845-025-1015
Definitions

For the purposes of OAR 845-025-1000 to 845-025-8590, unless otherwise specified, the following definitions apply:

(1) “Added substance” means any component or ingredient added to usable marijuana, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the final cannabinoid product, including but not limited to flavors, non-marijuana derived terpenes, and any substances used to change the viscosity or consistency of the cannabinoid product.

(2) "Adulterated" means to make a marijuana **or hemp** item impure by adding foreign or inferior ingredients or substances. A marijuana **or hemp** item may be considered to be adulterated if:

(a) **In the Commission’s judgment, it** ***it*** bears or contains any poisonous or deleterious substance in a quantity rendering the marijuana item injurious **that may pose a risk** to **human** health, including but not limited to tobacco or nicotine;

(b) It bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;

(c) It consists in whole or in part of any filthy, putrid, or decomposed substance, or otherwise is unfit for human consumption;

(d) It is processed, prepared, packaged, or is held under improper time-temperature conditions or under other conditions increasing the probability of contamination with excessive microorganisms or physical contaminants;

(e) It is processed, prepared, packaged, or held under insanitary conditions increasing the probability of contamination or cross-contamination;

(f) It is held or packaged in containers composed, in whole or in part, of any poisonous or deleterious substance rendering the contents potentially injurious to health;

(g) Any substance has been substituted wholly or in part therefor;

(h) Damage or inferiority has been concealed in any manner; or

(i) Any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

[…]

(43) “Industrial hemp”:

(a) Means all non-seed parts and varieties of the Cannabis plant, whether growing or not, that contain an average tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry weight basis.

(b) Means any Cannabis seed:

(A) That is part of a crop, as that term is defined in ORS 571.300;

(B) That is retained by a hemp grower for future planting;

(C) That is agricultural hemp seed;

(D) That is for processing into or for use as agricultural hemp seed; or

(E) That has been processed in a manner or to an extent that the Cannabis seed is incapable of germination.

(c) Does not mean industrial hemp commodities or products or marijuana.

(44) "Inhalable cannabinoid product" means a cannabinoid product that is intended for human inhalation.

(*44***45**) "Invited guests" means family member and business associates of the licensee, not members of the general public.

(XX) "Non-cannabis additive" means a substance or group of substances that are derived from a source other than marijuana or industrial hemp.

(a) "Non-cannabis additive" includes but is not limited to purified compounds, essential oils, oleoresins, essences or extractives, protein hydrolysates, distillates, or isolates.

(b) "Non-cannabis additive" does not include plant material that is in the whole, broken, or ground form.

845-025-2755
Industrial Hemp Handler Certificate Privileges; Prohibitions

[…]

(3) When transferring, selling, or transporting pursuant to subsection (2) of this rule a Commission-certified hemp handler:

(a) May only transfer, sell, or transport industrial hemp and hemp items that:

(A) Have been tested in accordance with the Authority's rules for testing the equivalent marijuana item in OAR 333-007-0300 to 333-007-0500 and OAR 333, division 64;

(B) Have been tested for THC and CBD concentration in accordance with OAR 333-007-0430, notwithstanding whether a test for potency would be required for the equivalent marijuana item; and

(C) Otherwise complies with the requirements for marijuana items under ORS 475B.010 to 475B.545, ORS 475B.550 to 475B.590, and 475B.600 to 475B.655 and Commission rules.

(b) May only transfer industrial hemp or hemp items from the location identified in the application under OAR 845-025-2705(2)(c).

(c) Must:

(A) Hold a valid Industrial Hemp Handler Certificate issued by the Commission.

(B) Provide the licensee a copy of any test result conducted on the industrial hemp or hemp items. Test results include, but are not limited to, any pre-harvest test result conducted under OAR 603-048-0600 and any results from research & development testing.

(C) Comply with CTS requirements in accordance with OAR 845-025-2775.

(D) Transport industrial hemp or hemp items in compliance with the requirements for a licensee transporting marijuana items under OAR 845-025-7700(2)(a), (2)(b)(A)-(C), (2)(b)(F)-(K), and (2)(d)(A)-(D).

(d) May not transfer to a licensee:

(A) Any industrial hemp that has failed the testing described in OAR 603-048-0600 to 603-048-0650;

(B) Any batch of harvested industrial hemp that exceeds the THC limits specified in OAR 845-025-2760;

(C) Any hemp item that exceeds the THC limits specified in OAR 845-025-2760;

(D) Any living industrial hemp plants; ~~*or*~~

(E) Industrial hemp seed~~.~~**; or**

(F) On or after July 1, 2021, any inhalable cannabinoid product that a licensee is prohibited from receiving under OAR 845-025-8520.

845-025-3220
General Processor Requirements

(1) A processor must:

(a) Use equipment, counters and surfaces for processing that are food-grade and do not react adversely with any solvent being used.

(b) Have counters and surface areas that are constructed in a manner that reduce the potential for development of microbials, molds and fungi and that can be easily cleaned.

(c) Maintain the licensed premises in a manner that is free from conditions which may result in contamination and that is suitable to facilitate safe and sanitary operations for product preparation purposes.

(d) Store all marijuana or hemp items not in use in a locked area, including products that require refrigeration in accordance with OAR 845-025-1410.

(e) Assign every process lot a unique identification number and enter this information into CTS.

(2) A processor may not process, transfer or sell a marijuana or hemp item:

(a) That by its shape, design or flavor is likely to appeal to minors, including but not limited to:

(A) Products that are modeled after non-cannabis products primarily consumed by and marketed to children; or

(B) Products in the shape of an animal, vehicle, person or character.

(b) That is made by applying cannabinoid concentrates or extracts to commercially available candy or snack food items.

(c) That contains Dimethyl Sulfoxide (DMSO).

(d) If such an item is an inhalable cannabinoid product that does not meet the requirements in OAR 845-025-3265, except that a processor may transfer or sell an inhalable cannabinoid product that does not meet the requirements in OAR 845-025-3265 that was processed prior to February 1, 2021, until July 1, 2021.

(~~3~~**4**) A processor may not treat or otherwise adulterate a cannabinoid product, concentrate or extract with any ~~*non-cannabinoid*~~ additive **or substance** that would increase potency, toxicity or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives **or substances** include but are not limited to nicotine, caffeine, polyethylene glycol, or any chemicals that increase carcinogenicity or cardiac effects.

(~~4~~**5**) A processor must maintain records of industrial hemp test results for 2 years.

845-025-3265

Inhalable Cannabinoid Product Processor Requirements

(1) A processor may only use a non-cannabis additive in an inhalable cannabinoid product if the non-cannabis additive is accompanied by:

(a) A Safety Data Sheet that:

(A) Lists all ingredients in the non-cannabis additive;

(B) For each ingredient of the non-cannabis additive, includes:

(i) A Chemical Abstracts Service Reference Number that specifies the ingredient's isomer and, if applicable, enantiomer; and

(ii) The ingredient's maximum concentration within the non-cannabis additive.

(C) Meets all requirements of 29 CFR 1910.1200(g); and

(D) Is available on a website that is accessible to any member of the public at any time without any form of password protection.

(b) A certificate of analysis that:

(A) Is issued by a lab licensed by the Commission;

(B) Confirms that the non-cannabis additive's ingredients substantially match those disclosed on the Safety Data Sheet;

(C) Confirms that the ingredients prohibited under section (2)(b) of this rule are not detected by a targeted analysis;

(D) Contains a 2D mobile barcode (QR codes) or other means to independently verify the authenticity and accuracy of the certificate of analysis; and

(E) Is available on a website that is accessible to any member of the public at any time without any form of password protection.

(2) A processor may not use a non-cannabis additive in an inhalable cannabinoid product that:

(a) Does not specify, under the non-cannabis additive's safety data sheet's identification header or on the non-cannabis additive's label, that it is for use in a product intended for human inhalation; or

(b) Contains any amount of:

(A) Squalene;

(B) Squalane;

(C) Vitamin E Acetate;

(D) Triglycerides, including but not limited to Medium-Chain Triglyceride (MCT) Oil; or

(E) Propylene Glycol.

(3) On or after February 1, 2021, a processor may not manufacture or process an inhalable cannabinoid product that does not meet the requirements of this rule.

(4) On or after July 1, 2021, a processor may not possess, sell, deliver, transfer, transport, purchase, or receive an inhalable cannabinoid product that does not meet the requirements of this rule.

(5) Violation of this rule is a Category I violation.

845-025-7000
Packaging and Labeling — Definitions

[…]

(23) "Generic label" means a label that contains only the information required by rule.

(a) A generic label does not include a label for an inhalable cannabinoid product that is processed or manufactured on or after February 1, 2021.

(~~a~~**b**) A generic label may not contain any graphics, pictures, or logos other than symbols required by these rules.

(~~b~~**c**) A generic label may include additional test information not required by rule or additional information described in OAR 845-025-7160(7)(c).

845-025-7120
Cannabinoid Products Other than Cannabinoid Edibles, Topicals, Tinctures or Capsules.

Prior to a cannabinoid product other than a cannabinoid edible, topical, tincture or capsule being sold or transferred to a consumer, patient or designated primary caregiver, the container holding the product must have a label that has the following information:

(1) Processor's business or trade name, license number, and place of address;

(2) Business or trade name of licensee, license number, and place of address for licensee that packaged the product, if different from the processor;

(3) Product identity;

(4) If the product is an inhalable cannabinoid product that contains non-cannabis additives, the product identity must clearly indicate the product contains non-cannabis additives;

(5) UID number;

(6) Date the product was made;

(7) Net weight or volume in U.S. customary and metric units;

(8) Serving size and number of servings per container;

(9) Amount, in milligrams, of THC and CBD in each serving and in the container;

(10) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product;

(11) If the product is an inhalable cannabinoid product that contain non-cannabis additives, in addition to a list of ingredients under section (10) of this rule, non-cannabis additive ingredients must be listed by their common name in a manner that unambiguously identifies the specific isomer, if applicable.

(12) Name of the lab that performed any test and any test analysis date;

(13) Universal symbol;

(14) Activation time expressed in words or through a pictogram;

(15) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";

(16) For cannabinoid products for sale to a consumer, warnings that state:

(a) "For use only by adults 21 and older. Keep out of reach of children."

(b) "Do not drive a motor vehicle while under the influence of marijuana."

(c) “DO NOT EAT” in bold, capital letters.

(17) For medical grade cannabinoid products for use by a patient, the medical grade symbol and medical warnings that state:

(a) "For use by OMMP patients only. Keep out of reach of children."

(b) "Do not drive a motor vehicle while under the influence of marijuana."

(c) “DO NOT EAT” in bold, capital letters.

(18) For inhalable cannabinoid products that contain non-cannabis additives, the date the label was approved by the Commission.

845-025-7160
Packaging and Labeling Pre-approval Process

(1) Prior to selling, offering for sale, or transferring a marijuana item or industrial hemp commodity or product that is for ultimate sale to a consumer, patient, or designated primary caregiver, a licensee, a license applicant or a registrant must submit both a package and a label application to and receive approval from the Commission.

(a) The initial submission shall be made electronically if required by the Commission. The licensee, license applicant or registrant must submit a physical prototype upon request by the Commission.

(b) If a license applicant submits packages and labels for pre-approval, final determination for packages and labels will not be made until the applicant has been issued a license.

(2) Except as provided in sections (5) to (7) of this rule, the packaging and label applications must be accompanied by the following:

(a) A fee as specified in OAR 845-025-1060; and

(b) Information including but not limited to:

(A) Documentation that the package has been certified as child resistant as defined by 16 CFR 1700 by a qualified third party child-resistant package testing firm.

(B) A picture of and description of the item to be placed in the package.

(C) For label applications for inhalable cannabinoid products that contain non-cannabis additives:

(i) The non-cannabis additive’s safety data sheet;

(ii) The non-cannabis additive’s certificate of analysis as required by OAR 845-025-3265;

(iii) If the non-cannabis additive’s safety data sheet’s identification header does not specify use in a product intended for human inhalation, photos of the non-cannabis additive’s label; and

(iv) In a form and manner prescribed by the Commission, information regarding the supplier of the non-cannabis additive, the additive or additives being used by the licensee, and attestation by the licensee of the accuracy of the information submitted for label pre-approval.

(3) The Commission will evaluate the packaging and label in order to determine whether:

(a) The packaging:

(A) Has been certified as child resistant by a qualified third party child-resistant package testing firm;

(B) Is attractive to minors or is marketed in a manner attractive to minors;

(C) Contains untruthful or misleading content; and

(D) Will contain a marijuana item or industrial hemp commodity or product that is not compliant with ORS 475B, OAR 333, Divisions 7 and 8, or OAR 845, Division 25.

(b) The label:

(A) Complies with the labeling rules, OAR 845-025-7000 to 845-025-7190, or any additional labeling requirements in ORS 475B, OAR 333, Divisions 7 and 8 or OAR 845, Division 25.

(B) Contains any material that is attractive to minors; ~~*and*~~

(C) Contains untruthful or misleading content~~.~~**; and**

(D) Is for an item that complies with all requirements of OAR 845, Division 25.

(4) The Commission must review the packaging and labeling and notify the licensee, licensee applicant or registrant whether the packaging and labeling is approved, and if not approved, a description of the packaging or labeling deficiencies.

(5) If a licensee or registrant's label or package is deficient, it must correct the deficiencies and resubmit the label or package for pre-approval, but the licensee or registrant is not required to submit an additional fee unless the label or package is found deficient for a second time in which case the application will be denied and the licensee or registrant must resubmit the packaging or labeling in accordance with section (1) of this rule.

(6) A licensee, applicant or registrant may submit packaging and labeling for approval on the same application for a product that may have different flavors, colors or sizes, if

the product and packaging is otherwise identical. Applications for approval of packaging and labeling under this section are subject to a single application fee.

(7) Packages and labels that have been previously approved do not need to be resubmitted if the only changes to the packaging or label are:

(a) Changes in the:

(A) Harvest or processing date;

(B) Strain;

(C) Test results;

(D) Net weight or volume; or

(E) UID numbers.

(b) The deletion of any non-mandatory label information.

(c) The addition, deletion or change in the:

(A) UPC barcodes or 2D mobile barcodes (QR codes);

(B) Website address, phone number, fax number, or place of address of the licensee or registrant; or

(C) Instructions for opening or using child-resistant packages.

(d) The repositioning of any label information on the package, as long as the repositioning of label information is consistent with these rules.

(8) Prior to a licensee transferring a package or label approval from one licensee to another, the licensee requesting to transfer the label must submit a form prescribed by the Commission and pay the applicable fee as described in OAR 845-025-1060.

(9) The Commission may publish a list of previously-approved, child-resistant, commercially available packaging. Packaging identified on this list as approved for certain product types does not need to be submitted for package approval if the packaging is identical to the previously-approved package.

(10) The Commission may publish a list of licensees and registrants who have approved label applications.

(11) Labels for marijuana items or industrial hemp commodity or products do not require pre-approval if they are generic labels as defined in OAR 845-025-7000**;** ~~*and*~~ contain

only the information required by these rules**;** ~~*and*~~ have no graphics, pictures or logos**; and are not for an inhalable cannabinoid product manufactured on or after February 1, 2021.**

(12) Packages that are not intended to be child resistant do not require pre-approval. Any package that has not been certified as child-resistant must contain the statement described in OAR 845-025-7030(20).

(13) Notwithstanding any provisions of this rule, the Commission may permit or require electronic submission of labels and packaging for approval.

845-025-7190

Effective Date

(1) These rules become effective on August 15, 2018. On and after August 15, 2018, all package and label applications received by the Commission will be reviewed and evaluated under these rules.

(2) All marijuana items and industrial hemp commodities and products packaged or transferred for sale to a consumer on or after April 1, 2019 must be labeled and packaged according to these rules.

(3) On and after January 1, 2020, marijuana items and industrial hemp commodities and products with labels approved prior to August 15, 2018, can no longer be sold, offered for sale, or transferred to a consumer, patient, or designated primary caregiver.

(4) All labels for inhalable cannabinoid products processed or manufactured on or after February 1, 2021, must be pre-approved by the Commission in accordance with these rules.

(a) An inhalable cannabinoid product with a label approved by the Commission prior to February 1, 2021, that does not meet the requirements of OAR 845-25-3265 or 845-025-7120, may not be possessed, sold, delivered, transferred, transported, purchased, or received on or after July 1, 2021.

(b) An inhalable cannabinoid product manufactured prior to February 1, 2021, that has a compliant generic label may be possessed, sold, delivered, transferred, transported, purchased, or received until June 30, 2021.

845-025-8520
Prohibited Conduct

[…]

(9) Visibly Intoxicated Persons. No licensee or permittee may sell, give, or otherwise make available any marijuana item to any person who is visibly intoxicated. Violation of this section is a Category III violation.

(10) Prohibited inhalable cannabinoid products.

(a) For purposes of this rule, a "prohibited inhalable cannabinoid product" is an inhalable cannabinoid product that does not meet the requirements of OAR 845-025-3265.

(b) No licensee or permittee may:

(A Process or manufacture a prohibited inhalable cannabinoid product on or after February 1, 2021; or

(B) Possess, sell, deliver, transfer, transport, purchase, or receive a prohibited Inhalable Cannabinoid Product on or after July 1, 2021.

(c) Violation of this section is a Category I violation.