Delta-9 THC results;
- o **(D)** Delta-8 THC results; or
- o (E) THCA results
- (m) A statement with the following language: "WARNING: Keep out of reach of children. This product contains cannabis. This product may cause impairment and may be habit-forming. This product may be unlawful outside the state of Ohio. Women who are, or plan to be, pregnant or breastfeeding should consult their physician prior to use."
- (n) If the plant material was subjected to any technology solutions, including remediation by irradiation, gas treatment such as ozone, radiofrequency, and UV light, the following additional information: "This plant material was treated by [name of technology solution utilized];" and
- (o) Any other requirements the division deems necessary.

(2) Cannabis Products Generally

- (a) The name and license number of the processor that manufactured the cannabis product;
- **(b)** If different than the entity outlined pursuant to paragraph (C)(2)(a) of this rule, the name and license number of the licensee that packaged the cannabis product;
- (d) The date the cannabis product was manufactured;
- **(e)** The date the cannabis product was packaged for direct customer sale;
- **(g)** The expiration date, which shall not exceed one calendar year from the date of manufacture;
- **(e)** In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;
- **(f)** The net weight in grams and ounces of cannabis or volume in fluid ounces and milliliters in each package, as outlined for dosing or serving size;
- (c) The state inventory tracking number associated with the specific lot submitted to state-required testing as outlined 1301:18 of the Administrative Code;
- **(h)** In accordance with rule 1301:18-4-02 of the Administrative Code, the intended method of administration;
- (i) If applicable, the serving size;
- (j) The name and license number of the testing laboratory that conducted all state-required testing;
- **(k)** The date the associated lot of cannabis products was submitted to all state-required testing;
- (I) The state inventory tracking number associated with the specific lot of cannabis products submitted to all state-required testing as outlined under division 1301:18 of the Administrative Code;
- (m) The following as reflected on the associated certificate of analysis, in total milligrams per package:
 - (i) The following cannabinoids:
 - (A) The THC content as defined by rule 1301:18-1-01 of the Administrative Code;
 - (B) Delta-8-tetraydrocannabinol;
 - (C) Delta-9-tetrahydrocannabinol;

- o (D) Delta-9-tetrahydrocannabinolic acid;
- (E) Cannabidiol (CBD);
- (F) Cannabidiolic acid (CBDA);
- o (G) THCv; and
- o **(H)** Any other cannabinoid deemed necessary by the division.
- (ii) The top three terpenes by percentage
 - o (A) The label shall not include any sum total of terpenes.
- (n) A statement with the following language: "WARNING: Keep out of reach of children. This product may cause impairment and may be habit-forming. This product may be unlawful outside the state of Ohio. Women who are pregnant or breastfeeding, or plan to be, should consult their physician prior to use."
- (o) Any other requirements the division deems necessary.
- (3) Specific Mandates for Certain Cannabis Products. In addition to the requirements outlined under paragraph (C)(1) and (2) of this rule, each package of cannabis products intended for direct customer sale shall also include the following additional information on the label, as applicable:
 - (a) For edibles or cannabis beverages, the following:
 - (i) In accordance with 21 CFR 101, a list of all ingredients and subingredients,;
 - (ii) In accordance with 21 USC 343, a list of all major food allergens; and
 - (iii) A statement with the following language: "Caution: When eaten or swallowed, effects and impairment may be delayed."
 - **(b)** For any product intended for vaporization or combustion, a list of all ingredients, sub-ingredients, and additives included and added to the cannabis extract to cannabis product.
 - (c) If a solvent-based cannabis concentrate was used in the manufacture of the
 product, a disclosure of the type of extraction process and any solvent, gas, or
 other chemical used in the extraction and manufacturing process or any other
 compound added to the extract;
 - (d) If the product was manufactured using hemp-derived non-marijuana ingredients as outlined under rule 1301:18-6-03 of the Administrative Code, the following information related to the originating state-licensed and regulated source that manufactured the hemp-derived ingredients:
 - (i) The business name of the source; and
 - (ii) The type of extraction process and any solvent, gas, or other chemical used by the originating source in the extraction and manufacturing process or other compound added to the extract.
- (4) Seeds, clones, and live plants.
 - (a) The name and license number of the cultivator that cultivated the seeds, clones, or live plants;
 - **(b)** If different than the entity outlined pursuant to paragraph (C)(4)(a) of this rule, the name and license number of the licensee that packaged the materials;
 - (c) The date the material was packaged for direct customer sale;
 - (d) In accordance with rule 1301:18-4-09 of the Administrative Code, the unique identifying product registration number as provided by the division;

- **(e)** In accordance with rule 1301:18-4-07 of the Administrative Code, the cannabis strain name, as reflected in and consistent with the cannabis strain name submitted by the licensee into the state inventory tracking system;
- **(f)** For seeds:
 - (i) The date the seeds were harvested by the originating cultivator;
 - (ii) The net weight in grams and ounces of the seeds in each package;
 - (iii) The total number of seeds contained within the package.
- (g) For clones and live plants,
 - (i) The date planted by the originating cultivator;
 - (ii) The height in inches of the clone or live plant when packaged; and
 - (iii) The total number of clones or live plants contained within the package.
- (h) "WARNING: Keep out of reach of children. This product was NOT subjected to state-required consumer health and safety testing as outlined by 1301:18 of the Administrative Code. This product may be unlawful outside the state of Ohio."

OAC 1301:18-4-21 Additional Limitations on Packaging and Labeling Intended for direct customer sale

- **(A)** No licensee shall manufacture, process, or distribute, or cause to be created, used, or distributed, any **cannabis packaged for direct customer sale** that is any of the following:
 - o (1) False or misleading;
 - o (2) Obscene or indecent;
 - (3) Attractive to children;
 - (4) Includes any image or text referencing or resembling a cartoon character, fictional character or pop culture icon whose target audience is children or youth;
 - (5) Encourages the consumption of cannabis in a manner that leads to excessive use, intoxication, overconsumption, or in combination or conjunction with other intoxicants, illegal substances, or in a method not otherwise authorized by this chapter;
 - o (6) Contains a depiction of cannabis consumption or administration;
 - (7) A departure from the cannabis registered name, including, slang terms, and similar references;
 - (8) Disparaging to a competitor's products;
 - o (9) Contains a health-related statement;
 - (10) Suggests, or otherwise indicates, that the cannabis is approved or endorsed by the
 division, the state of Ohio or any person or entity associated with the state of Ohio, or any
 other person without their consent;
 - o (11) Violates state of Ohio or federal trademark or copyright law; or
 - (12) Otherwise violates any provision of chapters 3780 and 3796 of the Revised Code or the rules promulgated pursuant to chapters 3780 and 3796 of the Revised Code.