

Division 7
MARIJUANA & HEMP CONCENTRATION LIMITS AND TESTING

~~333-007-0200~~

~~Concentration and Serving Size Limits: Definitions, Purpose, Scope and Effective Date~~

- ~~(1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:~~
- ~~(a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and~~
- ~~(b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.~~
- ~~(2) OAR 333-007-0200 through 333-007-0220 apply to:~~
- ~~(a) A Commission licensee as that is defined in OAR 845-025-1015; and~~
- ~~(b) A person registered with the Authority under ORS 475B.875 to 475B.949 who is not exempt under ORS 475B.630.~~
- ~~(3) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.~~
- ~~(4) A cannabinoid product or cannabinoid concentrate or extract meets the concentration limits permitted under OAR 333-007-0210 through 333-007-0220 if the THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent.~~
- ~~(5) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0220.~~
- ~~(6) For purposes of OAR 333-007-0200 through 333-007-0220:~~
- ~~(a) The definitions in OAR 333-007-0310 apply unless otherwise specified.~~
- ~~(b) "Cannabinoid capsule" means a small, soluble pill, tablet or container that contains liquid or powdered cannabinoid product, concentrate or extract and is intended for human ingestion.~~
- ~~(c) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.~~
- ~~(d) "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.~~
- ~~(e) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.~~
- ~~(f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.~~
- ~~(g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.~~
- ~~(h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:~~
- ~~(A) Intuitively determine how much of the product constitutes a single serving; and~~

Commented [FM1]: SB 408 and HB 3000 transfer authority to OLCC. OLCC to adopt rules to be effective 1/1/2022

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(B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.

Statutory/Other Authority: ORS 475B.625

Statutes/Other Implemented: ORS 475B.625

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 104-2018, minor correction filed 04/27/2018, effective 04/27/2018

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 33-2016, f. & cert. ef. 11-28-16

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0210

Retail Marijuana Item Concentration and Serving Size Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a retail adult use marijuana item is listed in Table 1. [Table not included. See ED. NOTE.]

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a consumer to determine when a single serving has been consumed.

(3) Serving size is as determined by the processor.

(4) A retail adult use marijuana item that does not fall within a category in Table 1 such as cannabinoid suppositories and transdermal patches or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 1.

[ED. NOTE: Tables referenced are available from the agency.]

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 475B.625

Statutes/Other Implemented: ORS 475B.625

History:

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 33-2016, f. & cert. ef. 11-28-16

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0220

Medical Marijuana Item Concentration Limits

(1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a medical marijuana item is listed in Table 2.

(2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:

(a) Sold and packaged with a measuring device that measures single servings; or

(b) Placed in packaging that clearly enables a patient to determine when a single serving has been consumed, as that serving size is determined by the processor.

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~~(3) Serving size is as determined by the processor.~~

~~(4) A medical marijuana item that does not fall within a category in Table 2 or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 2.~~

~~[ED. NOTE: Tables referenced are available from the agency.]~~

~~[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]~~

~~Statutory/Other Authority: ORS 475B.625~~

~~Statutes/Other Implemented: ORS 475B.625~~

~~History:~~

~~PH 9-2017, f. 5-26-17, cert. ef. 5-31-17~~

~~PH 33-2016, f. & cert. ef. 11-28-16~~

~~PH 21-2016, f. 6-24-16, cert. ef. 6-28-16~~

~~PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16~~

333-007-0300

Marijuana-Cannabis Testing: Purpose and Effective Date

(1) The purpose of these rules is to establish the minimum compliance testing standards for marijuana items and industrial hemp-derived vapor items. These rules are applicable to persons who process, sell, or transfer marijuana items or industrial hemp-derived vapor items except as exempted in section (2) of this rule.

~~(a) A licensee; and~~

~~(b) A registrant who is not exempt from the testing requirements.~~

(2) The testing requirements do not apply to:

(a) A grower if the person is transferring usable marijuana or an immature marijuana plant to:

(A) A patient who designated the grower to grow marijuana for the patient; or

(B) A designated primary caregiver or an organization or facility caregiver of the patient who designated the grower to grow marijuana for the patient; or

(b) A designated primary caregiver or an organization or facility caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver or organization or facility caregiver.

(c) Immature plants or seeds.

(3) A person registered with the Authority under ORS 475B.785 to 475B.828 who is subject to these rules may not:

(a) Transfer a marijuana item that is not sampled and tested in accordance with these rules; or

(b) Accept the transfer of a marijuana item that is not sampled and tested in accordance with these rules.

(4) A person licensed by the Commission must comply with these rules at all times.

(5) If a registrant, who is exempt from the testing requirements, chooses to have a marijuana item tested for pesticides, the requirements of OAR 333-007-0450 and 333-007-0500 still apply.

Statutory/Other Authority: ORS 475B.555; ORS 475B.550; SB 96

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 105-2018, minor correction filed 04/27/2018, effective 04/27/2018

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 33-2016, f. & cert. ef. 11-28-16

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PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0310

Definitions

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, 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, ~~as defined in ORS 571.300.~~

(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.

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(b) Does not mean a cannabinoid suppository.

~~(119)~~ "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.

~~(129)~~ "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.

~~(134)~~ "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 hemp.

~~(152)~~ "Cannabis Tracking System" or "CTS" means the Oregon Liquor ~~Control~~Cannabis Commission's system for tracking the transfer of marijuana items or industrial hemp-derived vapor item and other information as authorized by ORS 475B.177.

~~(163)~~ "Cannabinoid Transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.

~~(174)~~ "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.

~~(185)~~ "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.

~~(196)~~ "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, ~~or Commission~~ or Department of Agriculture.

~~(2047)~~ "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.

~~(2148)~~ "Commission" means the Oregon Liquor ~~Control~~Cannabis Commission.

~~(2249)~~ "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.

~~(239)~~ "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient, designated primary caregiver or organization or facility caregiver.

~~(244)~~ "Control study" means a study performed on products or matrices of unknown homogeneity to assure required uniformity of product accomplished through sampling and testing as described in OAR 333-007-0440.

~~(252)~~ "Cured" means a process of removing moisture from marijuana under controlled environmental conditions so the moisture content is 15 percent or less.

~~(26)~~ "Delta-8-tetrahydrocannabinol" or "Delta-8 THC" means (6aR, 10aR)-6,6,9-trimethyl-3-pentyl-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.

~~(273)~~ "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 ~~is the principal psychoactive constituent (the principal cannabinoid) of cannabis~~, Chemical Abstracts Service Number 1972-08-3.

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(28) "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.

(294)(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 475B.415(5)(b).

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

~~(3025)~~ "Field 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.

~~(3126)~~ "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.

~~(3227)~~ "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.

~~(3328)~~ "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.

~~(3429)~~ "Grower" has the same meaning as "person responsible for a marijuana grow site."

~~(359)~~ "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 475B.810.

~~(364)~~ "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location and cured under uniform conditions.

~~(372)~~ "High heat" means a temperature exceeding 180 degrees Fahrenheit.

~~(383)~~ "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.

~~(394)~~ "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.

~~(4035)~~ "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.

~~(4436)~~ "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 ~~Control~~Cannabis Commission under ORS 475B.560.

~~(4537)~~ "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.

~~(4638)~~ "Licensee" has the meaning given that term in ORS 475B.015.

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~~(4739)~~(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, ~~as defined in ORS 571.300.~~

~~(480)~~ "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

~~(494)~~ "Marijuana processing site" means a marijuana processing site registered under ORS 475B.840.

~~(5042)~~ "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.858.

~~(5143)~~ "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

~~(5244)~~ "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.

~~(5345)~~ "Patient" has the same meaning as "registry identification cardholder."

~~(5446)~~ "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 475B.810.

~~(5547)~~ "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.

~~(5648)~~ "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.

~~(5749)~~ "Processing site" means a processor registered with Authority under ORS 475B.840.

~~(580)~~ "Processor" has the meaning given that term in OAR 845-025-1015.

~~(594)~~ "Producer" has the meaning given that term in OAR 845-025-1015.

~~(6052)~~ "Producing" means:

(a) Planting, cultivating, growing, trimming or harvesting marijuana; or

(b) Drying marijuana leaves and flowers.

~~(6153)~~ "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.810, 475B.840 or 475B.858.

~~(6254)~~ "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

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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 475B.797(5)(a).

~~(6355)~~ "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.

~~(6456)~~ "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.

~~(6557)~~ "Remediation":

(a) Means a process or technique applied to a marijuana item or industrial hemp-derived vapor item to remove pesticides or solvents.

(b) Does not include dilution.

~~(6658)~~ "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.

~~(6759)~~ "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 or, in the case of a control study, is tested individually.

~~(689)~~ "Standard operating procedure" 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.

~~(694)~~ "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 or subjecting it to high heat.

~~(7062)~~ "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.

~~(7163)~~ "Texture" means the feel, appearance, or consistency of a marijuana item or industrial hemp-derived vapor item.

~~(7264)~~ "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.

~~(7365)~~ "THCA" means tetrahydrocannabinolic acid, ~~Chemical Abstracts Service Number 23978-85-0 and has the same meaning as Delta-9 THCa.~~

~~(7466)~~ "These rules" means OAR 333-007-0300 through 333-007-0500.

~~(7567)~~ ~~"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 means the molar sum of THC and THCA.~~

~~(7668)~~ "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.

~~(7769)~~ "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.

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Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 106-2018, minor correction filed 04/27/2018, effective 04/27/2018
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0315

Ordering Tests

- (1) To request a compliance test a requestor~~A registrant or licensee~~ must provide a laboratory, prior to laboratory taking samples, with at a minimum, the following information as applicable:
- (a) The registrant or licensee's registrant or license number.
 - (b) The name, address and contact information of the registrant or licensee.
 - (c) If a registrant, whether the registrant is subject to tracking in CTS, under OAR chapter 333, division 8.
 - (d) Type of marijuana item or industrial hemp-derived vapor item.
 - (e) Harvest lot number that is associated with the batch numbers, if applicable.
 - (f) Process lot number that is associated with the batch numbers, if applicable.
 - (g) Batch numbers to be sampled.
 - (h) Total mass or volume of each batch to be sampled.
 - (i) For cannabinoid products, the unit of sale.
 - (j) Identification of the test or tests the laboratory is being requested to conduct.
 - (k) Whether the test or tests being requested are compliance tests.
 - (l) Whether the test or tests being requested are quality control or research and development tests.
 - (m) Whether a batch is being re-sampled because of a failed test, the date the failed test result was received by the registrant or licensee and laboratory identification number of the laboratory that conducted the initial test.
 - (n) Whether the marijuana item or industrial hemp-derived vapor item has a certified control study or a control study is being requested.
 - (o) Whether the marijuana item or industrial hemp-derived vapor item was remediated, if remediation is permitted under OAR 333-007-0450.
- (2) If a registrant or licensee is requesting a control study the request must be submitted on a form prescribed by the Authority, ~~or~~ Commission or Department of Agriculture, as specified in OAR 333-007-0440.
- (3) If the registrant or licensee informs a laboratory that a marijuana item or industrial hemp-derived vapor item is being re-sampled after a failed test or has a certified control study, the registrant or licensee must provide the laboratory with documentation of the failed test or certified control study as applicable.
- (4) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.
- (5) A registrant or licensee may only order a compliance test for a marijuana item that the registrant or licensee has produced or processed, as applicable, except a wholesaler who may order a compliance test.

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(6) ~~A registrant or licensee may not order m~~More than one compliance test for the same marijuana item ~~or industrial hemp-derived vapor item may not be ordered.~~

(7) It is a violation of these rules for a registrant or licensee to:

(a) Fail to provide the information required in these rules to the laboratory; or

(b) Submit false or misleading information to a laboratory ~~or a directed agency to submit false or misleading information to a laboratory.~~

~~(8) Once a test order has been submitted to a laboratory by a registrant or licensee and at least one test has already been performed, the order may not be canceled unless written permission is given by the commission, the authority or the Department of Agriculture.~~

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 29-2017, amend filed 12/22/2017, effective 01/01/2018

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0320

Compliance Testing Requirements for Marijuana or Usable Marijuana

(1) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a consumer or patient prior to selling or transferring the marijuana or usable marijuana for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Water activity and moisture content in accordance with OAR 333-007-0420.

(c) ~~Adult use cannabinoid~~THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid concentrate or extract for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.

(3) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid product for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.

(4) A producer or grower must test one or more batches from a harvest lot of marijuana or usable marijuana for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(5) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

(6) A marijuana producer must test every batch from a harvest lot of marijuana or usable marijuana intended to produce kief for water activity prior to producing the kief unless the producer tests the kief for water activity per OAR 333-0070-0420.

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Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0330

Compliance Testing Requirements for Cannabinoid Concentrates and Extracts

- (1) A processor or processing site must test every process lot of a finished cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following:
 - (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
 - (c) [Adult use cannabinoid](#) ~~THC~~ and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following, except for a cannabinoid concentrate that meets the criteria in section (6) of this rule:
 - (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
- (3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:
 - (a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and
 - (b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or
 - (c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.
- (4) A processor or processing site must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.
- (6) A process lot of a cannabinoid concentrate that is made only using food grade animal fat or food grade plant-based oil is not required to be tested for pesticides if:
 - (a) All marijuana or usable marijuana used to make the concentrate was tested for pesticides and passed pesticide testing in accordance with OAR 333-007-0400; and
 - (b) The concentrate itself is only used to make a cannabinoid product intended for human consumption or use but not intended for inhalation and the concentrate is not sold directly to consumers or patients.
- (7) Marijuana producers producing kief as permitted under OAR 845-025-2020:
 - (a) Must test every process lot for use by a consumer or patient prior to selling or transferring the kief for the following:
 - (A) Pesticides in accordance with OAR 333-007-0400.

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(B) Water activity in accordance with OAR 333-007-0420.
(C) ~~Adult use cannabinoid~~THC and CBD concentration in accordance with OAR 333-007-0430.
(b) Must test every process lot intended for use by a processor in making a cannabinoid product for the following:

(A) Pesticides in accordance with OAR 333-007-0400; and
(B) Water activity in accordance with OAR 333-007-0420.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021
PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0340

Compliance Testing Requirements for Cannabinoid Products

(1) A processor or processing site must test every process lot of a finished cannabinoid product intended for human consumption, use or ingestion for use by a consumer or patient prior to selling or transferring the cannabinoid product for ~~adult use cannabinoid~~THC and CBD concentration in accordance with OAR 333-007-0430.

(2) A processor or processing site must test a process lot of a finished cannabinoid product intended for human consumption, use or ingestion for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.

(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products referenced in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-03XX

Compliance Testing Requirements for Industrial Hemp-Derived Vapor Items

(1) Every process lot of an industrial hemp-derived vapor item for use by a consumer or patient prior to selling or transferring the item must be tested for the following:

(a) Pesticides in accordance with OAR 333-007-0400.

(b) Solvents in accordance with OAR 333-007-0410.

(c) Adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430.

(2) Every process lot of an industrial hemp-derived vapor item may be tested for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Commission or the Department of Agriculture.

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(3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of industrial hemp-derived vapor items to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0350

Batch Requirements for Compliance Testing

(1) Marijuana or usable marijuana. A producer or grower must separate each harvest lot of marijuana or usable marijuana into no larger than 15 pound batches.

(2) Cannabinoid concentrates and extracts.

(a) A process lot of a cannabinoid concentrate, ~~or~~ extract or industrial hemp-derived vapor item is considered a batch.

(b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that concentrate, ~~or~~ extract or industrial hemp-derived vapor item for purposes of sampling and testing after a control study has been certified.

(c) A processor or processing site must separate process lots into not larger than 35 kilograms.

(3) Cannabinoid products.

(a) A processor or processing site must separate process lots into not larger than 35,000 unit of sale batches.

(b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that product for purposes of sampling and testing after a control study has been certified.

(4) Industrial hemp-derived vapor items.

(a) A process lot of an industrial hemp-derived vapor item is considered a batch.

(b) The size of a process lot submitted for sampling and testing for purposes of a control study under OAR 333-007-0440 defines the maximum process lot for that industrial hemp-derived vapor item for purposes of sampling and testing after a control study has been certified.

(4) A grower and processing site must assign each batch a unique batch number and that unique batch number must be:

(a) Documented and maintained in the grower and processing site records for at least two years and available to the Authority upon request;

(b) Provided to the individual responsible for taking samples; and

(c) Included on the batch label as required in OAR 333-007-0380.

(5) A grower and processing site may not reuse a unique batch number.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

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333-007-0360

Sampling and Sample Size Requirements for Compliance Testing

(1) Marijuana or usable marijuana.

(a) Usable marijuana may only be sampled after it is cured, unless the usable marijuana is intended for sale or transfer to a processor or processing site to make a cannabinoid concentrate or extract.

(b) Sample increments taken must in total represent a minimum of 0.5 percent of the batch, consistent with the laboratory's accredited sampling policies and procedures, described in OAR 333-064-0100(2).

(c) A portion of sample increments taken from multiple batches of usable marijuana from the same harvest lot may be combined into one sample for purposes of testing for adult use cannabinoid per OAR 333-007-0430THC and CBD if the batches are the same strain, regardless of the size of the multiple batches.

(2) Cannabinoid concentrates, extracts, ~~and~~ products and industrial hemp-derived vapor items.

(a) Samples of cannabinoid concentrates, extracts, ~~and~~ products and industrial hemp-derived vapor items intended for human consumption, use or ingestion for use by a consumer or patient must be taken from the finished cannabinoid concentrate, extract or product as those terms are defined in OAR 333-007-0310 except for as outlined in (e) of this rule.

(b) Until a control study has been certified under OAR 333-007-0440, the minimum number of sample increments that must be taken are established in Exhibit B, Table 5 or 6, incorporated by reference. Enough sample increments from a batch must be taken to determine whether the batch is homogeneous and must be taken in a manner consistent with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

(c) If a cannabinoid concentrate or extract has a certified control study, the minimum number of sample increments that must be taken for future batches of that concentrate or extract are established in Exhibit B, Table 7, incorporated by reference. The sample increments may be combined into a primary sample and a field duplicate sample in accordance with OAR 333-007-0440(9) and OAR 333-064-0100(2). The primary sample and the field duplicate sample must be prepared and analyzed separately.

(d) For a cannabinoid product that has a certified control study, at a minimum one unit of sale chosen at random, is required for the primary sample and one unit of sale chosen at random, is required for the field duplicate sample for testing future batches of that product in accordance with OAR 333-007-0440(9) and OAR 333-064-0100(2). The primary sample and the field duplicate sample must be prepared and analyzed separately.

(e) ~~A sufficient sample size must be taken for analysis of all requested tests and the quality control performed by the testing laboratory for these tests.~~

If baking of a cannabinoid edible is the final step to create a finished cannabinoid product, the processor or processing site may leave the production lot unbaked and only bake the samples chosen by the testing laboratory for sampling. Prior to sampling, the processor or processing site must ensure that the entire batch is available to the laboratory and in a form where the only remaining step to complete the edible is baking. If anything is added to the edible after baking, the entire batch must be baked and finished prior to sampling. Baking means to subject the item to dry heat especially by an oven.

(3) Industrial hemp-derived vapor items.

(a) Samples of industrial hemp-derived vapor items must be taken in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer.

(b) Until a control study has been certified under OAR 333-007-0440, the minimum number of sample increments that must be taken are established in Exhibit B, Table 5, incorporated by reference. Enough sample increments from a batch must be taken to determine whether the batch is homogeneous and must

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be taken in a manner consistent with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2).

(c) If an industrial hemp-derived vapor item has a certified control study, the minimum number of sample increments that must be taken for future batches of that industrial hemp-derived vapor item are established in Exhibit B, Table 7, incorporated by reference. The sample increments may be combined into a primary sample and a field duplicate sample in accordance with OAR 333-007-0440(9) and OAR 333-064-0100(2). The primary sample and the field duplicate sample must be prepared and analyzed separately.

(4) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.-

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0390

Standards for Microbiological Contaminants Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for microbiological contaminants under OAR 333-007-0320 to 333-007-03~~X~~40 must be sampled using appropriate aseptic technique and tested by a laboratory for total coliform count.

(2) If a laboratory detects the presence of any coliforms the sample must be assessed for Escherichia coli (E. coli).

(3) A batch fails microbiological contaminant testing if the laboratory detects the presence of E. coli at more than 100 colony forming units per gram in a sample:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in OAR 333-007-0450(1).

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 258-2018, minor correction filed 11/28/2018, effective 11/28/2018

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0400

Standards for Pesticides Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for pesticides must be tested by a laboratory for the analytes listed in Exhibit A, Table 3, incorporated by reference. [Table attached.]

Commented [FM3]: Place holder for industrial hemp-derived vapor item rule number

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(2) A batch fails pesticide testing if a laboratory detects the presence of a pesticide above the action levels listed in Exhibit A, Table 3 in any sample, including a field duplicate:

- (a) During an initial test where no reanalysis is requested; or
- (b) Upon reanalysis as described in OAR 333-007-0450(1).
- (3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0410

Standards for Solvents Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for solvents must be tested by a laboratory for the analytes listed in Exhibit A, Table 4 incorporated by reference. [Table attached.]

(2) A batch fails solvent testing if a laboratory, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

- (a) Detects the presence of a solvent above the action level listed in Exhibit A, Table 4 in a sample; or
- (b) Calculates a RPD of more than 15 percent between the field primary result and the field duplicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4.
- (3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years.

[ED. NOTE: To view attachments referenced in rule text, click here to view rule.]

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0430

Standards for ~~Adult Use Cannabinoid~~THC and CBD Compliance Testing

(1) A laboratory must test for the following when testing a marijuana item or industrial hemp-derived vapor item for potency:

- (a) Delta-9 THC.
- (b) Delta-9 THCA.
- (c) Delta-8 THC
- (c) CBD.
- (d) CBDA.

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(2) A process lot of a cannabinoid concentrate, extract or product that has not successfully completed a control study fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of total Delta-9 THC, Delta-8 THC, and CBD, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 20 percent RSD; or

(b) The amount or percentage of delta-8 THC and total delta-9 THC, as calculated pursuant to OAR 333-064-0100 for any sample increment exceeds the maximum concentration limits permitted in package by over 10 percent as specified in OAR ~~845-XXX-XXXX~~ 333-007-0200 to 333-007-0220, as applicable.

(3) A process lot of a cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item that has successfully completed a control study fails potency testing if, based on an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1):

(a) The amount of delta-8 THC, total delta-9 THC or CBD, as calculated pursuant to OAR 333-064-0100, between the primary sample and the field duplicate exceeds 15 percent RPD; or

(b) The amount or percentage of delta-8 THC, total delta-9 THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in a package by over 10 percent as specified in OAR ~~845-XXX-XXXX~~ 333-007-0200 to 333-007-0220, as applicable

(4) Notwithstanding subsection (2)(a) and (3)(a) of this rule:

(a) A cannabinoid product that has less than 5 mg of total delta-9 THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

(b) A cannabinoid product that has less than 510 mg of CBD per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

(c) A cannabinoid product that has less than 5 mg of delta-8 THC per unit of sale as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

(d) A cannabinoid concentrate, ~~or~~ extract or industrial hemp-derived vapor item that has less than 5 mg total delta-9 THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

(e) A cannabinoid concentrate, ~~or~~ extract or industrial hemp-derived vapor item that has less than 105 mg CBD per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

(f) A cannabinoid concentrate, extract or industrial hemp-derived vapor item that has less than 5 mg delta-8 THC per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in subsection (2)(a) or (3)(a) of this rule.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

Commented [FM4]: Place holder for OLCC concentration limit rules

Commented [FM5]: Place holder for OLCC concentration limits rule

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333-007-0440
Control Study

The purpose of a control study is to determine if a processor or processing site is using standard operating procedures (SOP) that result in a finished cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item that is homogeneous and for cannabinoid products meets the potency target identified in the SOPs.

(1) A laboratory may perform a control study on a process lot of cannabinoid concentrates, extracts, ~~or~~ products or industrial hemp-derived vapor item for a processor or processing site if the processor or processing site provides to a laboratory, in writing:

(a) A request for a control study on a form prescribed by the Authority, ~~or~~ Commission or Department of Agriculture; and

(b) For cannabinoid products provides:

(A) A reference number or name of the SOP for the product that is the subject of the control study, the version number of the SOP if applicable, and the date the SOP was created and last modified, if applicable;

(B) The amount of adult use cannabinoid ~~THC~~ the processor or processing site intends the cannabinoid product to have per unit of sale of the product;

(C) The number of uniform units of sale in the process lot;

(D) The final weight of the unit of sale;

(E) The number of servings in the unit of sale, if applicable;

(F) Product category (examples include edible, tincture, topical, capsule); and

(G) The texture of product.

(c) For cannabinoid concentrates, ~~and~~ extracts or industrial hemp-derived vapor items provides:

(A) A reference number or name of the SOP for the concentrate or extract that is the subject of the control study, the version number of the SOP if applicable, and the date the SOP was created and last modified, if applicable;

(B) The total weight of the batch;

(C) The final weight of the unit of sale, if applicable;

(D) Product category (concentrate or extract); and

(E) The texture of the concentrate or extract.

(d) A description of any variation of the product, concentrate, ~~or~~ extract or industrial hemp-derived vapor item the processor or processing site intends to include under the control study that would be permitted under section (11) of this rule, including for each separate product, concentrate or extract the weight of the unit of sale and the number of servings in the unit of sale, if applicable.

(2) Sample increments taken for purposes of a control study may not be combined and must be taken in accordance with OAR 333-007-0360, Exhibit B, Table 5 or 6, incorporated by reference.

(3) Sample increments from a cannabinoid concentrate, ~~or~~ extract or industrial hemp-derived vapor item must be tested for:

(a) Pesticides in accordance with OAR 333-007-0400;

(b) Solvents in accordance with OAR 333-007-0410; and

(c) Adult use cannabinoid ~~THC~~ concentration in accordance with OAR 333-007-0430 if the concentrate or extract is intended to be transferred or sold directly to a consumer or patient.

(4) Sample increments from a cannabinoid product must be tested for ~~THC~~ adult use cannabinoid concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.

(5) During a control study a batch passes:

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- (a) Pesticide testing if each sample increment is below the action limit established in OAR 333-007-0400.
- (b) Solvent testing if each sample increment is below the action limit established in OAR 333-007-0410; and
- (c) ~~Adult use cannabinoid~~THC and CBD concentration testing if:
- (A) The amount of delta-8 THC, total delta-9 THC and CBD, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch does not exceed 20 percent RSD;
- (B) For cannabinoid products, the amount of delta-8 THC or total delta-9 THC in any sample increment, as calculated pursuant to OAR 333-064-0100, does not exceed by more than 20 percent the amount of delta-8 THC or delta-9 THC the processor or processing site intended the product to contain as described in section (1) of this rule, unless all sample increments are below 10 mg delta-8 THC and total delta-9 THC per unit of sale in which case this paragraph does not apply; and
- (C) The amount or percentage of delta-8 THC or total delta-9 THC as calculated pursuant to OAR 333-064-0100 for any sample increment does not exceed the maximum concentration limit permitted in a package by more than 10 percent as specified in ~~OAR 845-XXX-XXXX~~~~333-007-0200 to 333-007-0220~~, as applicable.
- (6) A laboratory must identify on a form prescribed by the Authority if a batch undergoing a control study has passed for any of the following, and must send the form at the client's request to the Authority or the Commission:
- (a) Pesticides, if applicable.
- (b) Solvents, if applicable.
- (c) ~~Adult use cannabinoid~~THC concentration as calculated pursuant to OAR 333-064-0100.
- (7) A control study fails if:
- (a) Any sample increment exceeds an action limit in OAR 333-007-0400 (Pesticides) or 333-007-0410 (Solvents).
- (A) A sample increment that exceeds an action limit may not be reanalyzed and retested under OAR 333-007-0450(1) unless the laboratory determines that the result is due to laboratory error and the laboratory error is reported to the Authority or the Commission.
- (B) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400, 333-007-0410 may not be remediated under OAR 333-007-0450(5)(a) or (7)(c) for purposes of passing the control study.
- (C) A batch that has a sample increment fail for exceeding an action limit in OAR 333-007-0400 or 333-007-0410 may be remediated for purposes of selling or transferring the cannabinoid concentrate, extract or product, if permitted under OAR 333-007-0450, but sample increments from that batch may not be resubmitted for a control study.
- (b) The amount of delta-8 THC, total delta-9 THC or CBD in a cannabinoid concentrate, extract or product, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch exceeds:
- (A) 20 percent RSD; or
- (B) For cannabinoid products, the amount of delta-8 THC and total delta-9 THC the processor or processing site intended the product to contain as described in section (1) of this rule is exceeded by more than 20 percent, unless all sample increments are below 10 mg delta-8 THC and total delta-9 THC per unit of sale in which case this paragraph does not apply.
- (c) The amount or percentage of delta-8 THC or total delta-9 THC as calculated pursuant to OAR 333-064-0100 for any sample increment, exceeds the maximum concentration limit permitted in a package

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by more than 10 percent as specified in ~~OAR-845-XXX-XXXXXX~~ ~~333-007-0200 to 333-007-0220~~, as applicable.

(A) A batch that has a sample increment fail under subsections (b) or (c) of this section may not be re-mixed or re-packaged under OAR 333-007-0450(10)(a) or (b) for purposes of passing the control study.
(B) A batch that has a sample increment fail under subsections (b) or (c) of this section may be re-mixed or re-packaged for purposes of selling or transferring the cannabinoid concentrate, extract or product as permitted under OAR 333-007-0450(10)(a) or (b), but sample increments from that batch may not be resubmitted for a control study.
(8) A process lot sampled and tested for purposes of a control study may be sold or transferred if the sample increments pass all the required tests.

(9) If a cannabinoid concentrate, extract, ~~or~~ product, or industrial hemp-derived vapor item successfully passes a control study and the control study has been certified by the Authority, ~~or~~ the Commission or the Department of Agriculture, as applicable, the following applies to sampling and testing of future batches for two years except as provided in section (10) of this rule:

(a) For cannabinoid concentrates and extracts or industrial hemp-derived vapor items, sample increments may be collected and combined into a primary sample and a field duplicate sample as described in OAR 333-007-0360, Exhibit B, Table 7, OAR 333-064-0100, ORELAP-SOP-002 Rev. 4.1.

(b) For cannabinoid products, at a minimum, one unit of sale must be collected, at random, for the primary sample, and one unit of sale must be collected at random for the field duplicate sample.

(c) Both the primary sample and the field duplicate sample must be prepared and analyzed individually for any test that is required for the marijuana item or industrial hemp-derived vapor item.

(10) The certification of a control study is invalidated:

(a) If a processor or processing site makes any changes:

(A) To the standard operating procedures for that cannabinoid concentrate, extract or product, including changes that alter the texture, weight or volume of the unit of sale, homogeneity or for products, expected delta-8 THC or total delta-9 THC potency.

(B) In the type of ingredient in the cannabinoid concentrate, extract or product, except as outlined in section (11) of this rule.

(b) If a cannabinoid concentrate, extract, ~~or~~ product or industrial hemp-derived vapor item fails an adult use cannabinoid-THC or CBD test under OAR 333-007-0430(3)(a).

(11) For purposes of subsection (10)(a) of this rule it is not considered a change to standard operating procedures or a change in the type of ingredient if the processor or processing site is using:

(a) Different strains of usable marijuana in batches.

(b) An ingredient with a different level of purity as long as the purity of the ingredient complies with the Authority's or the Commission's processing rules.

(c) Different flavors or colors in batches, as long as the different flavors or colors do not have an effect on the potency of the finished cannabinoid product.

(d) The same type or form of an ingredient in the same or substantially the same amount where the only change is the taste or color of the finished cannabinoid product but does not change the texture or weight of the finished cannabinoid product.

(12) A processor or processing site does not qualify for reduced sampling and testing under a control study until either the Authority, ~~or~~ Commission or Department of Agriculture:

(a) Reviews documentation associated with the control study;

(b) Certifies the control study; and

(c) Notifies the laboratory and the processor that the control study is considered certified.

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(13) If a processor or processing site does not have a certified control study it must have the cannabinoid concentrate, extract or product sampled in accordance with OAR 333-007-0360, Exhibit B, Tables 5 and 6 and the sample increments prepared and analyzed separately.

(14) Any testing performed as part of a control study is considered a compliance test.

(15) A processor or processing site must report to the Authority or the Commission if a control study is invalidated under section (10) of this rule and failure to report is a violation of these rules.

(16) This rule also applies to producers producing kief under OAR 845-025-2020.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 1-2021, minor correction filed 01/05/2021, effective 01/05/2021

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

PH 29-2017, amend filed 12/22/2017, effective 01/01/2018

PH 9-2017, f. 5-26-17, cert. ef. 5-31-17

PH 38-2016(Temp), f. 12-13-16, cert. ef. 12-15-16 thru 5-30-17

PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0450

Failed Test Samples

(1) If a sample or a field duplicate sample (collectively referred to as "sample" for purposes of this rule) fails any initial test the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a field duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.

(a) If a registrant or licensee wishes to have a sample reanalyzed, the registrant or licensee must request a reanalysis within seven calendar days from the date the laboratory sent notice of the failed test to the registrant or licensee. The reanalysis must be completed by the laboratory within 30 days from the date the reanalysis was requested.

(b) If a registrant or licensee has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the registrant or licensee has seven calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

(c) A registrant or licensee must inform the Authority or the Commission immediately, of the following, in a manner prescribed by the Authority or the Commission:

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

(2) If a sample fails a test or a reanalysis under section (1) of this rule the batch:

(a) May be remediated or sterilized in accordance with this rule; or

(b) If it is not or cannot be remediated or sterilized under this rule, must be destroyed in a manner specified by the Authority or the Commission.

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- (3) If a registrant is permitted to remediate under this rule, the registrant must provide notice to the Authority of the registrant's intent to remediate.
- (4) Except as otherwise permitted under this rule, a cannabinoid concentrate, ~~or extract~~ or industrial hemp-derived vapor item that is permitted to undergo remediation cannot be further processed into a cannabinoid product during the remediation process.
- (5) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.
- (6) Failed microbiological contaminant testing.
- (a) If a sample from a batch of marijuana or usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.
- (b) If a sample from a batch of a cannabinoid concentrate, ~~or extract~~ or industrial hemp-derived vapor item fails microbiological contaminant testing the batch may be further processed if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.
- (c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.
- (d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.
- (7) Failed solvent testing.
- (a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.
- (b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.
- (c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.
- (8) Failed water activity or moisture content testing.
- (a) If a sample from a batch of marijuana or usable marijuana fails for water activity or moisture content the batch from which the sample was taken may:
- (A) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch; or
- (B) Continue to dry or cure.
- (b) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be sampled and tested in accordance with these rules.
- (9) Failed pesticide testing.
- (a) If a sample from a batch of marijuana or usable marijuana fails pesticide testing the batch may not be remediated and must be destroyed as ordered by the Authority or the Commission, except as permitted under subsection (c) of this section. A batch may not be destroyed without obtaining permission from the Authority or the Commission.
- (b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample of usable marijuana failed a pesticide test.

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(c) If a sample from a batch of marijuana or usable marijuana fails pesticide testing but only for the analytes piperonyl butoxide or pyrethrins, and the Oregon Department of Agriculture determines that the products used were listed on the Department's Guide List for Pesticides and Cannabis and the product was applied in accordance with the label, the Authority or the Commission may permit the producer or grower to remediate the usable marijuana using procedures that would reduce the concentration of pesticides to less than the action level. A batch of usable marijuana that is permitted to be remediated must be re-sampled and re-tested for pesticides in accordance with these rules.

(d) If a processor or a processing site is only processing with marijuana or usable marijuana that has passed pesticide testing under OAR 333-007-0320 and a sample from a batch of a cannabinoid concentrate or extract fails pesticide testing the batch may be remediated using procedures that would reduce the concentration of pesticides to less than the action level.

(e) If a batch of industrial hemp-derived vapor item fails pesticides testing, it may only be remediated using procedures that would reduce the concentration of pesticides to less than the action level if the input material used to make the industrial hemp-derived vapor item passed pesticide testing under OAR 333-007-0320.

(f) A batch that is remediated in accordance with subsection (d) of this section must be re-sampled and re-tested in accordance with these rules. A batch that is remediated but after being re-sampled and re-tested fails pesticide testing must be destroyed as ordered by the Authority or the Commission.

(10) Failed potency testing.

(a) A marijuana item or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-0430(2)(b) or (3)(b) may be repackaged in a manner that enables the item to meet the concentration limit standards in OAR 845-XXX-XXXX-333-007-0210 and 333-007-0220, as applicable. A marijuana item or industrial hemp-derived vapor item that is repackaged in accordance with this subsection must be re-sampled and re-tested in accordance with these rules.

(b) A marijuana item or industrial hemp-derived vapor item that fails potency testing under OAR 333-007-0430(2)(a) or (3)(a) may be re-mixed in an effort to meet the standards in OAR 333-007-0430(2)(a) or (3)(a). A marijuana item or industrial hemp-derived vapor item that is re-mixed must be re-sampled and re-tested in accordance with these rules.

(11) If a sample fails a test after undergoing remediation or sterilization as permitted under this rule the batch must be destroyed in a manner approved by the Authority or the Commission.

(12) A registrant must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.

(13) A registrant must, as applicable:

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.

(14) If a batch fails a test under these rules a registrant:

(a) Must store and segregate the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.

(b) May not remove the batch from the registered premises without permission from the Authority.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

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PH 29-2017, amend filed 12/22/2017, effective 01/01/2018
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17
PH 35-2016(Temp), f. & cert. ef. 12-2-16 thru 5-30-17
PH 21-2016, f. 6-24-16, cert. ef. 6-28-16
PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0470

Tentative Identification of Compounds

(1) Tentatively Identified Compounds (TICs) are compounds detected in a sample using gas chromatography mass spectrometry that are not among the target analytes for the residual solvent analysis.

(2) The Authority or Commission may initiate an investigation of a registrant or licensee upon receipt of a for TICs report from a laboratory and may require a registrant or licensee to submit samples for additional testing, including testing for analytes that are not required by these rules, at the registrant's or licensee's expense.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 21-2016, f. 6-24-16, cert. ef. 6-28-16

PH 22-2015(Temp), f. 11-13-15, cert. ef. 1-1-16 thru 6-28-16

333-007-0500

Quality Control and Research and Development Testing

(1) A registrant or a licensee may request that a laboratory conduct testing for the purpose of assuring quality control or for research and development, except as provided in section (2) of this rule.

(2) A registrant or a licensee may not request that a laboratory conduct pesticide testing on a marijuana item for the purpose of quality control or for research and development. A pesticide test on a marijuana item is considered by the Authority and the Commission to be a compliance test.

(3) A ~~registrant or licensee that submits a~~ marijuana item or industrial hemp-derived vapor item submitted for quality control or research and development testing is not subject to OAR 333-007-0320 to 333-007-0470.

(4) A laboratory result from a quality control or research and development test cannot be used as a compliance test result and a marijuana item or an industrial hemp-derived vapor item that has only undergone a quality control or research and development test may not be transferred or sold, unless the marijuana item is not required to have a compliance test before being transferred or sold.

(5) The certificate of analysis must clearly indicate that the testing performed was for quality control or research and development testing and is not considered a compliance test.

(6) Registrants and licensees must maintain and retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Authority or the Commission.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

History:

PH 89-2020, amend filed 12/30/2020, effective 01/01/2021

PH 282-2018, amend filed 12/20/2018, effective 01/01/2019

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PH 29-2017, amend filed 12/22/2017, effective 01/01/2018
PH 9-2017, f. 5-26-17, cert. ef. 5-31-17