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AMEND: 333-007-0310

RULE TITLE: Definitions

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0310

Definitions are being amended to ensure clarity within the division. A definition is being added for finished inhalable cannabinoid product.

The definition of control study and the use of the term control study is being removed from the definitions due to the repeal of the control study rule found under OAR 333-007-0440.

The definition of harvest lot is being amended to mean marijuana harvested within a 7-calendar day period instead of a 72 hour period.

The definition of remediation is being amended to include heavy metals as a contaminant that may be remediated.

The definition of sterilization is being amended to include other methods other than chemical or high heat that could result in sterilization of a marijuana item or industrial hemp-derived vapor item.

Statutes are being updated due to renumbering of chapter number.

Rule re-filed effective April 7, 2022 due to errors in definitions of sections (31) and (32).

RULE TEXT:

For purposes of OAR 333-007-0300 through 333-007-0500:

(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 finished 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) "Adult use cannabinoid" includes, but is not limited to, tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, the optical isomers of delta-8-tetrahydrocannabinol or delta-9 tetrahydrocannabinol and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.

(3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae.

(b) "Artificially derived cannabinoid" does not include:

(A) A naturally occurring chemical substance that is separated from the plant Cannabis family Cannabaceae by a chemical or mechanical extraction process;

(B) Cannabinoids that are produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst; or

(C) Any other chemical substance identified by the Commission, in consultation with the Authority and the Department of Agriculture, by rule.

(4) "Authority" means the Oregon Health Authority.

(5) "Batch" means:

(a) A quantity of marijuana or usable marijuana from a harvest lot; or

(b) A quantity of cannabinoid concentrate or extractor cannabinoid product from a process lot.

(6) "Cannabinoid" means any of the chemical compounds that are the active constituents of marijuana.

(7) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.

(8) "Cannabinoid edible" means food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.

(9)(a) "Cannabinoid product" means a cannabinoid edible or any other product intended for human consumption or use, including a product intended to be applied to a person's skin or hair, that contains cannabinoids or the dried leaves or flowers of marijuana; or

(b) Usable marijuana, cannabinoid extracts and cannabinoid concentrates that have been combined with an added substance.

(c) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

(B) A cannabinoid concentrate or extract by itself.; or

(C) Industrial hemp.

(10) "Cannabinoid capsule":

(a) Means a small, soluble pill, tablet, or container that contains liquid or powdered cannabinoid product, concentrate or extract and is intended for human ingestion.

(b) Does not mean a cannabinoid suppository.

(11) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.

(12) "Cannabinoid tincture" means a liquid cannabinoid product packaged in a container of four fluid ounces or less that consists of either:

(a) A non-potable solution of at least 25 percent non-denatured alcohol, in addition to cannabinoid concentrate, extract or usable marijuana, and perhaps other ingredients intended for human consumption or ingestion that is exempt from the Liquor Control Act under ORS 471.035; or

(b) A non-potable solution comprised of glycerin, plant-based oil, or concentrated syrup; cannabinoid concentrate, extract or usable marijuana; and perhaps other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.

(13) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair and for purposes of testing includes transdermal patches.

(14) "Cannabis" means the plant species Cannabis sativa and in these rules refers to all forms of the plant regardless of THC content and may also be used to refer to processed products that contain marijuana or industrial hemp.

(15) "Cannabis Tracking System" or "CTS" means the Oregon Liquor and Cannabis Commission's system for tracking the transfer of marijuana items or industrial hemp-derived vapor item and other information as authorized by ORS 475C.177.

(16) "Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid

product, concentrate or extract for absorption into the bloodstream.

(17) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

(18) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.

(19) "Chain of custody procedures" means procedures employed by laboratory personnel using a chain of custody form to record the possession of samples from the time of sampling through the retention time specified by the Authority, Commission or Department of Agriculture.

(20) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.

(21) "Commission" means the Oregon Liquor and Cannabis Commission.

(22) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a marijuana item or industrial hemp-derived vapor item.

(23) "Consumer" has the meaning given that term in ORS 475C.009 and does not include a patient, designated primary caregiver or organization or facility caregiver.

(24) "Cured" means a process of removing moisture from marijuana under controlled environmental conditions so the moisture content is 15 percent or less.

(25) "Delta-8-tetrahydrocannabinol" or "Delta-8 THC" means (6aR, 10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.

(26) "Delta-9-tetrahydrocannabinol" or "Delta-9 THC" means (6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol., Chemical Abstracts Service Number 1972-08-3.

(27) "Delta-9-tetrahydrocannabinolic acid" or "delta-9-THCA" means (6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-2- carboxylic acid, Chemical Abstracts Service Number 23978-85-0.

(28)(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475C.783(5)(b).

(b) "Designated primary caregiver" does not include the person's attending physician.

(29) "Duplicate sample" means sample increments taken in an identical manner to sample increments taken for the primary sample and representative of the same marijuana item or industrial hemp-derived vapor item being sampled that is prepared and analyzed separately from the primary sample.

(30) "Finished cannabinoid concentrate or extract" means a cannabinoid concentrate or extract that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.

(31) "Finished cannabinoid product" means a cannabinoid product that is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids.

(32) "Finished inhalable cannabinoid product" means a cannabinoid product that is intended for human use via inhalation, is in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer, and includes all ingredients whether or not the ingredients contain cannabinoids.

(33) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, chewing gum and includes beverages.

(34) "Grower" has the same meaning as "person responsible for a marijuana grow site."

(35) "Grow site" means a specific location registered by the Authority and used by the grower to produce marijuana for medical use by a specific patient under ORS 475C.792.

(36) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a seven calendar-day period at the same location and cured under uniform conditions.

(37) "High heat" means a temperature exceeding 180 degrees Fahrenheit.

(38) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.

- (39) "Human consumption or human ingestion" means to ingest, generally through the mouth, food, drink or other substances such that the substance enters the human body but does not include inhalation.
- (40) "Human use" includes human consumption or human ingestion, inhalation, topical application or any other use that allows a cannabinoid to enter the human body.
- (41) "Industrial hemp" has the meaning given that term in ORS 571.269.
- (42) "Industrial hemp-derived vapor item" means an industrial hemp concentrate or industrial hemp extract, as those terms are defined in ORS 571.269, whether alone or combined with other substances, that is intended for use in an inhalant delivery system.
- (43) "Inhalant delivery system" has the meaning given that term in ORS 431A.175.
- (44) "Laboratory" means a laboratory that is accredited under ORS 438.605 to 438.620 to sample or conduct tests on marijuana items and licensed by the Oregon Liquor and Cannabis Commission under ORS 475C.548.
- (45) "Level of quantification" means the minimum levels, concentrations, or quantities of a target variable, for example an analyte, that can be reported by a laboratory with a specified degree of confidence.
- (46) "Licensee" has the meaning given that term in ORS 475C.009.
- (47)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.
- (b) "Marijuana" does not include industrial hemp.
- (48) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.
- (49) "Marijuana processing site" means a marijuana processing site registered under ORS 475C.815.
- (50) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475C.833.
- (51) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.
- (52) "Organization or facility caregiver" means:
- (a) An organization that provides hospice, palliative or home health care services that:
- (A) Is licensed under ORS 443.014 to 443.105, 443.305 to 443.355, or 443.850 to 443.869;
- (B) Has significant responsibility for managing the well-being of a patient; and
- (C) Is designated by the Authority as an additional caregiver for a patient; or
- (b) A residential facility as defined in ORS 443.400 that:
- (A) Is licensed under ORS 443.400 to 443.455;
- (B) Has significant responsibility for managing the well-being of a patient: and
- (C) Is designated by the Authority as an additional caregiver for a patient.
- (53) "Patient" has the same meaning as "registry identification cardholder."
- (54) "Person responsible for a marijuana grow site" has the same meaning as "grower" and means a person who has been selected by a patient to produce medical marijuana for the patient and who has been registered by the Authority for this purpose under ORS 475C.792.
- (55) "Process lot" means:
- (a) Any amount of cannabinoid concentrate or extract or industrial hemp-derived vapor item of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or
- (b) Any amount of a cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of cannabinoid concentrate or extract.
- (56) "Processing" means:
- (a) The compounding or conversion of marijuana into cannabinoid products, or cannabinoid concentrates or extracts.
- (b) The compounding or conversion of industrial hemp into industrial hemp concentrates or industrial hemp extracts.

- (57) "Processing site" means a processor registered with Authority under ORS 475C.815.
- (58) "Processor" has the meaning given that term in OAR 845-025-1015.
- (59) "Producer" has the meaning given that term in OAR 845-025-1015.
- (60) "Producing" means:
- (a) Planting, cultivating, growing, trimming or harvesting marijuana; or
 - (b) Drying marijuana leaves and flowers.
- (61) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475C.792, 475C.815 or 475C.833.
- (62) "Registry identification cardholder" means a person who has been diagnosed by an attending physician with a debilitating medical condition and for whom the use of medical marijuana may mitigate the symptoms or effects of the person's debilitating medical condition, and who has been issued a registry identification card by the Authority under ORS 475C.783(5)(a).
- (63) "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100.
- (64) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.
- (65) "Remediation":
- (a) Means a process or technique applied to a marijuana item or industrial hemp-derived vapor item to remove heavy metals, pesticides or solvents.
 - (b) Does not include dilution.
- (66) "Replicate sample" means a sample in addition to the primary and duplicate samples that consists of the same number of increments taken in the same manner as the primary and duplicate samples.
- (67) "Sample" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.
- (68) "Sample increment" means an amount of a marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing.
- (69) "Standard operating procedure" means:
- (a) A written set of instructions or procedures using the same ingredients, methods and steps to create a single type of marijuana item or industrial hemp-derived vapor item.
 - (b) For the purposes of producing kief includes but is not limited to procedures for creating the kief, purging unwanted components from the kief, thoroughly cleaning all equipment, counters and surfaces used to produce the kief, and appropriate use of any necessary safety or sanitary equipment.
- (70) "Sterilization" means the removal of all microorganisms and other pathogens from a marijuana item or industrial hemp-derived vapor item by treating it with approved chemicals, subjecting it to high heat or other process.
- (71) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.
- (72) "Texture" means the feel, appearance, or consistency of a marijuana item or industrial hemp-derived vapor item.
- (73) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.
- (74) "THCA" means tetrahydrocannabinolic acid, and has the same meaning as delta-9 THCa.
- (75) "These rules" means OAR 333-007-0300 through 333-007-0500.
- (76) "Total delta-9-tetrahydrocannabinol" or "Total delta-9 THC" means the sum of the concentration or mass of delta-9-THCA multiplied by 0.877 plus the concentration or mass of delta-9-THC.
- (77) "Unit of sale" means an amount of a marijuana item or industrial hemp-derived vapor item commonly packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver, or capable of being packaged for transfer or sale to a consumer, patient, designated primary caregiver or organization or facility caregiver.
- (78) "Usable marijuana":
- (a) Means the dried leaves and flowers of marijuana.

(b) Includes, for purposes of these rules, pre-rolled marijuana as long as the pre-roll consists of only dried marijuana leaves and flowers, an unflavored rolling paper and a filter or tip.

(c) Does not include:

(A) The seeds, stalks and roots of marijuana; or

(B) Waste material that is a by-product of producing or processing marijuana.

STATUTORY/OTHER AUTHORITY: ORS 475C.544, ORS 475C.540

STATUTES/OTHER IMPLEMENTED: ORS 475C.544, ORS 475C.540