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AMEND: 333-007-0310

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.

CHANGES TO RULE:

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 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 475B.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 475BC.01509 and does not include a patient, designated primary caregiver or organization or facility caregiver.¶

~~(24) "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.¶~~

(25) "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-tetrahydro-6H-benzo[c]chromen-1-ol, Chemical Abstracts Service Number 5957-75-5.¶

(27) "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.¶

(28) "Delta-9-tetrahydrocannabinolic acid" or "Δdelta-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.¶

(29)(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.415C.783(5)(b).¶

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

~~(30) "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.¶~~

(31) "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 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.¶

(32) "Finished inhalable 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.¶

(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 475B.810C.792.¶

(36) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a ~~72-hour~~ 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 475BC.56048.¶

- (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 475BC.04509.¶
- (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 475BC.84015.¶
- (50) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475BC.85833.¶
- (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 475B.840C.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 475BC.84015.¶
- (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 475B.840C.792, 475BC.84015 or 475BC.85833.¶
- (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 475BC.79783(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.¶

~~(678)~~ "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,

~~(69)~~ "Standard operating procedure" means:¶

~~(a)~~ A written set of a control study, is tested individually.¶

~~(68)~~ "Standard operating procedure" ~~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.¶

~~(6970)~~ "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 or other process.¶

~~(701)~~ "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.¶

~~(712)~~ "Texture" means the feel, appearance, or consistency of a marijuana item or industrial hemp-derived vapor item.¶

~~(723)~~ "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.¶

~~(734)~~ "THCA" means tetrahydrocannabinolic acid, and has the same meaning as delta-9 THCa.¶

~~(745)~~ "These rules" means OAR 333-007-0300 through 333-007-0500.¶

~~(756)~~ "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. ¶

~~(767)~~ "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.¶

~~(778)~~ "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 475BC.55544, ORS 475BC.5540

Statutes/Other Implemented: ORS 475BC.55544, ORS 475BC.5540

AMEND: 333-007-0315

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0315

The ordering test section is being amended to state that a requestor must indicate all intended units of sale for a cannabinoid product. In this rule all references to control studies is being removed due to the repeal of the control study rule found under OAR 333-007-0440. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0315

Ordering Tests ¶¶

(1) To request a compliance test a requestor 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~~all intended units 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 for quality control or, research and development, or any other purpose other than a compliance 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, Commission or Department of Agriculture, as specified in OAR 333-007-0440.~~was remediated if remediation is permitted under OAR 333-007-0450.¶¶

~~(32) 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.~~¶¶

~~(43) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.~~¶¶

~~(54) 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.~~¶¶

~~(65) More than one compliance test for the same marijuana item or industrial hemp-derived vapor item may not be ordered.~~¶¶

~~(76) 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 agent to submit false or misleading information to a laboratory.~~¶¶

~~(87) 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 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0320

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0320

The compliance testing requirements for marijuana and usable marijuana are being amended to add new testing requirements. Marijuana and usable marijuana harvested on and after July 1, 2022 will be required to be tested for mycotoxins if the marijuana or usable marijuana is intended for use by a consumer or will be transferred to a processor or processing site to make a cannabinoid product except for an inhalable cannabinoid product. Marijuana and usable marijuana harvested on and after March 1, 2023 will be required to be tested for heavy metals and microbiological contaminants if the marijuana or usable marijuana is intended for use by a consumer or will be transferred to a processor or processing site to make a cannabinoid product, except for an inhalable cannabinoid product. Marijuana or usable marijuana harvested before March 1, 2023 will need to be tested for water activity if it is intended for use by a producer to make kief. Marijuana or usable marijuana harvested on or after March 1, 2023 will not be required to have a water activity test performed prior to being transferred to make a cannabinoid concentrate, extract, or finished inhalable cannabinoid product. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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 and CBD concentration in accordance with OAR 333-007-0430.¶¶

(d) Heavy metals in accordance with OAR 333-007-0415 if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.¶¶

(e) Mycotoxins in accordance with OAR 333-007-0425 if the marijuana or usable marijuana is or was harvested on or after July 1, 2022.¶¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390 if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.¶¶

(2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana harvested before March 1, 2023, intended for use by a processor or processing site in making a cannabinoid concentrate ~~or extract, or finished inhalable cannabinoid product~~ 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, except for a finished inhalable 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~~ (4c) Heavy metals in accordance with OAR 333-007-0415 if the marijuana or usable marijuana is or was harvested one or more batches from a harvest lot of marijuana or usable marijuana for after March 1, 2023.¶¶

(d) Mycotoxins in accordance with OAR 333-007-0425 if the marijuana or usable marijuana is or was harvested on or after July 1, 2022.¶¶

(e) Microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission if the marijuana or usable marijuana is or was harvested on or after March 1, 2023.¶¶

~~(54)~~ 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.100C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶¶

~~(65)~~ A marijuana producer must test every batch from a harvest lot of marijuana or usable marijuana harvested before March 1, 2023 intended to produce kief for water activity prior to producing the kief unless the producer

tests the kief for water activity per OAR 333-007-0420.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0330

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0330

The compliance testing requirements for cannabinoid concentrates and extracts are being amended to add new testing requirements. Cannabinoid concentrates, extracts and marijuana producers producing kief manufactured on and after July 1, 2022, will be required to be tested for mycotoxins if the concentrate, extract, or kief is intended for use by a consumer or will be transferred to a processor or processing site to make a cannabinoid product, except for an inhalable cannabinoid product. Cannabinoid concentrates, extracts and marijuana producer producing kief manufactured on and after March 1, 2023 will be required to be tested for heavy metals and microbiological contaminants if the concentrate, extract, kief is intended for use by a consumer or will be transferred to a processor or processing site to make a cannabinoid product, except for an inhalable cannabinoid product.

A cannabinoid concentrate made only using food grade animal fat or food grade plant-based oil will need to have marijuana or usable marijuana tested for mycotoxins starting July 1, 2022, heavy metals starting March 1, 2023 and microbiological contaminants starting March 1, 2023 in order for the cannabinoid concentrate to not be tested for mycotoxins, heavy metals and microbiological contaminates on those respective dates.

Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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 and CBD concentration in accordance with OAR 333-007-0430.¶

(d) Heavy metals in accordance with OAR 333-007-0415 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.¶

(e) Mycotoxins in accordance with OAR 333-007-0425 if the cannabinoid concentrate or extract is or was manufactured on or after July 1, 2022.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.¶

(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, other than a finished inhalable cannabinoid product, for the following, except for a cannabinoid concentrate that meets the criteria in section (65) of this rule:¶

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

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

(c) Heavy metals in accordance with OAR 333-007-0415 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.¶

(d) Mycotoxins in accordance with OAR 333-007-0425 if the cannabinoid concentrate or extract is or was manufactured on or after July 1, 2022.¶

(e) Microbiological contaminants in accordance with OAR 333-007-0390 if the cannabinoid concentrate or extract is or was manufactured on or after March 1, 2023.¶

(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.100C.093~~ and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶

(65) 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, heavy metals starting March 1, 2023, mycotoxins starting July 1, 2022, or microbiological contaminants starting March 1, 2023 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 passed:¶

(A) Pesticide testing in accordance with OAR 333-007-0400.¶

(B) Heavy metal testing in accordance with OAR 333-007-0415 on or after March 1, 2023.¶

(C) Mycotoxin testing in accordance with OAR 333-007-0425 on or after July 1, 2022.¶

(D) Microbiological contaminants in accordance with OAR 333-007-0390 on or after March 1, 2023.¶

(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.¶

(76) 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.¶

(B) Water activity in accordance with OAR 333-007-0420 for kief manufactured before March 1, 2023.¶

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

(D) Heavy metals in accordance with OAR 333-007-0415 if the kief is or was manufactured on or after March 1, 2023.¶

(E) Mycotoxins in accordance with OAR 333-007-0425 if the kief is or was manufactured on or after July 1, 2022.¶

(F) Microbiological contaminants in accordance with OAR 333-007-0390 if the kief is or was manufactured on or after March 1, 2023.¶

(b) Must test every process lot intended for use by a processor in making a cannabinoid product, other than a finished inhalable 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 for kief manufactured before March 1, 2023.¶

(~~BC~~) ~~Water activity in accordance with OAR 333-007-0420~~ Heavy metals in accordance with OAR 333-007-0415 if the kief is or was manufactured on or after March 1, 2023.¶

(D) Mycotoxins in accordance with OAR 333-007-0425 if the kief is or was manufactured on or after July 1, 2022.¶

(E) Microbiological contaminants in accordance with OAR 333-007-0390 if the kief is or was manufactured on or after March 1, 2023.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

ADOPT: 333-007-0341

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Adopt OAR 333-007-0341

Adopting compliance testing requirements for finished inhalable cannabinoid products which include testing them for pesticides, solvents, adult use cannabinoids and CBD concentration, mycotoxins if manufactured on or after July 1, 2022, heavy metals and microbiological contaminants if manufactured on or after March 1, 2023. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0341

Compliance Testing Requirements for Finished Inhalable Cannabinoid Products

(1) A processor or processing site must test every process lot of a finished inhalable Cannabinoid product prior to selling or transferring the product 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.¶

(d) Heavy metals in accordance with OAR 333-007-0415 if the finished inhalable cannabinoid product is or was manufactured on or after March 1, 2023.¶

(e) Mycotoxins in accordance with OAR 333-007-0425 finished inhalable cannabinoid product is or was manufactured on or after July 1, 2022.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390 finished inhalable cannabinoid product is or was manufactured on or after March 1, 2023.¶

(2) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of finished inhalable Cannabinoid products to a wholesaler licensed by the Commission under ORS 475C.093 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.¶

(3) To the extent that the testing required under this rule is also required under OAR 333-007-0340, a processor or processing site is only required to comply with the testing under this rule.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

AMEND: 333-007-0342

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0342

Amending compliance testing requirements for industrial hemp-derived vapor items to include testing for mycotoxins if manufactured on or after July 1, 2022, heavy metals and microbiological contaminants if manufactured on or after March 1, 2023. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0342

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.¶

~~(2d) Every process lot of an industrial hemp-derived vapor item may be tested for m~~Heavy metals in accordance with OAR 333-007-0415 if the industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023.¶

(e) Mycotoxins in accordance with OAR 333-007-0425 if the industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022.¶

(f) Microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Commission or the Department of Agriculture if the industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023.¶

~~(32)~~ 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 that the processor manufactured to a wholesaler licensed by the Commission under ORS 475B.100C.093 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 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0350

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0350

Starting July 1, 2022, a harvest lot of marijuana or usable marijuana must be separated into a maximum of 50.0-pound batches. All references to control studies are being deleted. Clarifying language is being added to indicate what constitutes a batch of cannabinoid concentrate, extract, product, finished inhalable product and industrial hemp-derived vapor item. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0350

Batch Requirements for Compliance Testing ¶

(1) Marijuana or usable marijuana. ¶

(a) A producer or grower must separate each harvest lot of marijuana or usable marijuana harvested before July 1, 2022, into no larger than 15 pound batches. ¶

(b) A producer or grower must separate each harvest lot of marijuana or usable marijuana harvested on or after July 1, 2022, into no larger than 50.0-pound batches. ¶

(2) Cannabinoid concentrates and extracts. ¶

(a) A process lot of a cannabinoid concentrate or extract 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 for purposes of sampling and testing after a control study has been certified. A batch of a cannabinoid concentrate or extract must be produced using a standard operating procedure and result in one finished cannabinoid concentrate or extract that is uniform in texture and form. ¶

(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. A batch of a cannabinoid product must be produced using a standard operating procedure and result in a finished cannabinoid product that is uniform in potency, texture, and weight. A standard operating procedure may use different flavors or colors in a batch if the different flavors or colors: ¶

(A) Are substituted for one another at a 1:1 ratio; and ¶

(B) Do not affect the potency, texture, or weight of the finished cannabinoid product. ¶

(c) If a cannabinoid product is or may be sold in different quantities in a unit of sale, then the process lot shall be sampled based on the smallest unit of sale for the purposes of sampling and testing. All proposed units of sales must meet the Commission's concentration limit rules found in chapter 845, division 26. ¶

(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 that is uniform in flavor, texture, and form. ¶

(5) Finished inhalable cannabinoid products. ¶

(a) A process lot of a finished inhalable cannabinoid product is considered a batch. ¶

(b) A batch of a finished inhalable cannabinoid product must be made from a standard operating procedure and result in one finished inhalable cannabinoid product that is uniform in flavor, texture, and form. ¶

(6) 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. ¶

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

(8) For the purposes of this rule, "flavor" means: ¶

(a) The essential oil or essence which contains the flavoring constituents derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material. ¶

(b) Any substance, the function of which is to impart flavor, which is not derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plan material. ¶

(c) Flavor does not include flavoring constituents derived from the cannabis plant.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0360

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend 333-007-0360

Clarifying that batches from the same harvest lot that are the same strain and appear to be substantially similar in appearance and quality may be combined for testing for adult use cannabinoids and CBD. Clarifying the new ORELAP sampling protocols for usable marijuana take effect July 1, 2022. The whole batch of marijuana or usable marijuana must be made available for sampling and placed in containers that hold no more than 15 pounds.

Amending how sampling for concentrates, extracts, finished cannabinoid products and industrial hemp-derived vapor items will occur removing Tables 5 and 6 and modifying Table 7.

Clarifying that if baking is the only step to finish an edible to create a finished cannabinoid product then the production batch may be left unbaked and only the samples chosen by the laboratory may be baked and taken for testing. No ingredients may be added after the edible is baked. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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~~ homogenized samples taken from multiple batches of usable marijuana from the same harvest lot as described in OAR 333-064-0100(2)(f) may be combined into one sample for purposes of testing for adult use cannabinoids and CBD if the batches are the same strain, ~~regardless of the size of the multiple batches.~~¶¶

~~(2) Cannabinoid concentrates, extracts and products.¶¶~~

~~(a) Samples of c and appear to be substantially similar in appearance and quality, regardless of the size of the multiple batches. Sampling must be performed in accordance with ORELAP-SOP-001 Rev 4.0 and on or after July 1, 2022, ORELAP-SOP-001 Rev 4.1.¶¶~~

~~(d) The whole batch of marijuana or usable marijuana must be made available for sampling and placed in containers that holds no more than 15 pounds of marijuana or usable marijuana. ¶¶~~

~~(2) Cannabinoid concentrates, extracts and, products intended for human consumption, use or ingestion for use by a consumer or patient must be taken from the, and finished inhalable cannabinoid products.¶¶~~

~~(a) The whole batch of finished cannabinoid concentrates, extract or s, product as those terms are defined in OAR 333-007-0310.¶¶~~

~~(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 describs, or finished inhalable cannabinoid products must be available for sampling.¶¶~~

~~(b) Samples of cannabinoid concentrates, extracts, products, and finished inhalable cannabinoid products intended for human consumption, use or ingestion for use by a consumer or patient must be taken from the finished cannabinoid concentrate, extract, product, or finished inhalable cannabinoid product as those terms are defined in OAR 333-06407-03100(2), except for as outlined in subsection (2)(f) of this rule. ¶¶~~

~~(c) ¶For a cannabinoid concentrate or, extract has a certified control study or finished inhalable cannabinoid product, 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 shall 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) as described in Exhibit B, Table 7, OAR 333-064-0100, and ORELAP-SOP-002 Rev. 4.3. The primary sample and, the field duplicate sample and any required replicate samples must be prepared and analyzed separately. ¶¶~~

~~(d) For a cannabinoid product that has a certified control study, at, a minimum of 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), and ORELAP-SOP-002 Rev. 4.3. 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. ¶

~~(3f) 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 be taken in a baking of a cannabinoid edible is the final step to create a finished cannabinoid product, the processor or processing site may leave the production batch 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 manner consistent with the laboratory's accredited sampling policies and procedures described in OAR 333-064-0100(2)s to subject the item to dry heat, typically by an oven. ¶~~

~~(3) Industrial hemp-derived vapor items. ¶~~

~~(a) The whole finished batch of industrial hemp-derived vapor items must be available for sampling. ¶~~

~~(b) If an Sample of 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 items must be taken in its final form ready for packaging for sale or transfer to a patient, designated primary caregiver or consumer. ¶~~

~~(c) The minimum number of sample increments that must be taken are established in Exhibit B, Table 7, incorporated by reference. The sample increments may shall 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) as described in OAR 333-064-0100, ORELAP-SOP-002 Rev. 4.3. The primary sample and, the field duplicate sample and any required replicate sample must be prepared and analyzed separately. ¶~~

~~(d) 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. ¶~~

(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. ¶

NOTE: ORELAP SOPs are available under OAR 333-064-0100

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

OAR 333-007-0360, Exhibit B

Table 7 - Sample increments per batch size of cannabinoid concentrates, extracts, finished inhalable cannabinoid products, or industrial hemp-derived vapor items for the primary sample, the duplicate sample, and replicate samples based on weight of the batch or process lot. Each replicate sample shall include the number of increments required for the primary and duplicate.

| Batch Weight | | Sample Increments Required | | Number of Replicates |
|---------------|--------------|----------------------------|-----------|----------------------|
| Pounds | Kilograms | Primary | Duplicate | |
| 0-3.31 | 0-1.50 | 1 | 1 | |
| 3.32-6.61 | 1.51-3.00 | 3 | 3 | |
| 6.62-13.23 | 3.01-6.00 | 5 | 5 | |
| 13.24-26.46 | 6.01-12.00 | 7 | 7 | |
| 26.47-55.12 | 12.01-25.00 | 7 | 7 | 1 |
| 55.13-110.23 | 25.01-50.00 | 7 | 7 | 2 |
| 110.24-220.46 | 50.01-100.00 | 7 | 7 | 3 |

For batches exceeding 100.00kg: apply the following formula to determine number of replicate samples: $X = (\text{batch weight in kg} / 50) * 1.5$ where X is the number of replicates, rounded to the nearest whole number.

Effective March 31, 2022

AMEND: 333-007-0390

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0390

Modifying the standards for microbiological contaminants compliance testing by requiring marijuana items and industrial hemp-derived vapor items to be tested for pathogenic *Aspergillus flavus*, *A. fumigatus*, *A. niger* and *A. terreus*, Shiga toxin-producing *E. coli* and *Salmonella* species. *Aspergillus* speciation testing must be performed using a qPCR analysis or other DNA-based method that has been certified by an independent scientific body. The certified method shall show equivalency in terms of fractional recovery with no statistically significant difference between the method and a reference method requiring enrichment such as plate culture. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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 333-007-0342 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*) pathogenic *Aspergillus flavus*, *A. fumigatus*, *A. niger* and *A. terreus*, Shiga toxin-producing *Escherichia coli* and *Salmonella* species.~~¶

~~(3) A batch fails microbiological contaminants testing if, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1) the laboratory detects:~~¶

~~(a) The presence of *E. coli* at more than 100 colony forming units per gram any of the following species of pathogenic molds in one gram of sample: *Aspergillus flavus*, *A. fumigatus*, *A. niger* and *A. terreus*;~~¶

~~(b) Shiga toxin-producing *Escherichia coli* in one gram; or~~¶

~~(c) *Salmonella* spp. in one gram.~~¶

~~(3) *Aspergillus* speciation testing as required in section (1) of this rule shall be performed using a sample:~~¶

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

~~(b) Upon reanalysis as described in OAR 333-007-0450(1) qPCR analysis or other DNA-based method that has been certified by an independent scientific body.~~¶

~~(a) The certified method shall show equivalency in terms of fractional recovery with no statistically significant difference between the method and a reference method requiring enrichment such as plate culture.~~¶

~~(b) Laboratories shall follow the protocol or product instructions provided by the manufacturer, including any enrichment steps. If enrichment is recommended but not required, the enrichment shall be performed.~~

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0400

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0400

This rule is included in the filing in order to update the attached Exhibit A. A technical change is being made to the text to remove the work "field" in front of duplicate to align with changes in the draft. The context of the rules is staying the same. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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 all the analytes listed in Exhibit A, Table 3, incorporated by reference. ~~[Table attached.]~~¶¶
- (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.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Exhibit A**OAR 333-007-0400: Table 3. Pesticide analytes and their action levels**

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|---------------------|--|------------------|
| Abamectin | 71751-41-2 | 0.5 |
| Acephate | 30560-19-1 | 0.4 |
| Acequinocyl | 57960-19-7 | 2 |
| Acetamiprid | 135410-20-7 | 0.2 |
| Aldicarb | 116-06-3 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-3 | 0.2 |
| Boscalid | 188425-85-6 | 0.4 |
| Carbaryl | 63-25-2 | 0.2 |
| Carbofuran | 1563-66-2 | 0.2 |
| Chlorantraniliprole | 500008-45-7 | 0.2 |
| Chlorfenapyr | 122453-73-0 | 1 |
| Chlorpyrifos | 2921-88-2 | 0.2 |
| Clofentezine | 74115-24-5 | 0.2 |
| Cyfluthrin | 68359-37-5 | 1 |
| Cypermethrin | 52315-07-8 | 1 |
| Daminozide | 1596-84-5 | 1 |
| DDVP (Dichlorvos) | 62-73-7 | 1 |
| Diazinon | 333-41-5 | 0.2 |
| Dimethoate | 60-51-5 | 0.2 |
| Ethoprophos | 13194-48-4 | 0.2 |

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|--------------------------|--|------------------|
| Etofenprox | 80844-07-1 | 0.4 |
| Etoazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-8 | 0.2 |
| Fenpyroximate | 134098-61-6 | 0.4 |
| Fipronil | 120068-37-3 | 0.4 |
| Fonicamid | 158062-67-0 | 1 |
| Fludioxonil | 131341-86-1 | 0.4 |
| Hexythiazox | 78587-05-0 | 1 |
| Imazalil | 35554-44-0 | 0.2 |
| Imidacloprid | 138261-41-3 | 0.4 |
| Kresoxim-methyl | 143390-89-0 | 0.4 |
| Malathion | 121-75-5 | 0.2 |
| Metalaxyl | 57837-19-1 | 0.2 |
| Methiocarb | 2032-65-7 | 0.2 |
| Methomyl | 16752-77-5 | 0.4 |
| Methyl parathion | 298-00-0 | 0.2 |
| MGK-264 | 113-48-4 | 0.2 |
| Myclobutanil | 88671-89-0 | 0.2 |
| Naled | 300-76-5 | 0.5 |
| Oxamyl | 23135-22-0 | 1 |
| Paclobutrazol | 76738-62-0 | 0.4 |
| Permethrins ¹ | 52645-53-1 | 0.2 |
| Phosmet | 732-11-6 | 0.2 |
| Piperonyl_butoxide | 51-03-6 | 2 |
| Prallethrin | 23031-36-9 | 0.2 |

¹ Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|-------------------------|--|------------------|
| Propiconazole | 60207-90-1 | 0.4 |
| Propoxur | 114-26-1 | 0.2 |
| Pyrethrins ² | 8003-34-7 | 1 |
| Pyridaben | 96489-71-3 | 0.2 |
| Spinosad | 168316-95-8 | 0.2 |
| Spiromesifen | 283594-90-1 | 0.2 |
| Spirotetramat | 203313-25-1 | 0.2 |
| Spiroxamine | 118134-30-8 | 0.4 |
| Tebuconazole | 80443-41-0 | 0.4 |
| Thiacloprid | 111988-49-9 | 0.2 |
| Thiamethoxam | 153719-23-4 | 0.2 |
| Trifloxystrobin | 141517-21-7 | 0.2 |

² Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS

numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

OAR 333-007-0410: Table 4. List of solvents and their action levels

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-------------------|--|---------------------|
| 1,4-Dioxane | 123-91-1 | 380 |
| 2-Butanol | 78-92-2 | 5000 |
| 2-Ethoxyethanol | 110-80-5 | 160 |
| 2-Propanol (IPA) | 67-63-0 | 5000 |
| Acetone | 67-64-1 | 5000 |
| Acetonitrile | 75-05-8 | 410 |
| Benzene | 71-43-2 | 2 |
| Butanes | See ³ | 5000 ⁴ |
| Cumene | 98-82-8 | 70 |
| Cyclohexane | 110-82-7 | 3880 |
| Dichloromethane | 75-09-2 | 600 |
| Ethyl acetate | 141-78-6 | 5000 |
| Ethyl ether | 60-29-7 | 5000 |
| Ethylene glycol | 107-21-1 | 620 |
| Ethylene Oxide | 75-21-8 | 50 |
| Heptane | 142-82-5 | 5000 |
| Hexanes | See ⁵ | 290 |
| Isopropyl acetate | 108-21-4 | 5000 |

³ Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

⁴ Limit based on similarity to pentanes

⁵ Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

⁶ Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-----------------|--|---------------------|
| Methanol | 67-56-1 | 3000 |
| Pentanes | See ⁶ | 5000 |
| Propane | 74-98-6 | 5000 ⁷ |
| Tetrahydrofuran | 109-99-9 | 720 |
| Toluene | 108-88-3 | 890 |
| Xylenes | See ⁸ | 2170 ⁹ |

⁷ Limit based on similarity to pentanes

⁸ Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

⁹ The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

OAR 333-007-0415: *Table 8. List of heavy metals and their action levels*

| Heavy Metal | Action Levels (ug/g) |
|--------------------|-----------------------------|
| Arsenic | 0.2 |
| Cadmium | 0.2 |
| Lead | 0.5 |
| Mercury | 0.1 |

OAR 333-007-0425: *Table 9. List of mycotoxins and their action levels.*

| Mycotoxin | Action Levels (ug/g) |
|---------------------------------------|-----------------------------|
| Total of Aflatoxin B1, B2, G1, and G2 | 0.02 ug/g |
| Ochratoxin A | 0.02 ug/g |

AMEND: 333-007-0410

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0410

Modifying standards for solvent compliance testing by indicating a batch fails solvent testing if the RSD or RPD is more than 10% between the samples as appropriate. Statutes are being updated due to renumbering of chapter.

CHANGES TO RULE:

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 all 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 150 percent between the field primary result and the field duplicate result and the duplicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4; or¶

(c) Calculates a RSD of more than 10 percent between the primary result, the duplicate result and any replicate 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.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Exhibit A**OAR 333-007-0400: Table 3. Pesticide analytes and their action levels**

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|---------------------|--|------------------|
| Abamectin | 71751-41-2 | 0.5 |
| Acephate | 30560-19-1 | 0.4 |
| Acequinocyl | 57960-19-7 | 2 |
| Acetamiprid | 135410-20-7 | 0.2 |
| Aldicarb | 116-06-3 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-3 | 0.2 |
| Boscalid | 188425-85-6 | 0.4 |
| Carbaryl | 63-25-2 | 0.2 |
| Carbofuran | 1563-66-2 | 0.2 |
| Chlorantraniliprole | 500008-45-7 | 0.2 |
| Chlorfenapyr | 122453-73-0 | 1 |
| Chlorpyrifos | 2921-88-2 | 0.2 |
| Clofentezine | 74115-24-5 | 0.2 |
| Cyfluthrin | 68359-37-5 | 1 |
| Cypermethrin | 52315-07-8 | 1 |
| Daminozide | 1596-84-5 | 1 |
| DDVP (Dichlorvos) | 62-73-7 | 1 |
| Diazinon | 333-41-5 | 0.2 |
| Dimethoate | 60-51-5 | 0.2 |
| Ethoprophos | 13194-48-4 | 0.2 |

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|--------------------------|--|------------------|
| Etofenprox | 80844-07-1 | 0.4 |
| Etoazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-8 | 0.2 |
| Fenpyroximate | 134098-61-6 | 0.4 |
| Fipronil | 120068-37-3 | 0.4 |
| Fonicamid | 158062-67-0 | 1 |
| Fludioxonil | 131341-86-1 | 0.4 |
| Hexythiazox | 78587-05-0 | 1 |
| Imazalil | 35554-44-0 | 0.2 |
| Imidacloprid | 138261-41-3 | 0.4 |
| Kresoxim-methyl | 143390-89-0 | 0.4 |
| Malathion | 121-75-5 | 0.2 |
| Metalaxyl | 57837-19-1 | 0.2 |
| Methiocarb | 2032-65-7 | 0.2 |
| Methomyl | 16752-77-5 | 0.4 |
| Methyl parathion | 298-00-0 | 0.2 |
| MGK-264 | 113-48-4 | 0.2 |
| Myclobutanil | 88671-89-0 | 0.2 |
| Naled | 300-76-5 | 0.5 |
| Oxamyl | 23135-22-0 | 1 |
| Paclobutrazol | 76738-62-0 | 0.4 |
| Permethrins ¹ | 52645-53-1 | 0.2 |
| Phosmet | 732-11-6 | 0.2 |
| Piperonyl_butoxide | 51-03-6 | 2 |
| Prallethrin | 23031-36-9 | 0.2 |

¹ Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|-------------------------|--|------------------|
| Propiconazole | 60207-90-1 | 0.4 |
| Propoxur | 114-26-1 | 0.2 |
| Pyrethrins ² | 8003-34-7 | 1 |
| Pyridaben | 96489-71-3 | 0.2 |
| Spinosad | 168316-95-8 | 0.2 |
| Spiromesifen | 283594-90-1 | 0.2 |
| Spirotetramat | 203313-25-1 | 0.2 |
| Spiroxamine | 118134-30-8 | 0.4 |
| Tebuconazole | 80443-41-0 | 0.4 |
| Thiacloprid | 111988-49-9 | 0.2 |
| Thiamethoxam | 153719-23-4 | 0.2 |
| Trifloxystrobin | 141517-21-7 | 0.2 |

² Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS

numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

OAR 333-007-0410: Table 4. List of solvents and their action levels

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-------------------|--|---------------------|
| 1,4-Dioxane | 123-91-1 | 380 |
| 2-Butanol | 78-92-2 | 5000 |
| 2-Ethoxyethanol | 110-80-5 | 160 |
| 2-Propanol (IPA) | 67-63-0 | 5000 |
| Acetone | 67-64-1 | 5000 |
| Acetonitrile | 75-05-8 | 410 |
| Benzene | 71-43-2 | 2 |
| Butanes | See ³ | 5000 ⁴ |
| Cumene | 98-82-8 | 70 |
| Cyclohexane | 110-82-7 | 3880 |
| Dichloromethane | 75-09-2 | 600 |
| Ethyl acetate | 141-78-6 | 5000 |
| Ethyl ether | 60-29-7 | 5000 |
| Ethylene glycol | 107-21-1 | 620 |
| Ethylene Oxide | 75-21-8 | 50 |
| Heptane | 142-82-5 | 5000 |
| Hexanes | See ⁵ | 290 |
| Isopropyl acetate | 108-21-4 | 5000 |

³ Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

⁴ Limit based on similarity to pentanes

⁵ Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

⁶ Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-----------------|--|---------------------|
| Methanol | 67-56-1 | 3000 |
| Pentanes | See ⁶ | 5000 |
| Propane | 74-98-6 | 5000 ⁷ |
| Tetrahydrofuran | 109-99-9 | 720 |
| Toluene | 108-88-3 | 890 |
| Xylenes | See ⁸ | 2170 ⁹ |

⁷ Limit based on similarity to pentanes

⁸ Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

⁹ The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

OAR 333-007-0415: *Table 8. List of heavy metals and their action levels*

| Heavy Metal | Action Levels (ug/g) |
|--------------------|-----------------------------|
| Arsenic | 0.2 |
| Cadmium | 0.2 |
| Lead | 0.5 |
| Mercury | 0.1 |

OAR 333-007-0425: *Table 9. List of mycotoxins and their action levels.*

| Mycotoxin | Action Levels (ug/g) |
|---------------------------------------|-----------------------------|
| Total of Aflatoxin B1, B2, G1, and G2 | 0.02 ug/g |
| Ochratoxin A | 0.02 ug/g |

ADOPT: 333-007-0415

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Adopt OAR 333-007-0415

Adopting standards for heavy metal compliance testing for marijuana items and industrial hemp-derived vapor items, including adoption of Exhibit A, Table 8. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0415

Standards for Heavy Metal Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for heavy metals must be tested by a laboratory for the analytes listed in Exhibit A, Table 8 incorporated by reference.¶

(2) A batch fails heavy metal testing if a laboratory detects the presence of a heavy metal above the action levels listed in Exhibit A, Table 8 in any sample, including a duplicate:¶

(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 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Exhibit A**OAR 333-007-0400: Table 3. Pesticide analytes and their action levels**

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|---------------------|--|------------------|
| Abamectin | 71751-41-2 | 0.5 |
| Acephate | 30560-19-1 | 0.4 |
| Acequinocyl | 57960-19-7 | 2 |
| Acetamiprid | 135410-20-7 | 0.2 |
| Aldicarb | 116-06-3 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-3 | 0.2 |
| Boscalid | 188425-85-6 | 0.4 |
| Carbaryl | 63-25-2 | 0.2 |
| Carbofuran | 1563-66-2 | 0.2 |
| Chlorantraniliprole | 500008-45-7 | 0.2 |
| Chlorfenapyr | 122453-73-0 | 1 |
| Chlorpyrifos | 2921-88-2 | 0.2 |
| Clofentezine | 74115-24-5 | 0.2 |
| Cyfluthrin | 68359-37-5 | 1 |
| Cypermethrin | 52315-07-8 | 1 |
| Daminozide | 1596-84-5 | 1 |
| DDVP (Dichlorvos) | 62-73-7 | 1 |
| Diazinon | 333-41-5 | 0.2 |
| Dimethoate | 60-51-5 | 0.2 |
| Ethoprophos | 13194-48-4 | 0.2 |

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|--------------------------|--|------------------|
| Etofenprox | 80844-07-1 | 0.4 |
| Etoazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-8 | 0.2 |
| Fenpyroximate | 134098-61-6 | 0.4 |
| Fipronil | 120068-37-3 | 0.4 |
| Fonicamid | 158062-67-0 | 1 |
| Fludioxonil | 131341-86-1 | 0.4 |
| Hexythiazox | 78587-05-0 | 1 |
| Imazalil | 35554-44-0 | 0.2 |
| Imidacloprid | 138261-41-3 | 0.4 |
| Kresoxim-methyl | 143390-89-0 | 0.4 |
| Malathion | 121-75-5 | 0.2 |
| Metalaxyl | 57837-19-1 | 0.2 |
| Methiocarb | 2032-65-7 | 0.2 |
| Methomyl | 16752-77-5 | 0.4 |
| Methyl parathion | 298-00-0 | 0.2 |
| MGK-264 | 113-48-4 | 0.2 |
| Myclobutanil | 88671-89-0 | 0.2 |
| Naled | 300-76-5 | 0.5 |
| Oxamyl | 23135-22-0 | 1 |
| Paclobutrazol | 76738-62-0 | 0.4 |
| Permethrins ¹ | 52645-53-1 | 0.2 |
| Phosmet | 732-11-6 | 0.2 |
| Piperonyl_butoxide | 51-03-6 | 2 |
| Prallethrin | 23031-36-9 | 0.2 |

¹ Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|-------------------------|--|------------------|
| Propiconazole | 60207-90-1 | 0.4 |
| Propoxur | 114-26-1 | 0.2 |
| Pyrethrins ² | 8003-34-7 | 1 |
| Pyridaben | 96489-71-3 | 0.2 |
| Spinosad | 168316-95-8 | 0.2 |
| Spiromesifen | 283594-90-1 | 0.2 |
| Spirotetramat | 203313-25-1 | 0.2 |
| Spiroxamine | 118134-30-8 | 0.4 |
| Tebuconazole | 80443-41-0 | 0.4 |
| Thiacloprid | 111988-49-9 | 0.2 |
| Thiamethoxam | 153719-23-4 | 0.2 |
| Trifloxystrobin | 141517-21-7 | 0.2 |

² Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS

numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

OAR 333-007-0410: Table 4. List of solvents and their action levels

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-------------------|--|---------------------|
| 1,4-Dioxane | 123-91-1 | 380 |
| 2-Butanol | 78-92-2 | 5000 |
| 2-Ethoxyethanol | 110-80-5 | 160 |
| 2-Propanol (IPA) | 67-63-0 | 5000 |
| Acetone | 67-64-1 | 5000 |
| Acetonitrile | 75-05-8 | 410 |
| Benzene | 71-43-2 | 2 |
| Butanes | See ³ | 5000 ⁴ |
| Cumene | 98-82-8 | 70 |
| Cyclohexane | 110-82-7 | 3880 |
| Dichloromethane | 75-09-2 | 600 |
| Ethyl acetate | 141-78-6 | 5000 |
| Ethyl ether | 60-29-7 | 5000 |
| Ethylene glycol | 107-21-1 | 620 |
| Ethylene Oxide | 75-21-8 | 50 |
| Heptane | 142-82-5 | 5000 |
| Hexanes | See ⁵ | 290 |
| Isopropyl acetate | 108-21-4 | 5000 |

³ Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

⁴ Limit based on similarity to pentanes

⁵ Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

⁶ Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-----------------|--|---------------------|
| Methanol | 67-56-1 | 3000 |
| Pentanes | See ⁶ | 5000 |
| Propane | 74-98-6 | 5000 ⁷ |
| Tetrahydrofuran | 109-99-9 | 720 |
| Toluene | 108-88-3 | 890 |
| Xylenes | See ⁸ | 2170 ⁹ |

⁷ Limit based on similarity to pentanes

⁸ Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

⁹ The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

OAR 333-007-0415: *Table 8. List of heavy metals and their action levels*

| Heavy Metal | Action Levels (ug/g) |
|--------------------|-----------------------------|
| Arsenic | 0.2 |
| Cadmium | 0.2 |
| Lead | 0.5 |
| Mercury | 0.1 |

OAR 333-007-0425: *Table 9. List of mycotoxins and their action levels.*

| Mycotoxin | Action Levels (ug/g) |
|---------------------------------------|-----------------------------|
| Total of Aflatoxin B1, B2, G1, and G2 | 0.02 ug/g |
| Ochratoxin A | 0.02 ug/g |

AMEND: 333-007-0420

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0420

Amending standards for testing water activity on kief. Starting January March1, 2023 kief will not need to be tested for water activity if the marijuana or usable marijuana used to make kief did not already pass testing for water activity.

Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0420

Standards for Testing Water Activity and Moisture Content ¶¶

(1) Usable marijuana must be tested by a laboratory for:¶¶

(a) Water activity; and¶¶

(b) Moisture content.¶¶

(2) Kief manufactured before March 1, 2023, must be tested by a laboratory for water activity unless the marijuana or usable marijuana used to produce the kief has already passed testing for water activity prior to producing the kief in accordance with OAR 333-007-0320(6).¶¶

(3) If a sample has a water activity rate of more than 0.65 Aw the sample fails.¶¶

(4) If a sample has a moisture content of more than 15 percent the sample fails.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

ADOPT: 333-007-0425

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Adopt OAR 333-007-0425

Adopting standards for mycotoxin testing for marijuana items and industrial hemp-derived vapor items, including adoption of Exhibit A, Table 9. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0425

Standards for Mycotoxin Contaminants Compliance Testing

(1) A marijuana item or industrial hemp-derived vapor item required to be tested for mycotoxin must be tested by a laboratory for:

(a) Aflatoxins B1, B2, G1, G2; and

(b) Ochratoxin A.

(2) A batch fails mycotoxin testing if, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1), the laboratory detects levels above the action levels listed in Exhibit A, Table 9 in any sample.

Statutory/Other Authority: ORS 475C.544

Statutes/Other Implemented: ORS 475C.544

RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Exhibit A**OAR 333-007-0400: Table 3. Pesticide analytes and their action levels**

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|---------------------|--|------------------|
| Abamectin | 71751-41-2 | 0.5 |
| Acephate | 30560-19-1 | 0.4 |
| Acequinocyl | 57960-19-7 | 2 |
| Acetamiprid | 135410-20-7 | 0.2 |
| Aldicarb | 116-06-3 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-3 | 0.2 |
| Boscalid | 188425-85-6 | 0.4 |
| Carbaryl | 63-25-2 | 0.2 |
| Carbofuran | 1563-66-2 | 0.2 |
| Chlorantraniliprole | 500008-45-7 | 0.2 |
| Chlorfenapyr | 122453-73-0 | 1 |
| Chlorpyrifos | 2921-88-2 | 0.2 |
| Clofentezine | 74115-24-5 | 0.2 |
| Cyfluthrin | 68359-37-5 | 1 |
| Cypermethrin | 52315-07-8 | 1 |
| Daminozide | 1596-84-5 | 1 |
| DDVP (Dichlorvos) | 62-73-7 | 1 |
| Diazinon | 333-41-5 | 0.2 |
| Dimethoate | 60-51-5 | 0.2 |
| Ethoprophos | 13194-48-4 | 0.2 |

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|--------------------------|--|------------------|
| Etofenprox | 80844-07-1 | 0.4 |
| Etoazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-8 | 0.2 |
| Fenpyroximate | 134098-61-6 | 0.4 |
| Fipronil | 120068-37-3 | 0.4 |
| Fonicamid | 158062-67-0 | 1 |
| Fludioxonil | 131341-86-1 | 0.4 |
| Hexythiazox | 78587-05-0 | 1 |
| Imazalil | 35554-44-0 | 0.2 |
| Imidacloprid | 138261-41-3 | 0.4 |
| Kresoxim-methyl | 143390-89-0 | 0.4 |
| Malathion | 121-75-5 | 0.2 |
| Metalaxyl | 57837-19-1 | 0.2 |
| Methiocarb | 2032-65-7 | 0.2 |
| Methomyl | 16752-77-5 | 0.4 |
| Methyl parathion | 298-00-0 | 0.2 |
| MGK-264 | 113-48-4 | 0.2 |
| Myclobutanil | 88671-89-0 | 0.2 |
| Naled | 300-76-5 | 0.5 |
| Oxamyl | 23135-22-0 | 1 |
| Paclobutrazol | 76738-62-0 | 0.4 |
| Permethrins ¹ | 52645-53-1 | 0.2 |
| Phosmet | 732-11-6 | 0.2 |
| Piperonyl_butoxide | 51-03-6 | 2 |
| Prallethrin | 23031-36-9 | 0.2 |

¹ Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

| Analyte | Chemical Abstract Services (CAS) Registry Number | Action Level ppm |
|-------------------------|--|------------------|
| Propiconazole | 60207-90-1 | 0.4 |
| Propoxur | 114-26-1 | 0.2 |
| Pyrethrins ² | 8003-34-7 | 1 |
| Pyridaben | 96489-71-3 | 0.2 |
| Spinosad | 168316-95-8 | 0.2 |
| Spiromesifen | 283594-90-1 | 0.2 |
| Spirotetramat | 203313-25-1 | 0.2 |
| Spiroxamine | 118134-30-8 | 0.4 |
| Tebuconazole | 80443-41-0 | 0.4 |
| Thiacloprid | 111988-49-9 | 0.2 |
| Thiamethoxam | 153719-23-4 | 0.2 |
| Trifloxystrobin | 141517-21-7 | 0.2 |

² Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS

numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively).

OAR 333-007-0410: Table 4. List of solvents and their action levels

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-------------------|--|---------------------|
| 1,4-Dioxane | 123-91-1 | 380 |
| 2-Butanol | 78-92-2 | 5000 |
| 2-Ethoxyethanol | 110-80-5 | 160 |
| 2-Propanol (IPA) | 67-63-0 | 5000 |
| Acetone | 67-64-1 | 5000 |
| Acetonitrile | 75-05-8 | 410 |
| Benzene | 71-43-2 | 2 |
| Butanes | See ³ | 5000 ⁴ |
| Cumene | 98-82-8 | 70 |
| Cyclohexane | 110-82-7 | 3880 |
| Dichloromethane | 75-09-2 | 600 |
| Ethyl acetate | 141-78-6 | 5000 |
| Ethyl ether | 60-29-7 | 5000 |
| Ethylene glycol | 107-21-1 | 620 |
| Ethylene Oxide | 75-21-8 | 50 |
| Heptane | 142-82-5 | 5000 |
| Hexanes | See ⁵ | 290 |
| Isopropyl acetate | 108-21-4 | 5000 |

³ Total butanes should be calculated as sum of n-butane (CAS# 106-97-8) and iso-butane (CAS# 75-28-5)

⁴ Limit based on similarity to pentanes

⁵ Total hexanes should be calculated as sum of n-hexane (CAS# 110-54-3), 2-methylpentane (CAS# 107-83-5), 3-methylpentane (CAS# 96-14-0), 2,2-dimethylbutane (CAS# 75-83-2), 2,3-dimethylbutane (CAS# 79-29-8)

⁶ Total pentanes should be calculated as sum of n-pentane (CAS# 109-66-0), iso-pentane (CAS# 78-78-4), and neo-pentane (CAS# 463-82-1)

| Solvent | Chemical Abstract Services (CAS) Registry Number | Action Level (µg/g) |
|-----------------|--|---------------------|
| Methanol | 67-56-1 | 3000 |
| Pentanes | See ⁶ | 5000 |
| Propane | 74-98-6 | 5000 ⁷ |
| Tetrahydrofuran | 109-99-9 | 720 |
| Toluene | 108-88-3 | 890 |
| Xylenes | See ⁸ | 2170 ⁹ |

⁷ Limit based on similarity to pentanes

⁸ Total xylenes are 1,2-dimethylbenzene (CAS# 95-47-6), 1,3-dimethylbenzene (CAS# 108-38-3), and 1,4-dimethylbenzene (CAS# 106-42-3).

⁹ The action limit for xylenes is based on combined toxicity of the xylenes listed in footnote 8 plus ethyl benzene (CAS# 100-41-4), which is not a xylene. Ethyl benzene and xylenes should be measured and reported separately, but the sum of xylenes and ethyl benzene should be calculated for comparison against the action limit for xylenes

OAR 333-007-0415: *Table 8. List of heavy metals and their action levels*

| Heavy Metal | Action Levels (ug/g) |
|--------------------|-----------------------------|
| Arsenic | 0.2 |
| Cadmium | 0.2 |
| Lead | 0.5 |
| Mercury | 0.1 |

OAR 333-007-0425: *Table 9. List of mycotoxins and their action levels.*

| Mycotoxin | Action Levels (ug/g) |
|---------------------------------------|-----------------------------|
| Total of Aflatoxin B1, B2, G1, and G2 | 0.02 ug/g |
| Ochratoxin A | 0.02 ug/g |

AMEND: 333-007-0430

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0430

Amending standards for adult use cannabinoid and CBD compliance testing by removing reference to control studies. In addition, the RPD and RSD is being reduced to 10%. Statutes are being updated due to renumbering of chapter number

CHANGES TO RULE:

333-007-0430

Standards for Adult Use Cannabinoid and CBD Compliance Testing ¶

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

(a) Delta-9 THC.¶

(b) Delta-9 THCA.¶

(c) On and after July 1, 2022, delta-8 THC.¶

(d) CBD.¶

(e) CBDA.¶

(2) A process lot of a cannabinoid concentrate, extract ~~or, product that has not successfully completed a control study, finished inhalable cannabinoid product, or industrial hemp-derived vapor item~~ 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, ~~total delta-8~~ THC, ~~and or~~ 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 the Commission's concentration limit rules in OAR chapter 845, division 26, as applicable.~~¶

(3) ~~A process lot of a cannabinoid concentrate, extract, 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, the primary sample and the duplicate sample exceeds 10 percent RPD or between the primary sample, duplicate sample and any replicate samples exceeds 150 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 the Commission's concentration limit rules in OAR chapter 845, division 26, 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 RSPD or RPSD as described in subsection (2)(a) or (3)(a) of this rule.¶~~

(b) ~~A cannabinoid product that has less than 10 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 RSPD or RPSD 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 RSPD or RPSD as described in subsection (2)(a) or (3)(a) of this rule.¶~~

(d) ~~A cannabinoid concentrate, extract, finished inhalable cannabinoid product, 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 RSPD or RPSD as described in subsection (2)(a) or (3)(a) of this rule.¶~~

(e) ~~A cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item that has less than 10 mg CBD per gram as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSPD or RPSD as described in subsection (2)(a) or (3)(a) of this rule.¶~~

(f) ~~A cannabinoid concentrate, extract, finished inhalable cannabinoid product, 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 RSPD or RPSD as described in subsection (2)(a) or (3)(a) of this rule.~~

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

REPEAL: 333-007-0440

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Repeal OAR 333-007-0440

Repealing rules regarding control studies due to changing how sampling and testing will occur with the adoption of additional testing for heavy metals, mycotoxins and microbiological contaminants.

CHANGES TO RULE:

~~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, 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, 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, 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 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, 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, 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, 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 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 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:~~

~~(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 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 the Commission's concentration limit rules in OAR chapter 845, division 26, 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) Total delta-9 THC and delta-8 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 by more than 10 percent as specified in the Commission's concentration limit rules in OAR chapter 845, division 26, 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, product, or industrial hemp-derived vapor item successfully passes a control study and the control study has been certified by the Authority, 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. 4.2.¶¶

(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.¶¶

(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, product or industrial hemp-derived vapor item fails an adult use cannabinoid 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, 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.¶¶

(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

AMEND: 333-007-0450

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0450

Adding language to address what needs to occur if a marijuana item or industrial hemp-derived vapor item fails for heavy metals, mycotoxins or microbiological contaminants. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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.¶¶

(3) If a registrant is permitted to remediate or sterilize under this rule, the registrant must provide notice to the Authority of the registrant's intent to remediate or sterilize.¶¶

(4) Except as otherwise permitted under this rule, a cannabinoid concentrate, extract, finished inhalable cannabinoid product, 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 either~~: ¶¶

(A) Be remediated using a sterilization process; or¶¶

(B) 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, extract, finished inhalable cannabinoid product, 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~~ remediated through a sterilization process in accordance with subsection (a) or (b) of this section must be sampled ~~and tested~~ in accordance with ~~these rules~~ OAR 333-007-0360 and must be tested ~~if not otherwise required for that product, for microbiological contaminants, solvents and pesticides~~ for microbiological contaminants, solvents if required per OAR 333-007-0410, pesticides, heavy metals if the

marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after March 1, 2023, and mycotoxins if the marijuana item or industrial hemp-derived vapor item was harvested or manufactured on or after July 1, 2022.¶

(d) A batch that fails microbiological contaminant testing after undergoing remediation through 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~~for solvents, pesticides, adult use cannabinoids and CBD, heavy metals if the marijuana item or industrial hemp-derived vapor item was manufactured on or after March 1, 2023, mycotoxins if the marijuana item or industrial hemp-derived vapor item was manufactured on or after July 1, 2022, and microbiological contaminants if the marijuana item or industrial hemp-derived vapor item was manufactured on and after March 1, 2023.¶

(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~~in accordance with OAR 333-007-0360 and tested for pesticides, water activity and moisture content, adult use cannabinoids and CBD, heavy metals if the marijuana or usable marijuana was harvested on or after March 1, 2023, mycotoxins if the marijuana or usable marijuana was harvested on or after July 1, 2022, and microbiological contaminants if the marijuana or usable marijuana was harvested on and after March 1, 2023.¶

(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.¶

(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~~in accordance with OAR 333-007-032400 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 in accordance with OAR 333-007-0400. ¶

(f) A batch that is remediated in accordance with subsection (d) or (e) of this section must be re-sampled ~~and re-tested in accordance with these rules~~in accordance with OAR 333-007-0360 and re-tested for pesticides, adult use cannabinoids and CBD, solvent testing if required per OAR 333-007-0410, heavy metals if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023, mycotoxins if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022, and microbiological contaminants if the concentrate, extract or industrial hemp-derived vapor item is or was manufactured on and after March 1, 2023. ¶

(g) If a sample from a batch of finished inhalable cannabinoid products fails pesticide testing, the batch may not be remediated and must be destroyed in a manner specified by the Authority or the Commission.¶

(h) 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 the Commission's concentration limit rules in OAR chapter 845, division 26, 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. A marijuana item or industrial hemp-derived vapor item that is re-mixed must be re-sampled in accordance with OAR 333-007-0360 and re-tested for pesticides, adult use cannabinoids and CBD, solvent testing if required per OAR 333-007-0410, heavy metals if the marijuana item or industrial hemp-derived vapor item is or was manufactured on or after March 1, 2023, mycotoxins if the marijuana item or industrial hemp-derived vapor item is or was manufactured on or after July 1, 2022, and microbiological contaminants if the marijuana item or industrial hemp-derived vapor item is or was manufactured on and after March 1, 2023.~~¶

(11) Failed heavy metal testing. ¶

(a) If a sample from a batch of a marijuana, usable marijuana, finished inhalable cannabinoid product, or industrial hemp-derived vapor item fails heavy metal testing, the batch may not be remediated and must be destroyed in a manner specified by the Authority, Commission, or the Department of Agriculture.¶

(b) If a sample from a cannabinoid concentrate or extract fails heavy metal testing, the batch may be remediated using procedures that would reduce the concentration of heavy metals to less than the action level.¶

(c) A batch that is remediated in accordance with subsection (b) of this section must be re-sampled in accordance with OAR 333-007-0360 and re-tested for pesticides, solvents if required under OAR 333-007-0410, adult use cannabinoids and CBD, heavy metals, mycotoxins if the concentrate or extract was manufactured on or after July 1, 2022, and microbiological contaminants if the concentrate or extract was manufactured on and after March 1, 2023.¶

(d) A batch that fails heavy metal testing that is not remediated or that fails testing after remediation must be destroyed in a manner specified by the Authority, Commission, or the Department of Agriculture.¶

(12) Failed mycotoxin testing. If a sample from a batch of a marijuana item or industrial hemp-derived vapor item fails mycotoxin testing the batch may not be remediated and must be destroyed in a manner specified by the Authority, Commission, or the Department of Agriculture.¶

(143) 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, ~~or the~~ Department of Agriculture.¶

(124) 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.¶

(135) 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.¶

(146) 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 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0480

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0480

Adding mycotoxin testing as a test that may be performed as part of audit or random testing if required by the Authority on a registrant. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-007-0480

Audit and Random Testing ¶¶

(1) The Authority may require a registrant to submit samples identified by the Authority to a laboratory of the Authority's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0500 or any other rule of the Authority.¶¶

(2) A laboratory doing audit testing under section (1) of this rule must comply with these rules unless otherwise authorized by the Authority.¶¶

(3) The Authority may, at any time, require a registrant to permit the sampling of or submit a sample of a marijuana item to the Authority for testing. Such testing may include testing for:¶¶

(a) Any microbiological contaminant.¶¶

(b) Heavy metals;¶¶

(c) Solvents;¶¶

(d) Pesticides;¶¶

(e) Mycotoxins;¶¶

(f) Adulterants, additives, or other contaminants that may pose a risk to public health and/or safety, or are prohibited by law.¶¶

(4) The Authority may require any testing ordered under sections (1) and (3) of this rule to be paid for by the registrant.¶¶

(5) The Authority may obtain a marijuana item from a registrant at any time and have it tested to ensure compliance with these rules and OAR chapter 333, division 8, or to protect the public health and safety.

Statutory/Other Authority: ORS 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-007-0500

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-007-0500

Amending rules regarding quality control and research and development testing to require that test results be entered into CTS. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

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. ¶¶

(a) A quality control test result, research and development test result, or test results from testing for any purpose other than compliance testing must be tracked and entered into CTS. ¶¶

(b) A registrant, licensee, or other requestor must ensure that relevant information regarding the registrant, licensee, or manufacturer of the item is provided to the laboratory conducting the testing in accordance with OAR 333-007-0315. ¶¶

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

(3) 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 475BC.55544

Statutes/Other Implemented: ORS 475BC.55544

AMEND: 333-064-0025

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-064-0025

Adding definitions for new terms being used in the rules. "Finished inhalable cannabinoid product" is a newly defined class of marijuana item included in cannabis testing rules. "Homogenization" is a required process described in the Division 64 rules and the ORELAP sampling protocols ORELAP-SOP-001 Revision 4.1 and ORELAP-SOP-002 Revision 4.3 that needed to be defined to ensure consistent understanding of the process by all accredited laboratories. "Replicate sample" is a term used in the updated OAR 333-007-0360 Exhibit B Table 7, in the ORELAP sampling protocol ORELAP-SOP-002 Revision 4.3 and in OAR 333-064-0100. Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-064-0025

Definitions ¶¶

As used in these rules, unless the context indicates otherwise:¶¶

(1) "Accrediting body" means the official accrediting authority for the Oregon Environmental Laboratory Accreditation Program comprised of the Administrator of the Oregon State Public Health Laboratory or designee, the Laboratory Administrator of the Department of Environmental Quality or designee and the Laboratory Administrator of the Department of Agriculture or designee.¶¶

(2) "Adult use cannabinoid" has the meaning given that term in OAR 333-007-0310. ¶¶

(3) "Air" as a matrix means air samples, which are analyzed for possible contaminants under the guidance of the Clean Air Act.¶¶

(4) "Artificially derived cannabinoid" has the meaning given that term in OAR 333-007-0310. ¶¶

(5) "Authority" means the Oregon Health Authority.¶¶

(6) "Batch" means:¶¶

(a) For sample analysis, this term has the meaning assigned in the TNI Standard which is a group of samples that are prepared or analyzed together in the laboratory with the same process and personnel, using the same lot(s) of reagents. ¶¶

(A) A preparation batch is composed of 1 to 20 environmental samples of the same quality systems matrix, meeting the above-mentioned criteria and with a maximum time between the start of processing the first and last sample in the batch to be 24 hours. ¶¶

(B) An analytical batch is composed of prepared environmental samples (extracts, digestates, or concentrates) which are analyzed together as a group. An analytical batch can include prepared samples originating from various quality system matrices and can exceed 20 samples. ¶¶

(b) For cannabis sampling, this term means:¶¶

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

(B) A quantity of cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item from a process lot.¶¶

(7) "Biological tissue" as a matrix means samples of biological tissue, excluding those of human origin.¶¶

(8) "Cannabis" has the meaning given that term in OAR 333-007-0310. ¶¶

(9) "Cannabis sampling" means an activity related to obtaining a representative sample of a marijuana item or industrial hemp-derived vapor item for purposes of testing in accordance with these rules and OAR 333-007-0300 to 333-007-0490.¶¶

(10) "Cannabis Tracking System" or "CTS" has the meaning given that term in OAR 333-007-0310.¶¶

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

(12) "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-85-2.¶¶

(13) "Clean Air Act (CAA)" means the enabling legislation, 42 U.S.C. 7401 et seq. (1974), Public Law 91-604, 84 Stat. 1676 Public Law 95-95, 91 Stat., 685 and Public Law 95-190, 91 Stat., 1399, that empowers the EPA to promulgate air quality standards, monitor and enforce them.¶¶

(14) "Clean Water Act (CWA)" means the enabling legislation under 33 U.S.C. 1251 et seq., Public Law 92-50086, Stat. 816 that empowers the EPA to set discharge limitations, write discharge permits, monitor and bring enforcement action for non-compliance.¶¶

(15) "Commission" means the Oregon Liquor and Cannabis Commission.¶¶

(16) "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.¶
- (17) "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. ¶
- (18) "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.¶
- (19) "Drinking water" as a matrix means samples of presumed potable water and source water, which are analyzed for possible contaminants under the guidance of the Safe Drinking Water Act.¶
- (20) "Fields of accreditation" means those matrix, technology/method, and analyte combinations for which ORELAP offers accreditation.¶
- (21) "Finished cannabinoid concentrate or extract" has the meaning given that term in OAR 333-007-0310. ¶
- (22) "Finished cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶
- (23) ~~"Industrial hemp-derived vapor item" has the meaning given that term in OAR 333-007-0310.¶~~
- ~~(24) "Finished inhalable cannabinoid product" has the meaning given that term in OAR 333-007-0310.¶~~
- ~~(24) "Industrial hemp-derived vapor item" has the meaning given that term in OAR 333-007-0310.¶~~
- (25) "Homogenization" means physically manipulating a sample to make the sample's material uniform in composition and properties throughout, including but not limited to reducing particle size to a fine uniform powder for solid materials or combining all layers or phases of a liquid or semi-solid sample into a uniform substance. ¶
- (26) "Laboratory" means a fixed location or mobile facility that collects or analyzes samples in a controlled and scientific manner with the appropriate equipment and instruments required by accredited sampling and testing methods.¶
- ~~(257) "Marijuana item" has the meaning given that term in OAR 333-007-0310.¶~~
- ~~(268) "Mobile Category 1 Laboratory" means any facility, deployed for no more than six consecutive months and no more than six months during a calendar year, that:¶~~
- ~~(a) Analyzes samples utilizing the staff and equipment from the parent fixed laboratory;¶~~
- ~~(b) Operates under the quality system of its parent fixed laboratory;¶~~
- ~~(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and¶~~
- ~~(d) May operate under the fixed laboratory's accreditation.¶~~
- ~~(279) "Mobile Category 2 Laboratory" means any facility that:¶~~
- ~~(a) Analyzes samples;¶~~
- ~~(b) Operates under its own quality system;¶~~
- ~~(c) Is capable of moving or being moved from site to site, such as but not limited to vans, trailers and motor coaches; and¶~~
- ~~(d) Issues the final reports or is a mobile laboratory operating with a fixed laboratory's quality system, but is deployed for more than six consecutive months or more than six months in a calendar year.¶~~
- ~~(2830) "National Environmental Laboratory Accreditation Program (NELAP)" means the program established to oversee the implementation of the TNI Standards.¶~~
- ~~(2931) "NELAP approved accrediting body" means a state or federal department/agency that has been approved by NELAP as being an entity whose accreditation and assessment program meets all of the requirements of the TNI Standards.¶~~
- ~~(302) "Non-potable water" as a matrix means aqueous samples, which are analyzed under the guidance of the Clean Water Act or the Resource, Conservation and Recovery Act.¶~~
- ~~(313) "On-site assessment" means an on-site visit to the laboratory to verify items addressed in the ORELAP application and to evaluate the facility and analytical performance for conformance with the TNI Standards. During a period when the Governor has declared a state of emergency, when an on-site visit would jeopardize the health and safety of the participants, assessments may be conducted remotely by electronic means to evaluate the facility for conformance to the TNI Standards.¶~~
- ~~(324) "ORELAP approved assessor" means an assessor whose qualification has been evaluated by ORELAP and found to meet TNI Standards for laboratory on-site assessors.¶~~
- ~~(335) "Primary accreditation" means accreditation by a NELAP approved accrediting body based on a laboratory's compliance to TNI Standards after a review of the laboratory's application, quality manual, PT results and on-site assessment results as described in the TNI Standards.¶~~
- ~~(346) "Proficiency testing (PT)" means the analysis of samples obtained from providers that meet the TNI standards for PT providers. The composition of the sample is unknown to the laboratory performing the analysis, and is used in part to evaluate the ability of the laboratory to produce precise and accurate results.¶~~
- ~~(357) "Public water system" means a water system as defined in OAR 333-061-0010.¶~~
- ~~(368) "Quality Manual (QM)" means a document stating the management policies, objectives, principles,~~

organizational structure and authority, responsibilities, accountability, and implementation of a laboratory to ensure the quality of its product and the utility of its product to its users.¶

(379) "Replicate sample" is 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.¶

(40) "Resource Conservation and Recovery Act (RCRA)" means the enabling legislation, 42 U.S.C. section 6901 et seq. (1976), that requires the EPA to protect human health and protecting and monitoring the environment by regulating hazardous waste disposal practices.¶

(3841) "Safe Drinking Water Act (SDWA)" means the SDWA enacted in 1974 and the Safe Drinking Water Amendments of 1986, 42 U.S.C. 300f et seq., Public Law 93-523, that is the enabling legislation that requires the EPA to protect the quality of drinking water in the U.S. by setting maximum allowable contaminant levels, monitoring, and enforcing violations.¶

(3942) "Scheduled proficiency testing" means a single complete sequence of circulation and scoring of proficiency testing sample for a participant in a proficiency test program with predefined opening and closing dates for any participant.¶

(403) "Secondary accreditation" means the recognition by reciprocity for the fields of accreditation, methods and analytes for which the laboratory holds current primary accreditation by another NELAP approved accrediting body.¶

(414) "Solids" as a matrix means samples of soil, sludge and other non-aqueous compounds analyzed under the guidance of the Resource, Conservation and Recovery Act. Cannabinoid products and concentrates or extracts and industrial hemp-derived vapor items as defined in OAR 333-007-0310 shall be included in this matrix as solids.¶

(425) "Supplemental proficiency testing" means a PT study that may be from a lot previously released by a PT provider but that does not have a pre-determined opening date and closing date but the closing date cannot exceed 45 days from the opening date.¶

(436) "TNI" means the NELAC Institute. TNI is a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.¶

(447) "TNI Standards" means the adopted TNI Standards (© 2016 The NELAC Institute), which are documents describing the elements of laboratory accreditation that was developed and established by the consensus principles of TNI and meets the approval requirements of TNI procedures and policies. Available at www.nelac-institute.org¶

(458) "These rules" means the Oregon Administrative Rules encompassed by OAR 333-064-0005 through 333-064-0120.¶

(469) "Third party assessor" means an ORELAP approved assessor who has a current contract with the Oregon Health Authority to perform on-site assessments of laboratories for ORELAP and is not employed by the state agencies comprising ORELAP's accrediting body.¶

(4750) "United States Environmental Protection Agency (EPA)" means the federal government agency with the responsibility for protecting public health and safeguarding and improving the natural environment (that is air, water, and land) upon which human life depends.

Statutory/Other Authority: ORS 438.605, 438.610, 438.615, 438.620, 448.131, 448.150, 448.280, 475BC.55544, 475BC.5650

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615, 438.620, 448.280, 475BC.55544, 475BC.5650

AMEND: 333-064-0100

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-064-0100

Updating revision numbers for ORELAP cannabis sampling protocols. The active protocol for usable marijuana remains at the current revision number (4.0) from the time the rules take effect until July 1, 2022 when the new batch and harvest lot limits become effective, at which point revision 4.1 becomes the active version. Revision 4.1 describes the required number of sample increments and minimum sample weight resulting from changes in OAR 333-007-0350 to the maximum allowed harvest lot and batch size. Clarifying instructions are also added when multiple-batch composite testing is occurring. Definitions are updated to match what is in the rules. The active protocol for concentrates, extracts, products, and industrial hemp-derived vapor items switches to revision 4.3 when the rules take effect. Revision 4.3 adds information about finished inhalable cannabinoid products, removes reference to control studies which are being repealed, and updates container requirements that amber glass is not required so long as clear glass containers are stored in mylar bags to protect samples from exposure to light. Adding instructions on sampling fresh-baked edible products and sampling of finished cannabinoid products. Definitions are updated for consistency with the rules. Updating Table 3 in the protocol (now named Table 1) on sample increments to be identical to the Table 7 in OAR 333-007-0360 Exhibit B.

Clarifying process of combining sample increments into primary, duplicate, and replicate samples.

Specifying the entire sample must be homogenized prior to any analysis or subsampling and clarifying how composite samples from different strains or batches can be combined where allowed by division 007 rules.

Describing how replicate samples are analyzed for concentrates, extracts, finished inhalable cannabinoid products, and industrial hemp-derived vapor items.

Adding descriptions of required quality control (QC) samples for microbiological and chemical tests. This includes new QC acceptance criteria for adult use cannabinoids and CBD, pesticides, solvents, heavy metals, and mycotoxins which are specified in Exhibit C Table 1 and changes RPD or RSD limits from 20% to 10%.

Adding requirement that laboratory limits of quantitation (LOQs) are less than or equal to one half of the action level. This was previously a requirement only for pesticides. An LOQ of less than or equal to 0.15% is also specified for total delta-9 THC and delta-8 THC. This aligns with less than or equal to one half of the federal legal level for THC of 0.3% and is meant to ensure laboratories have adequate sensitivity to analyze hemp and hemp-derived vapor items are below the state and federal legal limit of THC.

Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-064-0100

Cannabis Sampling Procedures and Testing ¶¶

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.¶¶

(2) Sampling.¶¶

(a) A laboratory must have and follow marijuana item and industrial hemp-derived vapor items sampling policies and procedures, accredited by ORELAP, that:¶¶

(A) Ensure sampling will result in a sample that is representative of the batch being sampled.¶¶

(B) Require sampling and laboratory personnel to document and collect any information necessary for compliance with these rules, OAR chapter 333, division 7, and any applicable TNI standards.¶¶

(C) Require chain of custody procedures consistent with TNI EL Standard V1M2 5.7 and 5.8.¶¶

(D) Are appropriate to the matrix being sampled.¶¶

(E) Are consistent with OAR 333-007-0360 and 333-007-0370 and the following ORELAP sampling protocols approved by the accrediting body, incorporated by reference:¶¶

(i) Usable Marijuana: until July 1, 2022 ORELAP-SOP-001 Rev 4.0 and on or after July 1, 2022 ORELAP-SOP-001 Rev 4.1; and¶¶

(ii) Concentrates, Extracts, Products and Industrial Hemp-derived Vapor Items: ORELAP-SOP-002 Rev.4.23.¶¶

- (F) Ensure that only the finished cannabinoid concentrate, extract, product or industrial hemp-derived vapor item is sampled if testing on the finished cannabinoid concentrate, extract, product or industrial hemp-derived vapor item is required under OAR 333-007-0330 and OAR 333-007-0340.¶
- (G) Contain training and education requirements for sampling personnel.¶
- (b) Sampling policies and procedures must be accredited by ORELAP prior to any marijuana or industrial hemp-derived vapor item samples being taken.¶
- (c) Laboratory personnel that perform sampling must:¶
- (A) Comply with the laboratory's accredited sampling policies and procedures.¶
- (B) After taking samples:¶
- (i) Document the samples in accordance with subsection (2)(e) of this rule; and¶
- (ii) If sampling for a licensee or a registrant required to comply with CTS tracking under ORS 475BC.89571, record the sampling and transfer information in the Commission's seed to sale system, as required by the Authority and the Commission; and¶
- (C) Take care while sampling to avoid contamination of the non-sampled material. Sample containers must be free of analytes of interest and appropriate for the analyses requested.¶
- (D) Take sample increments that are representative of the batch being sampled.¶
- (d) 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.¶
- (e) A laboratory must comply with any recording requirements for samples and sample increments in the accredited policies and procedures and at a minimum:¶
- (A) Record the location of each sample and sample increment taken.¶
- (B) Assign a field identification number for each sample, sample increment ~~and field duplicate, duplicate sample, and replicate sample~~ that have an unequivocal link to the laboratory analysis identification.¶
- (C) Assign a unique identification number for the test batch in accordance with OAR 333-007-0370 and TNI EL standard requirements.¶
- (D) Have a documented system for uniquely identifying the samples to be tested to ensure there can be no confusion regarding the identity of such samples at any time. This system must include identification for all samples, sample increments, preservations, sample containers, tests, and subsequent extracts or digestates.¶
- (E) Place the laboratory identification code as a durable mark on each sample container.¶
- (F) Enter a unique identification number into the laboratory records. This number must be the link that associates the sample with related laboratory activities such as sample preparation. In cases where the sample collector and analyst are the same individual, or the laboratory pre-assigns numbers to sample containers, the unique identification number may be the same as the field identification code.¶
- (f) Combining sample increments.¶
- (A) Sample increments collected from the same batch of usable marijuana ~~must~~shall be combined into a single sample by a laboratory prior to testing. ~~S~~¶
- (B) ~~Prior to testing, a laboratory shall combine sample increments from a batch of a cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item may be combined into a single sample by a laboratory prior to testing if the cannabinoid concentrate, extract, product or industrial hemp-derived vapor item has a certified control study.;~~ ¶
- (i) Increments from a primary sample are combined into a single sample. ¶
- (ii) Increments from a duplicate sample are combined into a single sample.¶
- (iii) Increments from each replicate sample are combined with each other but material from separate replicate samples are not combined.¶
- ~~(B)C~~ Prior to any testing, ~~th~~ or subsampling except as described in subparagraph (i) of this paragraph, the entire combined sample must undergo the laboratory's homogenization process. ¶
- (i) If the homogenization process would invalidate the analysis for a required test, the laboratory must utilize a subsampling procedure to withdraw a portion of the sample prior to homogenization for the required test. Testing that would be invalidated by the homogenization process includes but is not limited to, cryogenic sterilization of the sample prior to microbiological analysis.¶
- (Cii) Potency analysis shall not be performed on material subsampled prior to homogenization steps.¶
- (D) Sample increments and samples collected from different batches may not be combined, except as permitted by OAR 333-007-0360 and on or after July 1, 2022 using the process described in ORELAP-SOP-001 Rev. 4.1.¶
- ~~(D)E~~ Field duplicates may not be combined with the primary samples. Portions of homogenized samples that are combined for testing as permitted by OAR 333-007-0360(1)(c) shall use the laboratory's formal subsampling method to produce a proportionally representative sample from each batch involved.¶
- (g) Sample replicate analysis for concentrates, extracts, finished inhalable cannabinoid products, and industrial hemp-derived vapor items.¶
- (A) When replicate samples are required per OAR 333-007-0360 Exhibit B Table 7, each sample shall be analyzed

individually for residual solvents as described in OAR 333-007-0410 and adult use cannabinoids and CBD as described in OAR 333-007-0430. ¶

(B) Two samples shall be randomly selected according to the laboratory's policy and procedures and analyzed individually for the remaining required analyses as described in OAR 333-007-0330, 333-007-0341, and 333-007-0342. ¶

(3C) Adult use cannabinoid and CBD results for the batch or process lot are reported as the calculated average result from all sample replicates. ¶

(3) Compliance testing validity. ¶

(a) When testing a sample for adult use cannabinoids and CBD the required microbiological compliance tests as described in OAR 333-007-0390, a laboratory must comply with additional method validation as follows: ¶

(aA) Run a laboratory control standard for all adult use cannabinoids required per OAR 333-007-0430, CBD, and CBDA in accordance with TNI Standard requirements within acceptance criteria of 70 percent to 130 percent recovery negative control in accordance with TNI Standard requirements to demonstrate the procedure is free of microbiological contaminants that prevent accurate testing. ¶

(B) Run a positive control in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the positive control means accurate identification and quantitation of all regulated analytes. ¶

(b) When testing a sample for the required chemistry compliance tests as described in OAR 333-007-0400 to 333-007-0415 and 333-007-0425 to 333-007-0430, a laboratory must comply with additional method validation as follows: ¶

(A) Run a method blank in accordance with TNI Standard requirements to demonstrate the procedure is free of contaminants at or above the limit of quantitation. ¶

(B) Run a laboratory control standard (LCS) in accordance with TNI Standard requirements to demonstrate acceptable performance of the procedure. Acceptable performance of the LCS means percent recovery for all regulated analytes are within the limits specified in Exhibit C, Table 1. ¶

(bC) Analyze field-duplicates of samples with a precision limit of 210 percent RPD, if field-duplicates are required. The amount of delta-8 THC, total delta-9 THC, or total CBD between the primary sample and field duplicate may not exceed as specified in OAR 333-007-0360 and analyze all replicate samples with a precision limit of 150 percent RPD for concentrates, extracts, products, or industrial hemp-derived vapor items that have a control study in place. SD, if replicates are required as specified in OAR 333-007-0360. ¶

(4) Calculating total delta-9 THC and total CBD. ¶

(a) Total delta-9 THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: ¶

$M \text{ total delta-9 THC} = M \text{ delta-9 THC} + 0.877 * M \text{ delta-9 THCA.}$ ¶

(b) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: ¶

$M \text{ total CBD} = M \text{ CBD} + 0.877 * M \text{ CBDA.}$ ¶

(c) Each test report must include the results for delta-8 THC, total delta-9 THC, and total CBD. ¶

(5) Report delta-8 THC, total delta-9 THC, and total CBD for useable marijuana as Dry Weight. A laboratory must analyze the sample as received and report delta-8 THC, total delta-9 THC and total CBD content by dry weight calculated as follows: ¶

$P \text{ delta-8 THC(dry)} = P \text{ delta-8 THC(wet)} / [1 - (P \text{ moisture}/100)]$ ¶

$P \text{ total delta-9 THC(dry)} = P \text{ total delta-9 THC(wet)} / [1 - (P \text{ moisture}/100)]$ ¶

$P \text{ total CBD(dry)} = P \text{ total CBD(wet)} / [1 - (P \text{ moisture}/100)]$ ¶

(6) Calculating RPD and RSD. ¶

(a) A laboratory must use the following calculation for determining RPD: ¶

Relative Percent Difference ¶

$\%RPD = |(sample - duplicate)| / ((sample + duplicate) / 2) * 100$ ¶

(b) A laboratory must use the following calculation for determining RSD: ¶

Standard Deviation ¶

$S = (((x_i - x)^2) / (n - 1))$ ¶

Relative Standard Deviation ¶

$\%RSD = (S / x) * 100$ ¶

(c) For purposes of this section: ¶

(A) S = standard deviation. ¶

(B) n = total number of values. ¶

(C) xi = each individual value used to calculate mean. ¶

(D) x = mean of n values. ¶

(d) For calculating both RPD and RSD if any results are less than the Limit of Quantitation (LOQ) the absolute value of the LOQ is used in the equation. ¶

(e) The laboratory shall not substitute the LOQ for individual components of a totaled result, such as total delta-9 THC or total Hexanes, in the calculation of the totaled result for the purpose of calculating RPD or RSD.¶

(7) Tentative Identification of Unknown Compounds.¶

(a) If a laboratory is using a gas chromatography mass spectrometry instrument for analysis when testing cannabinoid concentrates, extracts, or industrial hemp-derived vapor items for solvents the laboratory shall have an established procedure for achieving tentative identification of unknown compounds in the sample. A tentatively identified compound (TIC) means an unknown chromatographic peak that is neither included in the list of analytes the laboratory is testing for nor expected to be naturally found in cannabis concentrates, extracts, or industrial hemp-derived vapor items such as terpenes.¶

(b) Tentative identification is achieved by searching NIST 2014 or an equivalent database (>250,000 compounds). Match scores for background subtracted or deconvoluted spectra should exceed 90 percent compared to the database library spectrum.¶

(c) Upon written request from the overseeing agency of the licensee or registrant, a laboratory shall report to the licensee or registrant and the Authority or the Commission all tentatively identified compounds (TICS) that meet the identification criteria in subsection (7)(b) of this rule.¶

(A) TIC quantitation is estimated by comparing analyte area to the closest internal standard area and assuming a response factor (RF) = 1.¶

(B) If a laboratory does not use internal standards, TICs shall be reported as "detected" and apparent relative concentration shall be judged based on peak area.¶

(8) A laboratory must provide:¶

(a) Any pesticide test result to the Department of Agriculture upon that agency's request.¶

(b) A sample or a portion of a sample to the Department of Agriculture upon that agency's request, document the chain of custody from the laboratory to the Department, and document that the sample or portion of the sample was provided to the Department in the Commission's seed to sale tracking system.¶

(9) A laboratory performing tests for a licensee or a registrant required to use CTS under ORS 475BC.89571 must enter any information required by the Commission or the Authority in CTS.¶

(10) A laboratory performing tests for a registrant must comply with the documentation requirements in OAR 333-007-0370 and must maintain the documentation required in these rules for at least three years and provide that information to the Authority upon request.¶

(11) The Authority may, in its discretion, deviate from TNI Standards in order to comply with OAR 333-007-04300 to 333-007-0500 and these rules based on the state's needs.¶

(12) A laboratory must be able to demonstrate that its LOQ is:¶

~~(a) Below limit of quantitation (LOQ) for all matrices in compliance testing is:¶~~

~~(a) Less than or equal to one-half of any action level established in OAR 333-007-0400, 333-007-0410, 333-007-0415, and 333-007-0440; 25 Exhibit A, Tables 3 and 4, 4, 8, and 9 except for as outlined in 333-064-0110(6); and¶~~

~~(b) For total delta-9 THC concentration below less than or equal to 0.315 percent.; and¶~~

~~(c) For delta-8 THC concentration below less than or equal to 0.315 percent. ¶~~

(13) Non-compliance testing. A laboratory that conducts a quality control or research and development test for a registrant or licensee may use methods not approved by the Authority but the laboratory may not identify those test results as accredited results.

Statutory/Other Authority: ORS 438.605, 438.610, 438.615 & 438.620, 475BC.55544, 475BC.5650

Statutes/Other Implemented: ORS 438.605, 438.610, 438.615 & 438.620, 475BC.55544, 475BC.5650






RULE ATTACHMENTS DO NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

| | | |
|---|---|---|
|  | <h1>Oregon</h1> <h2>Environmental Laboratory Accreditation Program</h2> |  |
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Protocol for Collecting Samples of Usable Marijuana

ORELAP-SOP-001 Rev. 4.0

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Protocol for Collecting Samples of Usable Marijuana

I. Introduction and Scope

Obtaining a representative sample from a larger batch is one of the key elements of accurate laboratory analysis. Laboratories collect representative samples by consistently using standard sampling methods and equipment, preventing contamination of the sample, and maintaining the sample identity within the batch. The laboratory must consistently use documented standard sampling practices, tools, and methods. These practices, tools, and methods must be appropriate for the matrix. If proper protocols are in place and adhered to for sample collection, the laboratory analysis of the sample should reflect the composition of the batch as a whole at the time the sampling occurred, within recognized tolerances.

This protocol is for use by ORELAP-accredited laboratories performing cannabis sampling as defined in OAR 333-064-0025. It focuses on standard and correct sampling practices that should be reflected in a laboratory's own sampling policies and procedures.

II. Records and Documentation

ORELAP-accredited laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

1. The laboratory's SOP shall be readily accessible to all pertinent personnel.
2. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
3. The laboratory's SOP should use this protocol as minimum requirements and must include additional detail specific to laboratory procedures. In cases where the published method (this protocol) has been modified or where the referenced method (this protocol) is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described in the laboratory's SOP. Any changes to the laboratory's protocol, including use of a selected option, shall be documented and included on the laboratory's sampling form.
4. All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-007-0310.

ORELAP-accredited laboratories shall maintain sampling plans.

1. The laboratory's sampling plans shall be made available at their location of use.
2. The laboratory's sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch.
3. Any deviation from or addition to the laboratory's sampling plan must be documented in detail and shall be included in the final report. The standardized or generic sampling plans can be included in the SOP however specialized client requests or products may require additional information.
4. The laboratory's sampling plans shall document the date and time of sampling.

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III. Client Contracts; Client Sampling and Testing Requests

The laboratory must have a sampling contract with a client that includes at least the following:

1. A test order containing the information required by OAR 333-007-0315
2. A site-specific sampling plan or process specific sampling plan that uses statistical design for each project to provide representative sampling.

IV. Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the Usable Marijuana is being kept, as this will determine the sampling plan. In cases where Usable Marijuana will be sold or transferred to a processor or processing site, analysis may occur prior to the drying and curing steps. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for Usable Marijuana are in OAR 333-007-0320. The requirements for sampling and sample size are in OAR 333-007-0360 and Appendix 2. Per Authority or Commission request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan must be designed such that each flower bud in the batch has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 15 lbs.**

V. Sampling Design and Plans

1. Sampling plans shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch. Standardized Sampling Plans can be included in the SOP however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.
2. Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity.
3. Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.
4. A sampling plan must include at a minimum:
 - a. Shape, size, and number of container(s) holding the batch from which sample increments will be collected;
 - b. Number of sample increments to be collected;
 - c. Minimum weight or mass of each sample increment;
 - d. Location of where sample increments will be taken within each container holding the

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batch. See Appendix 2 for information on random selection of locations.

5. The laboratory must have details in its SOP or a sampling plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

VI. Sampling Equipment and Supplies

1. A laboratory should, at a minimum, have the following equipment and supplies for sampling:
 - a. Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
 - b. Tongs
 - c. Corers
 - d. Teri-wipes or equivalent
 - e. Field balance (capable of 0.01 g measurements)
 - f. Calibrated verification weights appropriate to verify accuracy of field balance
 - g. Cleaning supplies – solvent, bleach, 70% Ethanol
 - h. Gloves (powder-free, nitrile, sterile)
 - i. Mylar bags (for final sample transport and storage) or amber glass jars (for final sample transport and storage)
2. Cleaning of Field Sampling Equipment
 - a. Field sampling equipment shall be certified clean prior to use by the laboratory.
 - b. Cleaning techniques will vary depending upon the desired analysis.
 - c. In general, sampling equipment must be sterile for microbiology samples and clean for chemistry samples.
 - d. The laboratory shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field.
 - e. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
 - f. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.
3. Field balance calibration verification
 - a. The laboratory sampling technician shall verify the calibration of the field balance at the sampling location.
 - b. When multiple sampling events occur on the same day, the balance calibration shall be verified at each sampling location.
 - c. Balance calibration verifications shall be documented.

VII. Procedures for Sampling Usable Marijuana

1. Locate the batch to be sampled. The sampler **must** have access to entire batch.
2. Check for any signs of non-uniformity within the batch and document the same.
 - a. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers
 - b. During sampling, the sampler shall look for differences in the usable marijuana being sampled such as color, shape, size, and treatment.

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- c. By definition, the batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the batch and that any sample drawn may not be representative for testing.
 - d. The sampler shall note these anomalies in the sample collection report.
3. Review the container label information for harvest lot number, producer, and other pertinent information. Each harvest lot must be separated into batches of 15 lbs. or less and must be assigned a unique batch number by the grower. Do not sample if a unique batch number is not available.
4. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container and confirm batch weight with client. Do not sample if the batch size is unavailable or exceeds 15 lbs.
5. Determine the number of containers from which sample increments must be collected (Appendix 2).
6. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
7. Sampling tool and other instruments like field balance must be clean prior to use to prevent cross-contamination of sample increments. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
 - a. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling.
8. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
9. Decontamination waste must be collected and properly disposed of if not used for analysis.
 - a. Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.
 - b. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures or discarded.
 - c. Where aseptic technique is required, samplers shall observe best practices to prevent microbiological contamination of samples. For an example of aseptic technique, see the FDA Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6).
10. Visually inspect each test sample increment to assess uniformity. If non-uniformity is identified, record observation in the sampling report.
11. When collecting sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected. Laboratory should refrain from sampling a batch from containers that because of their shape make it impossible to collect sample increments from all locations within the container. This includes subsurface or internal layers.
12. Weigh each sample increment, document weight on sampling report form, along with location sample increment was taken.
13. Combine all sample increments to form the composite sample.
14. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
15. Seal and label the composite sample with the following minimum requirements:
 - a. Laboratory license number

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- b. Unique identifier for sampling event
 - c. Sampling date and name of sampler
 - d. Producer's license or registration number
 - e. Harvest lot and batch numbers
 - f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font.
16. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the laboratory sample identification number.
 17. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the standards of accreditation.
 18. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
 19. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational marijuana or record in the laboratory's records the registrant number for tracking medical marijuana.

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler must complete a sampling report form for each batch sampled. Sample report forms must include at a minimum the following information:
 - a. Name and address of producer including licensee or registrant number;
 - b. Product type.
 - c. Total weight of batch.
 - d. Unique laboratory batch ID#, Metrc batch ID #, and/or OHA batch ID#.
 - e. Total number of containers sampled.
 - f. Number of sample increments taken from each container.
 - g. Number of sample containers collected.
 - h. Weight and location of each sample increment.
 - i. Total weight sampled.
 - j. Sampling plan ID and revision date.
 - k. Sampling Procedure ID and revision date.
 - l. Description of equipment and tools used.
 - m. Address where sampled.
 - n. Date sampled.
 - o. ORELAP Laboratory Identification number.
 - p. Lab License Number.
 - q. Sampler's identification and/or signature.
 - r. Name of responsible party for the batch and transport information.
 - s. Receiving laboratory and types of tests required or requested.
2. A chain of custody form must be used unless the laboratory is sampling for a client that is required to use Metrc. A chain of custody form must include at least the following information:
 - a. Sampler's name
 - b. Sample Identification (Lab ID number) if assigned before arrival at laboratory
 - c. Sampling Date/Time
 - d. Weight and location of increment samples
 - e. Final weight of composite sample
 - f. Custody transfer signatures

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- g. Custody Transfer Dates/Times
3. If any of the above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space with an explanation as to why the information is not available.
4. All sampling report forms must be signed by the sampler.

IX. Transportation and Handling of Samples

1. Samples must be transported to the laboratory performing the analysis by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody form continues to document sample integrity. Transportation must be done in compliance with OAR 845-025-5060. Note: The existing regulation does not permit shipping in any form such as USPS or FedEx.
2. Containers for sample transport must be designed to protect the sample from moisture and temperature extremes and to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling is a glass, amber jar with a PTFE-lined lid or a Mylar bag. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.
3. The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.
4. Submit the composite sample to the laboratory in its entirety. In a situation where the composite sample must be split for analysis by two different laboratories, for example when pesticide analysis is subcontracted to another laboratory, the composite sample shall be homogenized by the primary laboratory using the laboratory's approved sample homogenization process prior to subsampling. This shall be reflected on the chain of custody.
5. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

X. Quality Assurance and Quality Control

X.1 Sampler Qualifications

1. Basic qualifications for samplers of usable marijuana are:
 - a. Physically able to perform the duties of a sampler;
 - b. No conflict of interest;
 - c. Employed by an ORELAP accredited laboratory
 - d. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
 - e. Licensed under state law to transport the required quantity of usable marijuana items
2. Education and training for samplers:
 - a. Initial training: training shall include principles, procedures, and policies of sampling; Initial training must be performed by an Instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.
 - b. Field or on-the-job training: 8-hours of training on various sampling techniques;

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- c. Continuing education: periodic refresher training shall be done annually.

X.2 Demonstration of Capability

Prior to acceptance and institution of any accredited method, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method, and, 2) when the method has not been performed by the laboratory or sampler within a 12-month period.

This procedure shall employ one of the following approaches to demonstrating capability:

1. Comparison of replicate samples within a defined Relative Standard Deviation (%RSD)¹.
2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD.

Thereafter, ongoing continuing demonstration of capability (CDOC) is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

X.3 Field QC Samples

1. Field Duplicates
 - a. Field Duplicates are recommended for any Usable Marijuana sampling event, but not required. The Field Duplicate must be collected using the same procedure and contain the same number of sample increments as the Primary Sample. The lab must have documentation of the client request for a Field Duplicate with any client specified Quality objectives and precision limits must meet the client's need.
2. Equipment Blanks
 - a. Equipment rinse blank samples provide a QC check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning.
 - b. The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.
 - c. The Equipment Blank must pass the required analysis at <LOQ for cleaning validation.

¹ Standard Methods 20th Edition; 1020 B Quality Control, 11. QC Calculations, a. Initial Calibration.

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- d. If the Equipment Blank is collected at the sampling event, the lab must have detail in the sampling plan or procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

X.4 Field Audits

1. The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits must be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.
2. When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.
3. Required components of the Field Audit program:
 - a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol;
 - b. Observe the sampler conducting sampling procedures;
 - c. Record any deficiencies and initiate corrective action.

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<http://www.nelac-institute.org/content/CSDP/standards.php>

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Oregon Administrative Rules, *Marijuana Labeling, Concentration limits, and Testing*, Chapter 333, Division 7.

Oregon Administrative Rules, *General Requirements Applicable to all Marijuana Licensees*, Chapter 845, Division 25.

Standard Methods 20th Edition (1998); 1020 Quality Assurance

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Appendix 1 Definitions

**** If there are any inconsistencies between the definitions below and the definitions in OAR 333, Divisions 7 and 64, the definitions in the rules take precedence.**

Authority means Oregon Health Authority

Batch means a quantity, not to exceed 15 pounds, of marijuana or usable marijuana from a harvest lot.

Chain of Custody Form means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory. (Sample tracking document)

Commission means the Oregon Liquor Control Commission.

Composite sample means a sample containing all sample increments taken from a batch.

Container means a sealable, hard- or soft-bodied receptacle in which a marijuana item is placed during sampling, transport, and storage; or a physical division into which a marijuana batch is placed for random and representative sampling.

Decision Unit (DU) means the material from which the primary sample(s) is collected and to which the inference(s) is made.

Equipment Blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate the cleaning procedure or between sampling batches to demonstrate lack of contamination.

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 being sampled that is prepared and analyzed separately from the primary sample.

Fundamental Sampling Error (FSE) means a measure of the compositional heterogeneity of the batch, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

Harvest Lot means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location, and cured under uniform conditions.

Heterogeneity means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

Homogeneous means of a uniform composition and with similar properties throughout a batch of useable marijuana; means a cannabinoid product, concentrate, or extract has uniform composition and properties throughout each process lot.

Label means a tag or other device attached to or written, stamped, or printed on any container or accompanying any batch in bulk stating all required batch information.

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 Commission under ORS475B.560.

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include

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industrial hemp, as defined in ORS 571.300.

Marijuana item means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

Metrc means the state-administered cannabis tracking system (CTS).

ORELAP means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

Primary Sample means a composite sample composed of sample increments and tested for the required analysis methods.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.810.

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

Relative Percent Difference means comparing two quantities while taking into account the size of what is being compared. If the final result (i.e. Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

$$\%RPD = \frac{|(sample - duplicate)|}{(sample + duplicate)/2} \times 100$$

Relative Standard Deviation means the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If the final result (i.e. Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

Standard Deviation

$$S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{(n - 1)}}$$

Relative Standard Deviation

$$\%RSD = \frac{S}{\bar{x}} \times 100$$

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

\bar{x} = mean of n values.

Representative Sample means a sample obtained according to an incremental sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

Sample Increment means an amount of a marijuana item collected by laboratory personnel from a

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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.

Sample Quality Criteria (SQC) means a series of statements that clarify a sampling program's technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed means secured in such a way as to prove authenticity or integrity of the sample.

Sterilization means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

TNI Standard: TNI Environmental Laboratory Standard as defined in 333-007-0310.

Usable Marijuana means the dried leaves and flowers of marijuana. Usable Marijuana does not include the seeds, stalks and roots of marijuana or waste material that is a by-product of producing or processing marijuana.

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Appendix 2 Sampling Requirements

Random Sampling

As specified in the sampling plan, select random sample increments from different locations within a container or set of containers. Laboratories must develop procedures describing how to:

1. Assign location numbers within containers and among a set of containers;
2. Use a random number generator to determine which locations to sample; and
3. Document where each sample increment was sampled from and the volume collected from each increment.

Assign divisions based on the type of container in the site-specific sampling plan. For container types that are greater than four (4) inches deep, divisions must also include a layer or layers beneath the accessible portion of the batch. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers use existing or arbitrary order of containers to assign numbers to the total of “divisions multiplied by total number of containers” (divisions x # containers = total number of random increments) and record in the sampling report.

The laboratory must have details in its SOP or Sampling Plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

Sample size

Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. Per OAR 333-007-0350, the maximum batch size is 15 lbs.

The required sample size for a given batch size based on OAR 333-007-0360 varies depending upon the size of the batch (Table)

Table 1 – Sample size requirements based on size of batch.

| Batch size | Required sample size | | |
|---------------|----------------------|-------------|-----------|
| | Pounds (lbs) | Ounces (oz) | Grams (g) |
| ≤1 lbs | 0.005 | 0.08 | 2.3 |
| 1.01 ≤2 lbs | 0.010 | 0.16 | 4.5 |
| 2.01 ≤3 lbs | 0.015 | 0.24 | 6.8 |
| 3.01 ≤4 lbs | 0.020 | 0.32 | 9.1 |
| 4.01 ≤5 lbs | 0.025 | 0.40 | 11.3 |
| 5.01 ≤6 lbs | 0.030 | 0.48 | 13.6 |
| 6.01 ≤7 lbs | 0.035 | 0.56 | 15.9 |
| 7.01 ≤8 lbs | 0.040 | 0.64 | 18.1 |
| 8.01 ≤9 lbs | 0.045 | 0.72 | 20.4 |
| 9.01 ≤10 lbs | 0.050 | 0.80 | 22.7 |
| 10.01 ≤11 lbs | 0.055 | 0.88 | 25.0 |

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| Batch size | Required sample size | | |
|---------------|----------------------|-------------|-----------|
| | Pounds (lbs) | Ounces (oz) | Grams (g) |
| 11.01 ≤12 lbs | 0.060 | 0.96 | 27.3 |
| 12.01 ≤13 lbs | 0.065 | 1.04 | 29.6 |
| 13.01 ≤14 lbs | 0.070 | 1.12 | 31.9 |
| 14.01 ≤15 lbs | 0.075 | 1.20 | 34.2 |

Sampling a batch

1. When collecting a primary sample from a batch, a minimum of seven (7) sample increments shall be collected. Collect the sample increments by following different paths through the batch container or by taking the sample increments systematically at well-separated points along a heptagonal pattern.
2. As the batch increases in size, it is necessary to collect additional sample increments to make up the primary sample (Table 2).

Table 2 – Minimum number of sample increments for the primary sample based on batch size.

| Size of batch (lbs) | ≤ 2 | ≤ 4 | ≤ 6 | ≤ 8 | ≤ 10 |
|---------------------|-----|-----|-----|-----|------|
| No. of increments | 7 | 7 | 8 | 8 | 9 |

| Size of batch (lbs) | ≤ 12 | ≤ 14 | ≤ 15 |
|---------------------|------|------|------|
| No. of increments | 9 | 10 | 10 |

Table 3 – Revision history of this SOP.

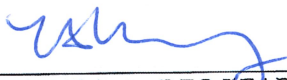
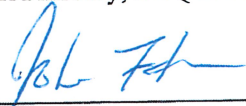
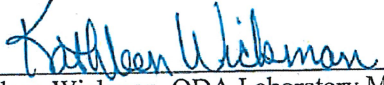
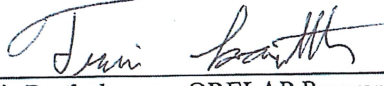
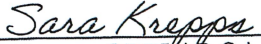
| Revision | Date | Summary of changes made, and initials of editor |
|----------|-----------|---|
| 4.0 | 7/20/2020 | Major updates and re-formatting, with input from Scott Hoatson and Department of Justice. Updated: OSPHL address; executive board and ORELAP staff names as needed; definitions in order to match OARs and ORS and arranged in alphabetical order. Added: this table (Revision history); subsection VI.3; additional information about subsampling for subcontracted analyses; mention of assigning layers for sampling deep containers; required calibration verification of field balances. Combined: information in section IX with information from former section X (Forwarding samples to the Primary and/or Retesting Laboratory) and deleted former section X and combined former section X.5 with section X.4. Minor updates for consistency and typo fixes. Includes fixing reference to minimum number of sample increments in Table 2. STJ 7/20/2020 |
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|--|---|---|
|  | <h1>Oregon</h1> <h2>Environmental Laboratory Accreditation Program</h2> |  |
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ORELAP-SOP-001 Rev. 4.1

ORELAP Executive Board and Program Approval Signatures:

| | |
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Acknowledgements

Version 1.0 of this document was authored by the Cannabis Sub-Committee with input from Technical Experts and approved by the ORELAP Executive Board. See Revision 2.0 for original committee authorship. Revision 3.0 was authored and reviewed by NEFAP/GLP sampling experts. Revision 4.0 was authored by Steven Jetter and reviewed by Travis Bartholomew and the ORELAP Executive Board.

Protocol for Collecting Samples of Usable Marijuana

I. Introduction and Scope

Obtaining a representative sample from a larger batch is one of the key elements of accurate laboratory analysis. Laboratories collect representative samples by consistently using standard sampling methods and equipment, preventing contamination of the sample, and maintaining the sample identity within the batch. The laboratory must consistently use documented standard sampling practices, tools, and methods. These practices, tools, and methods must be appropriate for the matrix. If proper protocols are in place and adhered to for sample collection, the laboratory analysis of the sample should reflect the composition of the batch as a whole at the time the sampling occurred, within recognized tolerances.

This protocol is for use by ORELAP-accredited laboratories performing cannabis sampling as defined in OAR 333-064-0025. For the purposes of this protocol, cannabis sampling also includes activities related to obtaining a representative sample of post-harvest cured hemp material but excludes activities related to pre-harvest sampling of hemp material. The protocol focuses on standard and correct sampling practices that should be reflected in a laboratory's own sampling policies and procedures.

II. Records and Documentation

ORELAP-accredited laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.

1. The laboratory's SOP shall be readily accessible to all pertinent personnel.
2. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
3. The laboratory's SOP should use this protocol as minimum requirements and must include additional detail specific to laboratory procedures. In cases where the published method (this protocol) has been modified or where the referenced method (this protocol) is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described in the laboratory's SOP. Any changes to the laboratory's protocol, including use of a selected option, shall be documented and included on the laboratory's sampling form.
4. All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-064-0025.

ORELAP-accredited laboratories shall maintain sampling plans.

1. The laboratory's sampling plans shall be made available at their location of use.
2. The laboratory's sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch.
3. Any deviation from or addition to the laboratory's sampling plan must be documented in detail and shall be included in the final report. The standardized or generic sampling plans can be included in the SOP however specialized client requests or products may require additional information.
4. The laboratory's sampling plans shall document the date and time of sampling.

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III. Client Contracts; Client Sampling and Testing Requests

The laboratory must have a sampling contract with a client that includes at least the following:

1. A test order containing the information required by OAR 333-007-0315
2. A site-specific sampling plan or process specific sampling plan that uses statistical design for each project to provide representative sampling.

IV. Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the Usable Marijuana is being kept, as this will determine the sampling plan. In cases where Usable Marijuana will be sold or transferred to a processor or processing site, analysis may occur prior to the drying and curing steps. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for Usable Marijuana are in OAR 333-007-0320. The requirements for sampling and minimum sample size are in OAR 333-007-0360 and Appendix 2. Per Authority or Commission request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan must be designed such that each flower bud, leaf, or other portion in the batch has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 50.0 lbs or 22.68kg.**

V. Sampling Design and Plans

1. Sampling plans shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch. Standardized Sampling Plans can be included in the SOP however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.
2. Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity.
3. Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.
4. A sampling plan must include at a minimum:
 - a. Shape, size, and number of container(s) holding the batch from which sample increments will be collected;
 - b. Number of sample increments to be collected;
 - c. Minimum weight or mass of each sample increment;
 - d. Location of where sample increments will be taken within each container holding the

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batch. See Appendix 2 for information on random selection of locations.

5. The laboratory must have details in its SOP or a sampling plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

VI. Sampling Equipment and Supplies

1. A laboratory should, at a minimum, have the following equipment and supplies for sampling:
 - a. Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
 - b. Tongs
 - c. Corers
 - d. Teri-wipes or equivalent
 - e. Field balance (capable of 0.01 g measurements)
 - f. Calibrated verification weights appropriate to verify accuracy of field balance
 - g. Cleaning supplies – solvent, bleach, 70% Ethanol
 - h. Gloves (powder-free, nitrile, sterile)
 - i. Mylar bags (for final sample transport and storage) or amber glass jars (for final sample transport and storage)
2. Cleaning of Field Sampling Equipment
 - a. Field sampling equipment shall be certified clean prior to use by the laboratory.
 - b. Cleaning techniques will vary depending upon the desired analysis.
 - c. In general, sampling equipment must be sterile for microbiology samples and clean for chemistry samples.
 - d. The laboratory shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field.
 - e. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
 - f. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.
3. Field balance calibration verification
 - a. The laboratory sampling technician shall verify the calibration of the field balance at the sampling location.
 - b. When multiple sampling events occur on the same day, the balance calibration shall be verified at each sampling location.
 - c. Balance calibration verifications shall be documented.

VII. Procedures for Sampling Usable Marijuana

1. Locate the batch to be sampled. The sampler **must** have access to entire batch.
2. Check for any signs of non-uniformity within the batch and document the same.
 - a. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers.
 - b. During sampling, the sampler shall look for differences in the usable marijuana being sampled such as color, shape, size, and treatment.

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- c. By definition, the batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the batch and that any sample drawn may not be representative for testing.
- d. The sampler shall note these anomalies in the sample collection report.
- e. Some batches may include more than one Metric package associated with different strains or different types of material from the same strain where allowed in OAR 333-007-0360 (1) (c).
 - i. In the situation described in (e) above, sampling occurs by each Metric package number composed of material that appears to be substantially similar in appearance and quality. Examples of materials that are not substantially similar include but are not limited to flower buds versus leafy stem material or “A buds” versus “B buds”.
 - ii. Combining multiple Metric packages shall occur in the laboratory AFTER sample homogenization steps are completed as required by OAR 333-064-0100 (2) (f).
3. Review the container label information for harvest lot number, producer, and other pertinent information. Each harvest lot must be separated into batches of 50.0 lbs. or less and must be assigned a unique batch number by the grower. Do not sample if a unique batch number is not available.
 - a. The batch shall be presented for sampling in containers holding no greater than 15.0lbs.
4. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container and confirm batch weight with client. Do not sample if the batch size is unavailable or exceeds 50.0 lbs.
5. Determine the number of containers from which sample increments must be collected (Appendix 2).
6. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
7. Sampling tool and other instruments like field balance must be clean prior to use to prevent cross-contamination of sample increments. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
 - a. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling.
8. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
9. Decontamination waste must be collected and properly disposed of if not used for analysis.
 - a. Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.
 - b. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory’s procedures or discarded.
 - c. Where aseptic technique is required, samplers shall observe best practices to prevent microbiological contamination of samples. For an example of aseptic technique, see the FDA Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6).
10. Visually inspect each test sample increment to assess uniformity. If non-uniformity is identified, record observation in the sampling report.

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11. When collecting sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected. Laboratory should refrain from sampling a batch from containers that because of their shape make it impossible to collect sample increments from all locations within the container. This includes subsurface or internal layers.
12. Weigh each sample increment, document weight on sampling report form, along with location sample increment was taken.
13. Combine all sample increments to form the composite sample.
14. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
15. Seal and label the composite sample with the following minimum requirements:
 - a. Laboratory license number
 - b. Unique identifier for sampling event
 - c. Sampling date and name of sampler
 - d. Producer's license or registration number
 - e. Harvest lot and batch numbers
 - f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font.
16. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the laboratory sample identification number.
17. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the standards of accreditation.
18. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
19. Record the sampling event in the OLCC seed to sale system under the licensee number for recreational marijuana or record in the laboratory's records the registrant number for tracking medical marijuana.

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler must complete a sampling report form for each batch sampled. Sample report forms must include at a minimum the following information:
 - a. Name and address of producer including licensee or registrant number;
 - b. Product type.
 - c. Total weight of batch.
 - d. Unique laboratory batch ID#, Metrc batch ID #, and/or OHA batch ID#.
 - e. Total number of containers sampled.
 - f. Number of sample increments taken from each container.
 - g. Number of sample containers collected.
 - h. Weight and location of each sample increment.
 - i. Total weight sampled.
 - j. Sampling plan ID and revision date.
 - k. Sampling Procedure ID and revision date.
 - l. Description of equipment and tools used.
 - m. Address where sampled.
 - n. Date sampled.
 - o. ORELAP Laboratory Identification number.

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- p. Lab License Number.
 - q. Sampler's identification and/or signature.
 - r. Name of responsible party for the batch and transport information.
 - s. Receiving laboratory and types of tests required or requested.
2. A chain of custody form must be used unless the laboratory is sampling for a client that is required to use Metrc. A chain of custody form must include at least the following information:
 - a. Sampler's name
 - b. Sample Identification (Lab ID number) if assigned before arrival at laboratory
 - c. Sampling Date/Time
 - d. Weight and location of increment samples
 - e. Final weight of composite sample
 - f. Custody transfer signatures
 - g. Custody Transfer Dates/Times
 3. If any of the above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space with an explanation as to why the information is not available.
 4. All sampling report forms must be signed by the sampler.

IX. Transportation and Handling of Samples

1. Samples must be transported to the laboratory performing the analysis by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody form continues to document sample integrity. Transportation must be done in compliance with OAR 845-025-5060. Note: The existing regulation does not permit shipping in any form such as USPS or FedEx.
2. Containers for sample transport must be designed to protect the sample from moisture and temperature extremes and to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling is a glass, amber jar with a PTFE-lined lid or a Mylar bag. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.
3. The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.
4. Submit the composite sample to the laboratory in its entirety. In a situation where the composite sample must be split for analysis by two different laboratories, for example when pesticide analysis is subcontracted to another laboratory, the composite sample shall be homogenized by the primary laboratory using the laboratory's approved sample homogenization process prior to subsampling. This shall be reflected on the chain of custody.
5. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

X. Quality Assurance and Quality Control

X.1 Sampler Qualifications

1. Basic qualifications for samplers of usable marijuana are:

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- a. Physically able to perform the duties of a sampler;
 - b. No conflict of interest;
 - c. Employed by an ORELAP accredited laboratory
 - d. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
 - e. Licensed under state law to transport the required quantity of usable marijuana items
2. Education and training for samplers:
 - a. Initial training: training shall include principles, procedures, and policies of sampling; Initial training must be performed by an Instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.
 - b. Field or on-the-job training: 8-hours of training on various sampling techniques;
 - c. Continuing education: periodic refresher training shall be done annually.

X.2 Demonstration of Capability

Prior to acceptance and institution of any accredited method, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method, and, 2) when the method has not been performed by the laboratory or sampler within a 12-month period.

This procedure shall employ one of the following approaches to demonstrating capability:

1. Comparison of replicate samples within a defined Relative Standard Deviation (%RSD)¹.
2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined RPD.

Thereafter, ongoing continuing demonstration of capability (CDOC) is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

X.3 Field QC Samples

1. Duplicates
 - a. Duplicates are recommended for any Usable Marijuana sampling event, but not required. The Duplicate must be collected using the same procedure and contain the same number of sample increments as the Primary Sample. The lab must have documentation of the client request for a Duplicate with any client specified Quality objectives and precision limits must meet the client's need.
2. Equipment Blanks
 - a. Equipment rinse blank samples provide a QC check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an

¹ Standard Methods 20th Edition; 1020 B Quality Control, 11. QC Calculations, a. Initial Calibration.

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equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning.

- b. The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.
- c. The Equipment Blank must pass the required analysis at <LOQ for cleaning validation.
- d. If the Equipment Blank is collected at the sampling event, the lab must have detail in the sampling plan or procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

X.4 Field Audits

1. The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits must be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.
2. When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.
3. Required components of the Field Audit program:
 - a. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol;
 - b. Observe the sampler conducting sampling procedures;
 - c. Record any deficiencies and initiate corrective action.

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Appendix 1 Definitions

**** If there are any inconsistencies between the definitions below and the definitions in OAR 333, Divisions 7 and 64, the definitions in the rules take precedence.**

Authority means Oregon Health Authority

Batch means a quantity, not to exceed 50.0 pounds or 22.68 kilograms, of marijuana or usable marijuana from a harvest lot.

Chain of Custody Form means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory. (Sample tracking document)

Commission means the Oregon Liquor Control Commission.

Composite sample means a sample containing all sample increments taken from a batch.

Container means a sealable, hard- or soft-bodied receptacle in which a marijuana item is placed during sampling, transport, and storage; or a physical division into which a marijuana batch is placed for random and representative sampling.

Decision Unit (DU) means the material from which the primary sample(s) is collected and to which the inference(s) is made.

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 being sampled that is prepared and analyzed separately from the primary sample.

Equipment Blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate the cleaning procedure or between sampling batches to demonstrate lack of contamination.

Fundamental Sampling Error (FSE) means a measure of the compositional heterogeneity of the batch, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

Harvest Lot means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 7 calendar day period at the same location, and cured under uniform conditions.

Heterogeneity means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

Homogeneous means of a uniform composition and with similar properties throughout a batch of useable marijuana; means a cannabinoid product, concentrate, or extract has uniform composition and properties throughout each process lot.

Label means a tag or other device attached to or written, stamped, or printed on any container or accompanying any batch in bulk stating all required batch information.

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 Commission under ORS 475B.560.

Protocol for Collecting Samples of Usable Marijuana

Marijuana means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae. This does not include industrial hemp, as defined in ORS 571.300.

Marijuana item means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.

Metrc means the state-administered cannabis tracking system (CTS).

ORELAP means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

Primary Sample means a composite sample composed of sample increments and tested for the required analysis methods.

Producer means a person licensed by the Commission under ORS 475B.070 or a grower registered by the Authority under ORS 475B.810.

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

Relative Percent Difference means comparing two quantities while taking into account the size of what is being compared. If the final result (i.e. Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

$$\%RPD = \frac{|(sample - duplicate)|}{(sample + duplicate)/2} \times 100$$

Relative Standard Deviation means the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If the final result (i.e. Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

Standard Deviation

$$S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{(n - 1)}}$$

Relative Standard Deviation

$$\%RSD = \frac{S}{\bar{x}} \times 100$$

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

\bar{x} = mean of n values.

Representative Sample means a sample obtained according to an incremental sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample means an amount of a marijuana item collected by laboratory personnel from a registrant or

Protocol for Collecting Samples of Usable Marijuana

licensee and provided to a laboratory for testing.

Sample Increment means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee that is combined into a sample for purposes of testing.

Sample Quality Criteria (SQC) means a series of statements that clarify a sampling program's technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed means secured in such a way as to prove authenticity or integrity of the sample.

Sterilization means the removal of all microorganisms and other pathogens from a marijuana item by treating it with approved chemicals or subjecting it to high heat.

TNI Standard: TNI Environmental Laboratory Standard as defined in 333-064-0025.

Usable Marijuana means the dried leaves and flowers of marijuana. Usable Marijuana does not include the seeds, stalks and roots of marijuana or waste material that is a by-product of producing or processing marijuana.

Protocol for Collecting Samples of Usable Marijuana

Appendix 2 Sampling Requirements

I. Random Sampling

As specified in the sampling plan, select random sample increments from different locations within a container or set of containers. Laboratories must develop procedures describing how to:

1. Assign location numbers within containers and among a set of containers;
2. Use a random number generator to determine which locations to sample; and
3. Document where each sample increment was sampled from and the volume collected from each increment.

Assign divisions based on the type of container in the site-specific sampling plan. For container types that are greater than four (4) inches deep, divisions must also include a layer or layers beneath the accessible portion of the batch. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers use existing or arbitrary order of containers to assign numbers to the total of “divisions multiplied by total number of containers” (divisions x # containers = total number of random increments) and record in the sampling report.

The laboratory must have details in its SOP or Sampling Plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

II. Sample size

Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The batch shall be presented for sampling in containers holding no greater than 15.0lbs. Per OAR 333-007-0350, the maximum batch size is 50.0 lbs.

The required sample size for a given batch size based on OAR 333-007-0360 varies depending upon the size of the batch. Example batch sizes and the corresponding sample mass are presented in Table . The laboratory shall calculate the actual minimum required sample size based on the actual batch weight. Taking more sample than the minimum required mass or more increments than the required number of increments is encouraged and will improve representativeness of the sample in relation to the batch.

Table 1 – Examples of required sample size based on size of batch.

| Batch size | | Required sample size | |
|------------|-----------|----------------------|-----------|
| Pounds | Kilograms | Pounds (lbs) | Grams (g) |
| 1.0 | 0.45 | 0.005 | 2.3 |
| 2.0 | 0.90 | 0.010 | 4.5 |
| 3.0 | 1.36 | 0.015 | 6.8 |
| 5.0 | 2.27 | 0.025 | 11.4 |
| 10.0 | 4.54 | 0.050 | 22.7 |

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| Batch size | | Required sample size | |
|------------|-----------|----------------------|-----------|
| Pounds | Kilograms | Pounds (lbs) | Grams (g) |
| 15.0 | 6.80 | 0.075 | 34.0 |
| 20.0 | 9.07 | 0.100 | 45.4 |
| 30.0 | 13.61 | 0.150 | 68.1 |
| 40.0 | 18.14 | 0.200 | 90.7 |
| 50.0 | 22.68 | 0.250 | 113.4 |

III. Sampling a batch

1. When collecting a primary sample from a batch, a minimum of seven (7) sample increments shall be collected. Collect the sample increments according to the sampling plan or the procedure described in the laboratory's SOP. The procedure used shall ensure that any part or portion of the batch has equal odds of being selected in order to provide a representative sample.
2. As the batch increases in size, it is necessary to collect additional sample increments to make up the primary sample (Table 2).

Table 2 – Minimum number of sample increments for the primary sample based on batch size.

| | | | | | |
|----------------------------|-------|-------|--------|--------|--------|
| Size of batch (lbs) | ≤ 4.0 | ≤ 8.0 | ≤ 12.0 | ≤ 16.0 | ≤ 20.0 |
| No. of increments | 7 | 8 | 9 | 10 | 12 |

| | | | | | |
|----------------------------|--------|--------|--------|--------|--------|
| Size of batch (lbs) | ≤ 24.0 | ≤ 28.0 | ≤ 32.0 | ≤ 36.0 | ≤ 40.0 |
| No. of increments | 14 | 16 | 18 | 20 | 24 |

| | | | |
|----------------------------|--------|--------|--------|
| Size of batch (lbs) | ≤ 44.0 | ≤ 48.0 | ≤ 50.0 |
| No. of increments | 28 | 32 | 36 |

Table 3 – Revision history of this SOP.

| Revision | Date | Summary of changes made, and initials of editor |
|----------|-----------|---|
| 4.0 | 7/20/2020 | Major updates and re-formatting, with input from Scott Hoatson and Department of Justice. Updated: OSPHL address; executive board and ORELAP staff names as needed; definitions in order to match OARs and ORS and arranged in alphabetical order. Added: this table (Revision history); subsection VI.3; additional information about subsampling for subcontracted analyses; mention of assigning layers for sampling deep containers; required calibration verification of field balances. Combined: information in section IX with information from former section X (Forwarding samples to the Primary and/or Retesting Laboratory) and deleted |

Protocol for Collecting Samples of Usable Marijuana

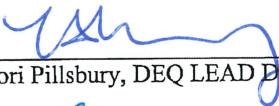
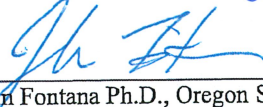
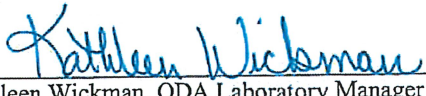


| | | |
|-----|--|---|
| | | <p>former section X and combined former section X.5 with section X.4. Minor updates for consistency and typo fixes. Includes fixing reference to minimum number of sample increments in Table 2. STJ 7/20/2020</p> |
| 4.1 | | <p>Minor formatting updates, removed historical authorship captured in previous versions. Added to Section I that the protocol also applies to post-harvest cured hemp. Clarification in section IV that the samples must be representative and that increased sampled material improves representativeness. Addition to section VII on how to sample for pooled sampling, explanation on what batch material homogeneity means with descriptions of dissimilar materials, and requirement that batch be presented for sampling in containers holding no more than 15.0 lbs. Removed reference to “field” when discussing duplicate samples in section X.3. Updated definitions of “batch” and “field duplicate” and “harvest lot”. Updated Table 1 and Table 2 to reflect increased batch size. STJ 11/17/2021</p> |
| | | |

| | | |
|--|--|---|
|   | <h1>Oregon</h1> <h2>Environmental Laboratory Accreditation Program</h2> |  |
| <p>Department of Agriculture, Laboratory Services Division</p> <p>Department of Environmental Quality, Laboratory and Environmental Assessment Division</p> <p>Oregon Health Authority, Public Health Laboratory</p> | <p>Oregon State Public Health Laboratory 7202 NE Evergreen Parkway, Suite 100 Hillsboro, OR 97124 (503) 693-4122 FAX (503) 693-5602 TTY (503) 731-4031</p> | |

Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, Products, and Industrial Hemp- derived Vapor Items

ORELAP-SOP-002 Rev 4.3

ORELAP Executive Board and Program Approval Signatures:

| | |
|--|--|
|  <hr/> <p>Lori Pillsbury, DEQ LEAD Division Administrator</p> | <p style="text-align: center; font-size: 1.2em;">03/10/2022</p> <hr/> <p style="text-align: center;">Date</p> |
|  <hr/> <p>John Fontana Ph.D., Oregon State Public Health Laboratory Director</p> | <p style="text-align: center; font-size: 1.2em;">03/08/2022</p> <hr/> <p style="text-align: center;">Date</p> |
|  <hr/> <p>Kathleen Wickman, ODA Laboratory Manager</p> | <p style="text-align: center; font-size: 1.2em;">March 8, 2022</p> <hr/> <p style="text-align: center;">Date</p> |
|  <hr/> <p>Travis Bartholomew, ORELAP Program Manager</p> | <p style="text-align: center; font-size: 1.2em;">3/08/2022</p> <hr/> <p style="text-align: center;">Date</p> |
|  <hr/> <p>Sara Krepps, ORELAP QA Officer</p> | <p style="text-align: center; font-size: 1.2em;">03/10/2022</p> <hr/> <p style="text-align: center;">Date</p> |

Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items

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Acknowledgements

Version 1.0 of this document was authored by Cannabis Sub-Committee with input from Technical Experts and approved by the ORELAP Executive Board. See Revision 2.0 for original committee authorship. Revision 3.0 was authored and reviewed by NEFAP/GLP sampling experts. Revision 4.0 was authored by Steven Jetter and reviewed by Travis Bartholomew and the ORELAP Executive Board.

Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items

I. Introduction and Scope

Obtaining a representative sample from a larger batch is one of the key elements of accurate laboratory analysis. Laboratories collect representative samples by consistently using standard sampling methods and equipment, preventing contamination of the sample, and maintaining the sample identity within the batch. The laboratory must consistently use documented standard sampling practices, tools, and methods. These practices, tools, and methods must be appropriate for the matrix. If proper protocols are in place and adhered to for sample collection, the laboratory analysis of the sample should reflect the composition of the batch as a whole at the time the sampling occurred, within recognized tolerances.

Controlling manufacturing error is the responsibility of the processor of the cannabinoid concentrate, extract or product. Sampling error must be controlled by the laboratory in order to obtain a representative sample of the defined batch. This is accomplished by maintaining the sample identity within the defined batch, prevention of contamination of the sample, and consistent use of standard sampling methods and equipment.

This protocol is for use by ORELAP-accredited laboratories performing finished cannabinoid concentrate or extract, finished cannabinoid product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item sampling as defined in OAR 333-064-0025. It focuses on standard and correct sampling practices that should be reflected in a laboratory's own sampling policies and procedures

II. Records and Documentation

1. ORELAP-accredited laboratories shall maintain standard operating procedures (SOP) that accurately reflect current sampling activities.
 - a. The laboratory's SOP shall be readily accessible to all pertinent personnel.
 - b. The laboratory's SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
 - c. The laboratory's SOP should use this protocol as minimum requirements and must include additional detail specific to laboratory procedures. In cases where the published method (this protocol) has been modified or where the referenced method (this protocol) is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described in the laboratory's SOP. Any changes to the laboratory's protocol, including use of a selected option, shall be documented and included on the laboratory's sampling form.
 - d. All documents shall be controlled and retained in accordance with the TNI Environmental Laboratory standard as defined in 333-064-0025.
2. ORELAP-accredited laboratories shall maintain sampling plans.

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- a. The laboratory's sampling plans shall be made available at their location of use.
- b. The laboratory's sampling plans shall be based on appropriate statistical methods and shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch.
- c. Any deviation from or addition to the laboratory's sampling plan must be documented in detail and shall be included in the final report. The standardized or generic sampling plans can be included in the SOP however specialized client requests or products may require additional information.
- d. The laboratory's sampling plans shall document the date and time of sampling.

III. Client Contracts; Client Sampling and Testing Requests

The laboratory must have a sampling contract with a client that includes at least the following:

1. A test order containing the information required by OAR 333-007-0315
2. A site-specific sampling plan or process specific sampling plan that uses statistical design for each project to provide representative sampling.

IV. Planning

Prior to beginning the sampling procedure, the sampler shall survey the site to identify the conditions under which the cannabinoid concentrate, extract, or product is being kept, as this will determine the sampling plan. All sampling must be performed by personnel employed by an ORELAP accredited laboratory and must be in accordance with OAR 333-007-0360 and OAR 333-064-0100.

The testing requirements for cannabinoid concentrates and extracts are in OAR 333-007-0330; those for cannabinoid products are in OAR 333-007-0340; those for industrial hemp-derived vapor items are in OAR 333-007-0342. The requirements for sampling and sample size are in OAR 333-007-0360 and Appendix 2 of this protocol. Per Authority or Commission request or client request, additional analyses may be required and must be considered in the planning process.

To ensure representativeness, the sampling plan must be designed such that any part or individual unit of sale in the batch or process lot has an equal chance of being selected. **The sample size must be sufficient to complete all analyses required, including necessary re-analyses and laboratory QC samples.**

V. Sampling Design and Plans

1. Sampling plans shall address factors to be controlled to ensure the subsequent laboratory test results accurately reflect the composition of the batch or process

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lot. Standardized Sampling Plans can be included in the SOP however specialized client requests or products may require additional information. Any deviation from or addition to the sampling plan must be documented in detail and shall be included in the final report.

2. Sampling plans shall be designed to meet specified sample quality criteria. This includes using a sampling plan that meets a 95% confidence level for representative sampling and limits the fundamental sampling error. The most common way to achieve this is by increasing the number of sample increments from the minimum required to compensate for normal batch heterogeneity.
3. Sampling plans must ensure that adequate sample mass is collected for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.
4. A sampling plan must include at a minimum:
 - a. Shape, size, and number of container(s) holding the batch or process lot from which sample increments will be collected;
 - b. Number of sample increments to be collected;
 - c. Total mass of sample needed to perform testing and approximate mass needed for each increment to ensure adequate mass;
 - d. Location of where sample increments will be taken within each container holding the batch. See Appendix 2 for information on random selection of locations.
5. The laboratory must have details in its SOP or a sampling plan, from appropriate industry reference where possible, on how it will achieve random sampling in an unclear decision unit.

VI. Sampling Equipment and Supplies

1. A laboratory should, at a minimum, have the following equipment and supplies for sampling:
 - a. Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
 - b. Tongs
 - c. Corers
 - d. Teri-wipes or equivalent
 - e. Field balance (capable of 0.01 g measurements)
 - f. Calibrated verification weights appropriate to verify accuracy of field balance
 - g. Cleaning supplies – solvent, bleach, 70% Ethanol
 - h. Gloves (powder-free, nitrile, sterile)
 - i. Mylar bags (for final sample transport and storage) or amber or colorless glass jars (for final sample transport and storage)
2. Cleaning of Field Sampling Equipment

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- a. Field sampling equipment shall be certified clean prior to use by the laboratory.
 - b. Cleaning techniques will vary depending upon the desired analysis.
 - c. In general, sampling equipment must be sterile for microbiology samples and clean for chemistry samples.
 - d. The laboratory shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field.
 - e. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses.
 - f. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.
3. Field balance calibration verification
 - a. The laboratory sampling technician shall verify the calibration of the field balance at the sampling location.
 - b. When multiple sampling events occur on the same day, the balance calibration shall be verified at each sampling location.
 - c. Balance calibration verifications shall be documented.

VII. Procedures for Sampling Concentrates, Extracts, Products, Finished Inhalable Cannabinoid Products, and Industrial Hemp-derived Vapor Items.

1. Locate the cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item batch to be sampled. The sampler **must** have access to the entire batch or process lot.
2. Check for any signs of non-uniformity within the batch or process lot and document the observations.
 - a. Some obvious indicators may be different types or sizes of containers, variations in marks and labels, or mixed batch numbers
 - b. During sampling, the sampler shall look for differences in the marijuana items or industrial hemp-derived vapor items being sampled such as color, visible layers, size of items, or texture.
 - c. By definition, the batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate non-uniformity in the batch or process lot and that any sample drawn may not be representative for testing.
 - d. The sampler shall note these anomalies in the sample collection report.
3. Review the container label information for batch and process lot number and other pertinent information. Do not sample if a unique batch and process lot numbers are not available.

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4. Determine if the sample matrix is a liquid, semi- solid, solid, or freshly-baked edible item either in bulk form or in packaged units. Determine and record the total batch weight or volume and the number of containers or units of sale comprising the batch. If the product is already in final packaging, determine and record the total number of final package units. Do not sample if there are deviations from the manifest or questions about the statistical certainty of the sampling plan.
5. Establish which tests will be performed. Ensure sufficient sample increments are taken to meet sample size requirements determined in the sampling plan and record the number of increments collected. The minimum sample amount is determined by the analytical method(s) being performed but for cannabinoid concentrates, extracts, finished inhalable cannabinoid products, or industrial hemp-derived vapor items can be no less than number of increments in OAR 333-007-0360, Exhibit B, Table 7 (see Appendix 2.) For cannabinoid products, a minimum of one unit of sale each is required for the primary and duplicate. If the product is sold in packages with variable units of sale, the smallest unit of sale is the minimum amount required for sampling.
6. Ensure that appropriate equipment and containers are used for the tests being performed. For residual solvent analysis, use glass containers that can be properly sealed to prevent the loss of solvent gas and minimize the headspace remaining in the sample container. If colorless glass containers are used, the container must also be enclosed in a mylar bag to protect the sample from light.
7. Select the appropriate sampling tool to ensure that it reaches all portions of the batch.
8. Collection instruments must be cleaned appropriately prior to use to prevent cross-contamination of samples. Sampling tools which appear to be dirty or otherwise compromised shall not be used.
 - a. To prevent contamination, sampling tools may be cleaned and sealed at the laboratory prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling.
9. Results from cleaning procedures must be below the reporting limit of the target analyte(s) for the associated analyses.
10. Decontamination waste must be collected and properly disposed of if not used for analysis.
 - a. Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler shall bring enough sets of sampling equipment to use a new set at each facility visited.
 - b. All field equipment shall be returned to the laboratory following sampling and cleaned according to the laboratory's procedures.

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- c. Where aseptic technique is required, samplers shall observe best practices to prevent microbiological contamination of samples. For an example of aseptic technique, see the FDA (2015) Aseptic Sample Guidelines (Investigations Operations Manual Subchapter 4.3.6).
11. When collecting sample increments, approximately equal amounts are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the material which is not being collected. See sections below for more detail on sampling liquid, semi-solid, or solid sample matrices.
12. Once taken, seal and label the sample increments, composite sample, primary sample, duplicate sample, or replicate sample as applicable with the following minimum requirements:
 - a. Laboratory license number
 - b. Unique identifier for sampling event
 - c. Sampling date and name of sampler
 - d. Processor's license or registration number
 - e. Process lot and batch numbers
 - f. Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font
13. Apply a custody seal to the sample container in a manner that prevents the marijuana item or industrial hemp-derived vapor item from being tampered with prior to testing. This seal may contain the laboratory sample identification number.
14. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form as outlined in the standards of accreditation.
15. Forward the sample and sampling report to the laboratory or other designated location using packaging appropriate for secure and timely transport.
16. Record the sampling event in the OLCC seed to sale system under the licensee number or under the registrant number, as applicable.
17. Apply the following steps when taking **Solid** and **Semi-Solid** samples:
 - a. Establish the total batch weight or volume. If the batch is in final product packaging, determine how many units of sale there are and the total batch mass.
 - b. Each sample increment should be taken from a randomly chosen position in the batch, as far as practically possible. A sample increment should be taken from each container if possible. If more containers exist than sample increments required, sample from as many as possible to obtain a representative sample. If permitted by OHA's rules, sample increments may be combined into a composite sample, or a primary sample, duplicate sample, or replicate sample as applicable.

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- c. The samples shall consist of sufficient material to perform the required laboratory methods. The mass of the sample increments can be increased or decreased as long as they are equivalent to each other.
 - d. The minimum number of sample increments is in OAR 333-007-0360, Exhibit B and included in Appendix 2, but more sample increments may be collected if needed for laboratory analysis or at client request based on the statistical design in the site-specific sampling plan. If not using the minimum requirements in rule the laboratory shall use its statistical design training, procedures, and calculators to determine the increments needed for a confidence interval that meets the client request.
 - e. Consideration must be taken for specific concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item types that may be difficult to sample or weigh due to the physical nature of the item. When a sample type, such as kief, moonrocks, or infused pre-rolled joints, requires deviation from laboratory protocols, it is the responsibility of the sampler to document the actions taken.
 - f. Store each sample increment or combine all sample increments if allowed, as specified in the site-specific sampling plan, in a glass container with PTFE-lined screw cap to form the sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the sample increments are combined into a primary sample, complete the same procedure with a second set of equivalent sample increments to form the duplicate sample. Repeat the same procedure with equivalent sample increments to form the replicate sample(s), as specified in Appendix 2.
18. Apply the following steps when taking **Liquid** samples:
- a. If the sample increments are to be taken from a bulk container, ensure proper homogenization of the product prior to taking the sample by mixing the container thoroughly and employing any process for homogenization that the processor would use to disperse the concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item into packaging. Use an appropriate sample device for sampling bulk liquid in a container. Collect the appropriate number of sample increments based on the site-specific sampling plan for the client.
 - b. Store each sample increment or combine all sample increments if allowed, as specified in the site-specific sampling plan, in a glass container with PTFE-lined screw cap to form the sample for testing. If residual solvent testing is required, ensure minimal headspace remains in sample container and lid is secure. If the sample increments are combined into a primary sample, complete the same procedure with a second set of equivalent sample increments to form the duplicate sample. Repeat the same procedure with equivalent sample increments to form the replicate sample(s), as specified in Appendix 2.

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19. Apply the following steps when sampling fresh-baked edible products:
 - a. The batch or process lot must be presented in its final portioned form where the only remaining step to create a finished cannabinoid product is the baking step.
 - b. Select the required number of unbaked units of sale (with the minimum being one unit of sale) to provide sufficient material for all required testing.
 - c. Repeat the process outlined in b) above to select units of sale for the duplicate.
 - d. **While remaining onsite** and in custody of the selected samples, request that the samples are baked.
 - e. Combine the units of sale as applicable to form the primary and duplicate sample. Store each sample in a glass container with PTFE-lined screw cap or a mylar bag as appropriate.

VIII. Sampling Records/Field Data

1. At the time samples are collected the sampler must complete a sampling report form for each batch or process lot sampled. Sample report forms must include at a minimum the following information:
 - a. Name and address of producer including licensee or registrant number
 - b. Item type.
 - c. Total weight of batch or total number of units of sale of batch.
 - d. Unique laboratory batch ID#, Metrc batch ID #, and/or OHA batch ID#.
 - e. Total number of containers sampled.
 - f. Number of sample increments taken from each container.
 - g. Number of sample increments combined into a primary, duplicate, and replicate sample, if applicable
 - h. Number of sample containers collected.
 - i. Weight and location of each sample increment.
 - j. Total weight sampled.
 - k. Sampling plan ID and revision date.
 - l. Sampling Procedure ID and revision date.
 - m. Description of equipment and tools used.
 - n. Address where sampled.
 - o. Date sampled.
 - p. ORELAP Laboratory Identification number.
 - q. Lab License Number.
 - r. Sampler's identification and/or signature.
 - s. Name of responsible party for the batch and transport information.
 - t. Receiving laboratory and types of tests required or requested.
2. A chain of custody form must be used unless the laboratory is sampling for a client that is required to use Metrc. A chain of custody form must include at least the

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following information:

- a. Sampler's name
 - b. Sample Identification (Lab ID number) if assigned before arrival at laboratory
 - c. Sampling Date/Time
 - d. Weight and location of increment samples
 - e. Final weight of composite sample
 - f. Custody transfer signatures
 - g. Custody Transfer Dates/Times
3. If any of the above information requested on the sampling report form is unavailable, indicate "N/A" in the appropriate space with an explanation as to why the information is not available.
 4. All sampling report forms must be signed by the sampler.

IX. Transportation and Handling of Samples

1. Transport the sample increments or composite sample to the laboratory performing the analysis by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the process lot sampled and the chain of custody form continues to document sample integrity. Transportation must be done in compliance with OAR 845-025-5060. Note: Current law does not permit shipping in any form such as USPS or FedEx.
2. Containers for sample transport must be designed to protect the sample from moisture and temperature extremes and to prevent damage, contamination, spillage, or commingling of the sample during transport. The required container for sampling is an amber or colorless glass jar with a PTFE-lined lid or a Mylar bag and should be appropriate for the sample matrix and the tests required. If a colorless glass jar is used, the container must also be placed in a mylar bag to protect the sample from light exposure. A tamper-proof seal is required and must be marked with the sampler's name, date, and sample number.
3. The laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.
4. Submit the sample increments or composite samples to the laboratory in their entirety. In a situation where the composite sample must be split for analysis by two different laboratories, for example when residual solvent analysis is subcontracted to another laboratory, the composite sample(s) shall be homogenized by the laboratory's approved sample homogenization process prior to subsampling. Care must be taken to maintain sample integrity during this process and to prevent the loss of volatile components. This shall be

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reflected on the chain of custody.

5. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report.

X. Quality Assurance and Quality Control

The sampler must be prepared to collect adequate sample mass for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the laboratory, such as duplicates or matrix spikes.

1. Sampler qualifications

- a. Basic qualifications for samplers of marijuana items and industrial hemp-derived vapor items are:

- i. Physically able to perform the duties of a sampler;
- ii. No conflict of interest;
- iii. Employed by an ORELAP accredited laboratory;
- iv. Pass initial and ongoing demonstrations of capability as defined by the laboratory (see below);
- v. Licensed under state law to transport the required quantity of marijuana items or industrial hemp-derived vapor items.

- b. Required education and training for samplers:

- i. Initial training: training shall include principles, procedures, and policies of sampling; Initial Training must be performed by an Instructor that has demonstrated competency in performing the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.
- ii. Field or on-the-job training: 8-hours of training on various sampling techniques.
- iii. Continuing education: periodic refresher training shall be done annually.

2. Demonstration of Capability

- a. Prior to acceptance and institution of any accredited method, a satisfactory initial demonstration of capability (IDOC) is required. The laboratory shall have a documented procedure for performing the IDOC. The IDOC will be repeated: 1) every time there is a change in personnel or method; and 2)

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when the method has not been performed by the laboratory within a 12-month period.

- b. This procedure shall employ one of the following approaches to demonstrating capability:
 - i. Comparison of replicate samples within defined Relative Standard Deviation (%RSD) acceptance criteria.
 - ii. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within defined Relative Percent Difference (%RPD) acceptance criteria.
- c. Thereafter, ongoing continuing demonstration of capability (CDOC) is required annually. The laboratory shall have a documented procedure for performing the CDOC. The laboratory shall retain documentation verifying CDOC for each sampler and make this documentation available to ORELAP upon request.

3. Field QC Samples

- a. Duplicates
 - i. A Duplicate Sample is required for any sampling event that takes place according to this protocol. The duplicate and replicate samples must be collected using the same procedure as the primary sample. Comparison of primary and duplicate results must be evaluated against %RPD requirements as specified in the applicable OAR sections. Comparison of primary, duplicate, and replicate results must be evaluated against %RSD requirements as specified in the applicable OAR sections.
- b. Equipment Blanks
 - i. Equipment rinse blank samples provide a QC check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning.
 - ii. The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank

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samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.

- iii. The equipment blank must pass the required analysis at <LOQ for cleaning validation.
- iv. If the equipment blank is collected at the sampling event, the lab must have detail in the sampling plan or procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

c. Transport Blank

- i. A transport blank is **required** as part of a sampling plan that includes collection for residual solvent analysis.
- ii. A single transport blank must be collected and analyzed per trip regardless of amount of sampling events and each event's samples must be linked to the acceptability of its result.
- iii. The transport blank must pass solvent analysis at <LOQ for the sampling event to be considered valid.

4. Field Audits

- a. The laboratory shall adopt an ongoing system for performing audits of field activities. Field audits must be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the laboratory's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.
- b. When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated laboratory shall take timely corrective action, and shall notify customers in writing if investigations show that test results may have been affected. Laboratory management shall have a policy that specifies the time frame for notifying clients of events that cast doubt on the validity of the results. Follow up audit activities shall verify and document the implementation and effectiveness of any corrective actions taken as a result of the field audit.
- c. Required components of the Field Audit program:
 - i. Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol.
 - ii. Observe the sampler conducting sampling procedures.
 - iii. Record any deficiencies and initiate corrective action.

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XI. References

NDA (2006). *Standard operating procedure on sampling and analysis of agricultural products of plant origin to determine agrochemical residue levels and risk management as part of the export inspection and certification in terms of agricultural products standards act.*

FDA (2015). *Salmonella sampling plan.* Investigations Operations Manual 2015. ASTA. *Clean, Safe Spices.* Guidance from the American Spice Trade Association.

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Sampling and Sample Handling Working Group FDA, AAFCO, AFDO, APHL and Industry, October 2015. *Good Samples: Guidance on Obtaining Defensible Samples.*

National Environmental Field Activities Program (NEFAP); TNI EL Standard (2009), Volume 1 *Management and Technical Requirements for Laboratories Performing Environmental Analysis.*

<http://www.nelac-institute.org/content/CSDP/standards.php>

Oregon Administrative Rules, *Marijuana Labeling, Concentration limits, and Testing,* Chapter 333, Division 7.

Oregon Administrative Rules, *General Requirements Applicable to all Marijuana Licensees,* Chapter 845, Division 25.

Standard Methods 20th Edition (1998); 1020 Quality Assurance

Technical and Regulatory Guidance, Incremental Sampling Methodology, February 2012, Prepared by The Interstate Technology & Regulatory Council, Incremental Sampling Methodology Team

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Appendix 1 – Definitions

**If there are any inconsistencies between the definitions below and the definitions in OAR 333, Divisions 7 or 64, the definitions in the rules take precedence.

Authority means Oregon Health Authority

Batch means a quantity of cannabinoid concentrate, extract, product, finished inhalable cannabinoid product, or industrial hemp-derived vapor item from a process lot.

Chain of Custody Form means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory. (Sample tracking document)

Commission means the Oregon Liquor and Cannabis Commission.

Composite Sample means a sample containing all sample increments taken from a batch.

Container means a sealable, hard- or soft-bodied receptacle in which a marijuana item is placed during sampling, transport, and storage; or a physical division of an extract or concentrate process lot for random sampling.

Decision Unit (DU) or Sampling Unit means the material from which the primary sample(s) is collected and to which the inference(s) is made.

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 being sampled that is prepared and analyzed separately from the primary sample.

Equipment Blank means a sample of analyte-free media, collected after decontamination and prior to sampling, which has been used to rinse the sampling equipment after cleaning to validate cleaning procedure or between sampling batches to demonstrate lack of contamination.

Fundamental Sampling Error (FSE) means a measure of the compositional heterogeneity, which is controlled through the collection of sufficient sample mass (mass is inversely proportional to error).

Heterogeneity means the state or quality of being heterogeneous.

Heterogeneous means non-uniform or consisting of dissimilar parts or components.

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

Industrial hemp-derived vapor item has the meaning given that term in OAR 333-007-0310.

Kief means the resinous trichomes of marijuana that accumulate or fall off when marijuana flowers are sifted through a mesh screen or sieve.

Label means a tag or other device attached to or written, stamped, or printed on any container or accompanying any batch in bulk stating all required batch information.

Laboratory means a laboratory that is accredited under ORS 438.605 to 438.620 to

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sample or conduct tests on marijuana items and licensed by the Oregon Liquor and Cannabis Commission under ORS475B.560.

Marijuana has the meaning given that term in OAR 333-007-0310.

Marijuana Item has the meaning given that term in OAR 333-007-0310.

Metrc means the state-administered cannabis tracking system (CTS).

ORELAP means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.

Primary Sample means a composite sample composed of sample increments and tested for the required analysis methods.

Process Lot has the meaning given that term in OAR 333-007-0310.

Producer has the meaning given that term in OAR 845-025-1015.

Registrant has the meaning given that term in OAR 333-007-0310.

Relative Percent Difference means the comparison of two quantities while taking into account the size of what is being compared. If the final result (i.e., Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

$$\%RPD = \frac{|(sample - duplicate)|}{(sample + duplicate)/2} \times 100$$

Relative Standard Deviation means the standard deviation expressed as a percentage of the mean recovery, i.e., the coefficient of variation multiplied by 100. If the final result (i.e., Total THC) is <LOQ in either sample, the absolute value of the LOQ is used in the equation.

Standard Deviation

$$S = \sqrt{\frac{\sum_{i=1}^n (x_i - \bar{x})^2}{(n - 1)}}$$

Relative Standard Deviation

$$\%RSD = \frac{S}{\bar{x}} \times 100$$

S = standard deviation.

n = total number of values.

x_i = each individual value used to calculate mean.

\bar{x} = mean of n values.

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Replicate sample is a sample in addition to the primary and duplicate samples that consists of the same number of increments and taken in the same manner as the primary and duplicate samples.

Representative Sample means a sample obtained according to an incremental sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample means an amount of marijuana item or industrial hemp-derived vapor item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.

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.

Sample Quality Criteria (SQC) means a series of statements that clarify a sampling program's technical and quality needs to support defensible decisions, including statement of the question to be answered, definition of the decision unit, and the desired confidence in the inference.

Sealed means secured in such a way as to provide authenticity or integrity of the sample.

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.

TNI Standard means the TNI Environmental Laboratory Standard as defined in OAR 333-064-0025.

Transport Blank means a sample of analyte-free media which has been carried to the field and returned to the lab and is used to demonstrate that the process did not add volatile contamination in solvent analysis.

Usable marijuana has the meaning given that term in OAR 333-007-0310.

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Appendix 2 – Sampling Requirements

Random sampling

1. As specified in the sampling plan, sample increments should be randomly selected from different locations within a container or set of containers. Laboratories must develop procedures describing how to:
 - a. Assign location numbers within containers and among a set of containers;
 - b. Use a random number generator to determine which location to sample; and
 - c. Document where each sample increment was sampled and the volume or mass collected from each increment.
2. Assign divisions based on the type of container in the site-specific sampling plan. For container types that are greater than four (4) inches deep, divisions must also include a layer or layers beneath the upper portion of the container. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers, use existing or arbitrary order of containers to assign numbers to the total of “divisions multiplied by total number of containers” (divisions x # containers = total number of random sample increments) and record in the sampling report.
3. The laboratory must have details in their SOP or Sampling Plan, from appropriate industry reference where possible, on how they will achieve random sampling in unclear decision unit.

Sample size and increments

1. Per OAR 333-007-0360, the sample size must be sufficient to complete all analyses required.
2. The required sample increments for a given batch or process lot of cannabinoid concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item varies depending upon the size of the batch. Taking more sample increments than required is encouraged and will improve representativeness of the sample in relation to the batch. (See Table 1)
3. Sample increments are combined into a primary sample. An equivalent number of increments sampled using the same procedure are combined into the duplicate sample. An equivalent number of increments sampled using the same procedure are combined into the replicate sample. The combined samples are put in separate containers and are prepared and analyzed separately.

Table 1 – Sample increment and replicate requirements based on size of concentrate, extract, finished inhalable cannabinoid product, or industrial hemp-derived vapor item batch. (From 333-007-0360, Exhibit

Protocol for Collecting Samples of Cannabinoid Concentrates, Extracts, Products, and Industrial Hemp-derived Vapor Items

B, Table 7)

| Batch Weight | | Sample Increments Required | | Number of Replicates |
|---------------|--------------|----------------------------|-----------|----------------------|
| Pounds | Kilograms | Primary | Duplicate | |
| 0-3.31 | 0-1.50 | 1 | 1 | |
| 3.32-6.61 | 1.51-3.00 | 3 | 3 | |
| 6.62-13.23 | 3.01-6.00 | 5 | 5 | |
| 13.24-26.46 | 6.01-12.00 | 7 | 7 | |
| 26.47-55.12 | 12.01-25.00 | 7 | 7 | 1 |
| 55.13-110.23 | 25.01-50.00 | 7 | 7 | 2 |
| 110.24-220.46 | 50.01-100.00 | 7 | 7 | 3 |

For batches exceeding 100.00kg: apply the following formula to determine number of replicate samples: $X = (\text{batch weight in kg} / 50) * 1.5$ where X is the number of replicates, rounded to the nearest whole number.

4. Finished cannabinoid products require a primary and duplicate sample. A minimum of one unit of sale each shall be selected for the primary and duplicate sample. The primary and duplicate samples are placed in separate containers and are prepared and analyzed separately.

Table 2 – Revision history of this SOP.

| Revision | Date | Summary of changes made, and initials of editor |
|----------|------------|---|
| 4.0 | 07/22/2020 | Major updates and re-formatting based on input from Scott Hoatson (former ORELAP QA Officer) and Department of Justice. Updated: OSPHL address; executive board and ORELAP staff names/titles as needed; definitions in order to match OARs and ORS. Added: Tables 1, 2, 3, and 4 (this table); information regarding required calibration verification of field balances; mention of assigning divisions to layers in deep containers; section II; section III; condensed general document requirements in new section II, and specific sampling forms under section VIII; condensed Planning section, now section IV; reference to FDA aseptic sampling document; definition of Metrc. Combined: sampling design and plans and representative sampling sections; forwarding samples section with transportation section Minor updates and typo fixes for consistency with Useable Marijuana sampling SOP. STJ 07/22/2020 |
| 4.1 | 10/19/2020 | Minor updates to include definition of kief and inclusion of consideration of tricky/unusual sample matrices in section 17 e. STJ 10/19/2020 |
| 4.2 | 9/27/2021 | Minor formatting updates, removed historical authorship captured in previous versions, added reference to industrial hemp-derived vapor items. Updated definitions in Appendix 1 to align with those in applicable administrative rules. Updated Tables 5 and 7 to show more accurate mass ranges. STJ 9/27/2021 |
| 4.3 | 11/18/2021 | Added information about finished inhalable cannabinoid products. Removed reference to control studies. Updated container requirements |

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| | | |
|--|--|---|
| | | that amber glass is not required so long as the clear glass containers are stored in mylar bags. Added instruction on sampling fresh-baked edible products. Added information about sampling of finished cannabinoid products. Added definition of 'replicate sample' and removed 'field' from reference to duplicate samples for consistency with OARs. Updated table on sample increments (formerly Table 7) to be copy of new sampling format from 333-007-0360 Exhibit B. STJ12/15/2021 |
|--|--|---|

OAR 333-064-0100, Exhibit C

Table 1 – Accuracy requirements for laboratory control samples (LCS).

| Test | Analyte | LCS Limits (%R) |
|--|---------------------|------------------------|
| Pesticides in accordance with OAR 333-007-0400 | Abamectin | 50 - 150 |
| | Acephate | 60 - 120 |
| | Acequinocyl | 40 - 160 |
| | Acetamiprid | 60 - 120 |
| | Aldicarb | 60 - 120 |
| | Azoxystrobin | 60 - 120 |
| | Bifenazate | 60 - 120 |
| | Bifenthrin | 50 - 150 |
| | Boscalid | 60 - 120 |
| | Carbaryl | 60 - 120 |
| | Carbofuran | 60 - 120 |
| | Chlorantraniliprole | 60 - 120 |
| | Chlorfenapyr | 60 - 120 |
| | Chlorpyrifos | 60 - 120 |
| | Clofentezine | 60 - 120 |
| | Cyfluthrin | 50 - 150 |
| | Cypermethrin | 50 - 150 |
| | Daminozide | 60 - 120 |
| | DDVP (Dichlorvos) | 60 - 120 |
| | Diazinon | 60 - 120 |
| | Dimethoate | 60 - 120 |
| | Ethoprophos | 60 - 120 |
| | Etofenprox | 50 - 150 |
| | Etoxazole | 60 - 120 |
| | Fenoxycarb | 60 - 120 |
| | Fenpyroximate | 60 - 120 |
| | Fipronil | 60 - 120 |
| | Flonicamid | 60 - 120 |
| | Fludioxonil | 50 - 150 |
| | Hexythiazox | 60 - 120 |
| | Imazalil | 60 - 120 |
| | Imidacloprid | 60 - 120 |
| | Kresoxim-methyl | 60 - 120 |
| Malathion | 60 - 120 | |
| Metalaxyl | 60 - 120 | |
| Methiocarb | 60 - 120 | |
| Methomyl | 60 - 120 | |

| Test | Analyte | LCS Limits (%R) |
|--|-------------------------------|------------------------|
| Pesticides in accordance with OAR 333-007-0400 continued | Methyl parathion | 50 - 150 |
| | MGK-264 | 50 - 150 |
| | Myclobutanil | 60 - 120 |
| | Naled | 50 - 150 |
| | Oxamyl | 60 - 120 |
| | Paclobutrazol | 60 - 120 |
| | Permethrins | 50 - 150 |
| | Phosmet | 50 - 150 |
| | Piperonyl butoxide | 60 - 120 |
| | Prallethrin | 60 - 120 |
| | Propiconazole | 60 - 120 |
| | Propoxur | 60 - 120 |
| | Pyrethrins | 60 - 120 |
| | Pyridaben | 50 - 150 |
| | Spinosad | 50 - 150 |
| | Spiromesifen | 60 - 120 |
| | Spirotetramat | 60 - 120 |
| | Spiroxamine | 60 - 120 |
| | Tebuconazole | 60 - 120 |
| Thiacloprid | 60 - 120 | |
| Thiamethoxam | 60 - 120 | |
| Trifloxystrobin | 60 - 120 | |
| | | |
| Residual Solvents in accordance with OAR 333-007-0410 | 1,4-Dioxane | 60 - 120 |
| | 2-Butanol | 60 - 120 |
| | 2-Ethoxyethanol | 60 - 120 |
| | 2-Propanol (IPA) | 60 - 120 |
| | Acetone | 60 - 120 |
| | Acetonitrile | 60 - 120 |
| | Benzene | 60 - 120 |
| | Butanes | 60 - 120 |
| | Cumene (aka isopropylbenzene) | 60 - 120 |
| | Cyclohexane | 60 - 120 |
| | Dichloromethane | 60 - 120 |
| | Ethyl acetate | 60 - 120 |
| | Ethyl benzene | 60 - 120 |
| | Ethyl ether | 60 - 120 |
| | Ethylene glycol | 60 - 120 |
| | Ethylene Oxide | 60 - 120 |

| Test | Analyte | LCS Limits (%R) |
|--|-------------------|------------------------|
| Residual Solvents in accordance with OAR 333-007-0410 continued | Heptane | 60 - 120 |
| | Hexanes | 60 - 120 |
| | Isopropyl acetate | 60 - 120 |
| | Methanol | 60 - 120 |
| | Pentanes | 60 - 120 |
| | Propane | 60 - 120 |
| | Tetrahydrofuran | 60 - 120 |
| | Toluene | 60 - 120 |
| | Xylenes | 60 - 120 |
| Adult use cannabinoids and CBD in accordance with OAR 333-007-0430 | delta-9 THC | 90 - 110 |
| | delta-9 THCA | 90 - 110 |
| | delta-8 THC | 90 - 110 |
| | CBD | 90 - 110 |
| | CBDA | 90 - 110 |
| Heavy Metals in accordance with OAR 333-007-0415 | Arsenic | 80-115 |
| | Cadmium | 80-115 |
| | Lead | 80-115 |
| | Mercury | 80-115 |
| Mycotoxins in accordance with OAR 333-007-0425 | Aflatoxin B1 | 60-120 |
| | Aflatoxin B2 | 60-120 |
| | Aflatoxin G1 | 60-120 |
| | Aflatoxin G2 | 60-120 |
| | Ochratoxin A | 60-120 |

AMEND: 333-064-0110

NOTICE FILED DATE: 01/09/2022

RULE SUMMARY: Amend OAR 333-064-0110

Adding reference to reporting requirements for heavy metals, mycotoxin, and microbiological contaminants testing to bring reporting of the new testing requirements in line with the existing testing requirements.

Describing the process laboratories can use when reporting essentially pure cannabinoid concentrates/extracts and the calculated result exceeds 100% THC or CBD.

Clarifying reporting requirements when subcontracted analyses are used for compliance testing.

Statutes are being updated due to renumbering of chapter number.

CHANGES TO RULE:

333-064-0110

Reporting Cannabis Test Results ¶

(1) For purposes of this rule the definitions in OAR 333-007-0310 apply unless the context indicates otherwise.¶

(2) A test report must clearly identify for the licensee or registrant:¶

(a) Whether a sample has exceeded an action limit for an analyte in OAR 333-007-0400, 333-007-0410, 333-007-0415, and 333-007-0410, 25 Exhibit A, Tables 3, 4, 8, or 49, or has otherwise failed a test as described in OAR 333-007-0300 to 333-007-0500.¶

(b) A "detected" pesticide result as required in section (6) of this rule.¶

(c) The batch unique identification number required under OAR 333-007-0350 and the test batch number associated with the samples tested, as required by OAR 333-064-0100.¶

(d) Identification of the test as a compliance test or a quality control or research and development test. If the test is not for compliance, the report shall indicate clearly on the first page the testing was for quality control or research and development. ¶

(e) If applicable, a statement that the test was done on a sample from a remediated marijuana item or industrial hemp-derived vapor item.¶

(3) Within 24 hours of completion of the laboratory's data review and approval procedures a laboratory must report all failed tests for testing required under OAR 333-007-0300 to 333-007-0500 except for failed water activity, whether or not the lab is reanalyzing the sample under OAR 333-007-0450:¶

(a) Into CTS if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8; and¶

(b) To the Authority electronically at www.healthoregon.org/ommp if performing testing for a registrant, along with a copy of the test order information required in OAR 333-007-0315, regardless of whether the laboratory is also reporting into CTS on behalf of a registrant that is subject to CTS tracking under OAR chapter 333, division 8.¶

(c) If the laboratory discovers that an error has occurred after reporting, an amended report shall be generated and communicated to the licensee or registrant, the Commission for licensees, and the Authority for registrants. The laboratory shall ensure that results entered into the CTS are accurate and updated if necessary to reflect the amended report. The laboratory shall ensure that the amended report, communication, and updates to CTS as described in this rule are completed within 48 hours of learning of the error.¶

(4) The laboratory must report all test results required under OAR 333-007-0300 to 333-007-0500 that have not been reported under section (3) of this rule into the Commission's seed to sale tracking system if performing testing for a licensee or a registrant who is subject to CTS tracking under OAR chapter 333, division 8.¶

(5) A laboratory must determine and include on each test report its limit of quantification (LOQ) and action level for each analyte listed in OAR 333-007-0400 Table 3, 333-007-0410 Table 4, 333-007-0415 Table 8, and 333-007-0410, 25 Table 49.¶

(6) When reporting pesticide testing results the laboratory must include in the report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 5:1 and meets identification criteria with a result of "detected." This additional reporting is not required if the laboratory's LOQ is less than or equal to one half of the action level in Table 3.¶

(7) A laboratory must include in a test report the results of all associated batch quality control samples, with the date of analysis of the quality control samples and the acceptance limits used to determine acceptability.¶

(a) Batch quality control samples are the method blank and laboratory control sample.¶

(b) The report must clearly show the association to the client samples in the report by listing the batch identification numbers.¶

(8) A laboratory that is reporting failed test results to the Commission or the Authority in accordance with section (3) of this rule must report the failed test at the same time or before reporting to the licensee or registrant.¶

(9) If requested by the Authority, a laboratory must report sampling and testing information to the Authority, in a manner prescribed by the Authority.¶

(10) If a laboratory's calculated adult use cannabinoid or CBD result exceeds 100 percent and the difference between the result and 100 percent is within the laboratory's calculated analytical uncertainty, the laboratory may report the result as 100 percent with a qualifying statement on the certificate of analysis or the laboratory may report the calculated result with or without a qualifying statement. If the difference between the result and 100 percent is outside the calculated analytical uncertainty, the calculated result shall be reported without correction.¶

(a) The qualifying statement on the certificate of analysis shall clearly state the calculated value and the laboratory's analytical uncertainty.¶

(b) For the purposes of calculating RPD or RSD, a laboratory shall use the calculated result and not the adjusted result described in this rule.¶

(11) A primary accredited laboratory may subcontract with accredited laboratories to perform required compliance testing. The primary accredited laboratory shall issue the final report.¶

(a) Accredited, subcontracted laboratories shall validate the results of any sample analysis and report that analysis to their client laboratory within 24 hours of completing the analytical run if the analysis results in a failed compliance test.¶

(b) The accredited laboratory that issues the final test report shall validate and report the results of any failed sample analysis as described in section (3) of this rule.

Statutory/Other Authority: ORS 475BC.55544, ORS 475BC.5650

Statutes/Other Implemented: ORS 475BC.55544, ORS 475BC.5650