

OREGON ADMINISTRATIVE RULES
OREGON HEALTH AUTHORITY, PUBLIC HEALTH DIVISION
CHAPTER 333

DIVISION 7

MARIJUANA LABELING, CONCENTRATION LIMITS, AND TESTING

Labeling

333-007-0010

Purpose, Scope and Effective Date

(1) The purpose of OAR 333-007-0010 through 333-007-0100 is to set the minimum standards for the labeling of marijuana items that are sold to a consumer. These minimum standards are applicable to:

- (a) A Commission licensee as that is defined in OAR 845-025-1015; and
- (b) A person registered with the Authority under ORS 475.300 to 475.346 who is not exempt from the labeling requirements as described in section (2) of this rule.

(2) The labeling requirements in these rules do not apply to:

- (a) A grower if the grower is transferring usable marijuana or an immature marijuana plant to:
 - (A) A patient who designated the grower to grow marijuana for the patient; or
 - (B) A designated primary caregiver of the patient who designated the grower to grow marijuana for the patient; or
- (b) A designated primary caregiver of a patient if the caregiver is transferring a marijuana item to a patient of the designated primary caregiver.

(3) Nothing in these rules prohibits the Commission or the Authority from:

- (a) Imposing additional labeling requirements in their respective rules governing licensees and registrants, including but not limited to labeling requirements that apply to marijuana packaged for sale to other licensees or labeling requirements for testing samples, as long as those additional labeling requirements are not inconsistent with these rules; or
- (b) Requiring licensees or registrants to provide informational material to a consumer at the point of sale.

(4) On and after April 1, 2016:

- (a) A marijuana item received or transferred by a dispensary must meet the labeling requirements in these rules; and
- (b) A dispensary may not transfer a marijuana item that does not meet the labeling requirements in these rules.

(5) By April 1, 2016, a dispensary must have either transferred marijuana items that do not meet the labeling requirements in these rules to a patient or caregiver or must have returned any marijuana item that does not meet labeling requirements in these rules to the individual who transferred the item to the dispensary, and must document who the item was returned to, what was returned and the date of the return.

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0020

Definitions

For the purposes of OAR 333-007-0100 through 333-007-0100, unless otherwise specified:

- (1) "Activation time" means the amount of time it is likely to take for an individual to begin to feel the effects of ingesting or inhaling a marijuana item.
- (2) "Authority" means the Oregon Health Authority.
- (3) "Cannabinoid concentrate or extract" means a substance obtained by separating cannabinoids from marijuana by a mechanical, chemical or other process.
- (4)(a) "Cannabinoid edible" means:
 - (A) Food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated; or
 - (B) For purposes of labeling, includes any cannabinoid concentrate, extract or cannabinoid product that is intended for human consumption or marketed in a manner that implies the item is for human consumption.
- (b) "Cannabinoid edible" does not include a cannabinoid tincture.
- (5)(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.
- (b) "Cannabinoid product" does not include:
 - (A) Usable marijuana by itself;
 - (B) A cannabinoid concentrate or extract by itself; or
 - (C) Industrial hemp, as defined in ORS 571.300.
- (6) "Cannabinoid tincture" means a solution of alcohol, cannabinoid concentrate or extract, and perhaps other ingredients intended for human consumption or ingestion, and that is exempt from the Liquor Control Act under ORS 471.035.
- (7) "Cannabinoid topical" means a cannabinoid product intended to be applied to skin or hair.
- (8) "CBD" means cannabidiol.
- (9) "Commission" means the Oregon Liquor Control Commission.
- (10) "Consumer":
 - (a) Has the meaning given that term in section 1, chapter 614, Oregon Laws 2015; or
 - (b) Means a patient or designated primary caregiver receiving a transfer from a medical marijuana dispensary.
- (11) "Container" means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed.
- (12) "Date of harvest" means the date the mature marijuana plants in a harvest lot were removed from the soil or other growing media. If the harvest occurred on more than one day, the "date of harvest" is the day the last mature marijuana plant in the harvest lot was removed from the soil or other growing media.
- (13) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis.
- (14)(a) "Designated primary caregiver" means an individual:
 - (A) Who is 18 years of age or older;
 - (B) Who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition; and
 - (C) Who is designated as the person responsible for managing the well-being of a person who has been diagnosed with a debilitating medical condition on that person's application for a registry identification card or in other written notification submitted to the Authority.

- (b) "Designated primary caregiver" does not include a person's attending physician.
- (15) "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, or chewing gum.
- (16) "Grower" has the same meaning as "person responsible for a marijuana grow site."
- (17) "Harvest lot" means marijuana that is uniform in strain, cultivated utilizing the same growing practices and harvested at the same time.
- (18) "Human consumption" 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.
- (19)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.
- (b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.
- (20) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.
- (21) "Medical marijuana dispensary" means a facility registered under ORS 475.314.
- (22) "Net weight" means the gross weight minus the tare weight of the packaging.
- (23) "Patient" has the same meaning as "registry identification cardholder".
- (24) "Person responsible for a marijuana grow site" 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 and has the same meaning as "grower".
- (25) "Place of address" means the name, mailing address, city, state and zip code of the processor who made the cannabinoid edible.
- (26) "Principle display panel" means the portion of the package that is most likely to be seen by the consumer at the point of purchase, must include the product identity, net weight and universal symbol, and if only a single panel is used for labeling, the principle display panel must also include place of address and ingredient list.
- (27) "Processor" means a person:
- (a) Licensed by the Commission to process marijuana under section 14, chapter 614, Oregon Laws 2015; or
- (b) Registered with the Authority under ORS 475.300 to 475.346 as a processor and who is not exempt from labeling requirements under section 106, chapter 614, Oregon Laws 2015.
- (28) "Process lot" means:
- (a) Any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and batches from the same or different harvest lots; or
- (b) Any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.
- (29) "Producer" means a person:
- (a) Licensed by the Commission to produce marijuana under section 12, chapter 614, Oregon Laws 2015; and
- (b) Registered with the Authority under ORS 475.300 to 475.346 as a grower and who is not exempt from labeling requirements under section 106, chapter 614, Oregon Laws 2015.
- (30) "Product identity" means a truthful or common name of the product that is contained in the package.
- (31) "Registrant" means a person registered with the Authority under ORS 475.304, 475.314, or section 85, chapter 614, Oregon Laws 2015.

(32) "Registry identification cardholder" means a person to whom a registration card has been issued under ORS 475.309.

(33) "Test batch" means:

(a) A group of test samples that are collectively submitted to a laboratory for testing purposes.

(b) "Test batch" does not mean a combination of marijuana flowers, marijuana leaves, cannabinoid products, or cannabinoid concentrate or extract.

(34) "Test sample" means anything collected by an individual authorized by the Authority to collect a sample from a licensee or registrant that is provided to a laboratory for testing, including but not limited to marijuana items, soil, growing medium, water, solvent or swab of a counter or equipment.

(35) "THC" means tetrahydrocannabinol and has the same meaning as delta-9 THC.

(36) "These rules" means OAR 333-007-0010 through 333-007-0100.

(37) "Universal symbol" means the image, established by the Authority and made available to licensees and registrants, indicating the marijuana item contains marijuana.

(38)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" 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.

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0030

Marijuana Plant Labeling Requirements

Prior to a marijuana plant being sold or transferred to a consumer a tag or label must be affixed to the plant or plant container that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Name of the strain; and

(3) Universal symbol.

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0040

Marijuana Seed Labeling Requirements

Prior to marijuana seeds being sold or transferred to a consumer the container holding the seeds must have a label that has the following information:

(1) Producer's business or trade name and licensee or registrant number;

(2) Name of the strain of seed;

(3) Date of harvest;

(4) Number of seeds or net weight in ounces or grams as appropriate; and

(5) Universal symbol.

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0050

Usable Marijuana Labeling Requirements

Prior to usable marijuana being sold or transferred to a consumer the container holding the usable marijuana must have a label that has the following information:

- (1) Producer's business or trade name and licensee or registrant number;
 - (2) Harvest lot number;
 - (3) Date of harvest;
 - (4) Name of strain;
 - (5) Net weight in grams;
 - (6) Concentration of THC and CBD;
 - (7) Activation time expressed in words or through a pictogram;
 - (8) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (9) Universal symbol;
 - (10) For usable marijuana sold by a licensee, warnings that state:
 - (a) "For use by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (11) For usable marijuana transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
- Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0060

Cannabinoid Topical Labeling Requirements

Prior to a cannabinoid topical product being sold or transferred to a consumer the container holding the cannabinoid product must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
 - (2) Process lot number;
 - (3) Date the product was made;
 - (4) Net weight or volume using the metric scale;
 - (5) Amount suggested for use by the consumer at any one time;
 - (6) Concentration or amount by weight or volume of THC and CBD in the container;
 - (7) List of ingredients in descending order or predominance by weight or volume used to process the cannabinoid topical;
 - (8) Activation time, expressed in words or through a pictogram;
 - (9) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (10) Universal symbol;
 - (11) For cannabinoid topicals sold by a licensee, warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "DO NOT EAT" in bold, capital letters; and
 - (12) For cannabinoid topicals transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "DO NOT EAT" in bold, capital letters.
- Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0070

Cannabinoid Edible Labeling Requirements

Prior to a cannabinoid edible being sold or transferred to a consumer the container holding the edible must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Place of address;
- (3) Product identity (common or usual name);
- (4) Process lot number;
- (5) Date the edible was made;
- (6) Net weight or volume in both US lb/oz. (Avoirdupois oz.) and metric scale;
- (7) Serving size and number of servings per container;
- (8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
- (9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid edible;
- (10) List of potential allergens:
 - (a) Using a "contains" statement to summarize the allergen information at the end of or immediately adjacent to the ingredient list; or
 - (b) Placing the term for the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen;
- (11) The amount, in grams, of sodium, sugar, carbohydrates and total fat;
- (12) If the edible is perishable, a statement that the edible must be refrigerated or kept frozen;
- (13) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (14) Activation time, expressed in words or through a pictogram;
- (15) Universal symbol; and
- (16) For cannabinoid edibles sold by a licensee, warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."; and
- (17) For cannabinoid edibles transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "BE CAUTIOUS" in bold, capital letters, followed by "Cannabinoid edibles can take up to 2 hours or more to take effect."

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0080

Labeling Requirements for Cannabinoid Concentrates and Extracts

Prior to a cannabinoid concentrate or extract being sold or transferred to a consumer the container holding the concentrate or extract must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Process lot number;
- (3) Date the concentrate or extract was made;

- (4) Net weight or volume using the metric scale;
 - (5) If applicable, serving size and number of servings per container or amount suggested for use by the consumer at any one time;
 - (6) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;
 - (7) Activation time, expressed in words or through a pictogram;
 - (8) Name of the lab that performed any test, any associated test batch number and any test analysis date;
 - (9) Universal symbol;
 - (10) For cannabinoid concentrates and extracts sold by a licensee, warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "DO NOT EAT" in bold, capital letters; and
 - (11) For cannabinoid concentrates and extracts transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
 - (c) "DO NOT EAT" in bold, capital letters.
- Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0083

Cannabinoid Tincture Labeling Requirements

Prior to a cannabinoid tincture being sold or transferred to a consumer the container holding the tincture must have a label that has the following information:

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Place of address;
- (3) Product identity (common or usual name);
- (4) Process lot number;
- (5) Date the tincture was made;
- (6) Net weight or volume in both US lb/oz. (Avoirdupois oz.) and metric scale;
- (7) Serving size and number of servings per container;
- (8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
- (9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid tincture;
- (10) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (11) Universal symbol;
- (12) Activation time expressed in words or through a pictogram;
- (13) For cannabinoid tinctures sold by a licensee, warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana"; and
- (14) For cannabinoid tinctures transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0085

Cannabinoid Products Other than Cannabinoid Edibles, Topicals, or Tinctures

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

- (1) Processor's business or trade name and licensee or registrant number;
- (2) Place of address;
- (3) Product identity (common or usual name);
- (4) Process lot number;
- (5) Date the product was made;
- (6) Net weight or volume in both US lb/oz. (Avoirdupois oz.) and metric scale;
- (7) Serving size and number of servings per container;
- (8) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
- (9) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product;
- (10) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (11) Universal symbol;
- (12) Activation time expressed in words or through a pictogram;
- (13) For cannabinoid products sold by a licensee, warnings that state:
 - (a) "For use only by adults 21 and older. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."; and
- (14) For cannabinoid products transferred by a dispensary, warnings that state:
 - (a) "For use by OMMP patients only. Keep out of reach of children."
 - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0090

General Label Requirements; Prohibitions; Exceptions

- (1) Every container that contains a marijuana item for sale or transfer to a consumer must have a principle display panel, as that term is defined in OAR 333-007-0020.
- (2) A label required by these rules must:
 - (a) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2015), Uniform Packaging and Labeling Regulation, incorporated by reference.
 - (b) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;
 - (c) Be in English, though it can be in other languages; and
 - (d) Be unobstructed and conspicuous.
- (3) A marijuana item may have one or more labels affixed to the container.
- (4) The universal symbol:
 - (a) Must be at least 0.48 inches wide by 0.35 inches high.
 - (b) May only be used by licensees or registrants.
 - (c) May be downloaded at www.healthoregon.org/marijuana on or after January 1, 2016.

- (5) The Commission or the Authority may permit a licensee or registrant to use a pictogram instead of a warning on a label.
- (6) A label may not contain any untruthful or misleading statements, including but not limited to a health claim that is not supported by the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), and for which there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims.
- (7) A marijuana item that falls within more than one category, for example a product that is both a cannabinoid concentrate and cannabinoid edible, must comply with the labeling requirements that apply to both categories, with the exception of the "DO NOT EAT" warning if the product falls within the cannabinoid edible category for labeling purposes or the "BE CAUTIOUS" warning if the effects of the product are customarily felt immediately.
- (8) The THC and CBD amount required to be on a label must be the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100.
- (9) If a marijuana item has more than one test batch number, laboratory, or test analysis date associated with the marijuana item that is being sold or transferred, each test batch number, laboratory and test analysis date must be included on a label.
- (10) If a marijuana item is placed in a package that is being re-used, the old label or labels must be removed and it must have a new label or labels.

Stat. Auth.: Section 101, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 101, chapter 614, Oregon Laws 2015

333-007-0100

Pre-Approval of Labels

- (1) A registrant must submit labels for pre-approval in accordance with OAR 845-025-7060 and must keep all records related to the pre-approval process and provide those records at the request of the Authority.
- (2) A registrant may not transfer a marijuana item unless the label has been pre-approved in accordance with OAR 845-025-7060.

Stat. Auth.: Section 102, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 102, chapter 614, Oregon Laws 2015

Concentration and Serving Size Limits

333-007-0200

Definitions, Purpose, Scope, Effective Date

- (1) In accordance with section 105, chapter 614, Oregon Laws 2015, the Authority must establish, for marijuana items sold or transferred to a consumer through a Commission licensed marijuana retailer or medical marijuana dispensary:
 - (a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and
 - (b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.
- (2) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid

product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.

(3) The amounts of THC listed on a label are based on an average from samples taken from a harvest or process lot and may not represent the exact amount of THC in a marijuana item purchased by a consumer.

(4) On and after April 1, 2016:

(a) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220; and

(b) A dispensary may not receive or transfer a marijuana item that does not meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220.

(5) By April 1, 2016, a dispensary must have either transferred marijuana items that do not meet the concentration and serving size limits in OAR 333-007-0210 or 333-007-0220 to a patient or caregiver or must have returned any marijuana item that does not meet the requirements to the individual who transferred the item to the dispensary, and must document who the item was returned to, what was returned and the date of the return.

(6) A marijuana item that falls within the category of a cannabinoid edible, even if that item also falls within another category, for example the category of a cannabinoid concentrate, must meet the concentration and serving size limits applicable to a cannabinoid edible.

(7) For purposes of OAR 333-007-0200 through 333-007-0220:

(a) The definitions in OAR 333-007-0020 apply, unless otherwise specified:

(b) "Scorable" means to physically demark a cannabinoid edible that is in solid form at room temperature in a way that enables a reasonable person to:

(A) Intuitively determine how much of the product constitutes a single serving; and

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

Stat. Auth.: Section 105, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 105, chapter 614, Oregon Laws 2015

333-007-0210

Retail Marijuana Item Concentration and Serving Size Limits

(1) The maximum concentration or amount of THC permitted in a container, the size of a marijuana item, and the number of servings permitted in a container, as applicable, for marijuana items bought and sold by a Commission licensed marijuana retailer is listed in Table 1, subject to sections (2) and (3) of this rule. [Table not included. See ED. NOTE.]

(2) Non-Scorable Cannabinoid Edibles. A non-scorable cannabinoid edible that contains two servings in a container must be:

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

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

(3) A non-scorable cannabinoid edible that does not meet the requirements in section (2) of this rule must be packaged as a single serving with no more than 5 mg of THC.

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: Section 105, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 105, chapter 614, Oregon Laws 2015

333-007-0220

Medical Marijuana Item Concentration Limits

(1) The maximum concentration or amount of THC permitted in a container, and the number of servings permitted in a container, as applicable, for marijuana items transferred to and from a medical marijuana dispensary is listed in Table 2, subject to sections (2) and (3) of this rule.

[Table not included. See ED. NOTE.]

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

(b) A container of cannabinoid edibles may not contain more than 100 mg of THC regardless of the number of servings.

(2) Cannabinoid edibles that are capable of being scored as described in the definition of "scorable" in OAR 333-007-0200, must be scored.

(3) Non-Scorable cannabinoid edibles that contain more than one serving per container must be:

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

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

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: Section 105, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 105, chapter 614, Oregon Laws 2015

Marijuana Testing

333-007-0300

Purpose and Effective Date

(1) The purpose of these rules is to establish the minimum testing standards for marijuana items, prior to marijuana items being sold or transferred to a consumer, applicable to:

(a) A Commission licensee as defined in OAR 845-025-1015; and

(b) A person registered with the Authority under ORS 475.300 to 475.346 who is not exempt from the testing requirements.

(2) The testing requirements do not apply to:

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

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

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

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

(3) These rules are intended to specify the specific testing that must be done for the various types of marijuana items, rather than to specify which type of licensee or registrant must ensure that the testing is done in accordance with these rules. It is up to Commission licensees and registrants to determine as a business practice who is responsible for arranging for samples to be taken and for those samples to be tested in accordance with these rules.

(4) All marijuana items must be tested in accordance with these rules on and after June 1, 2016.

(5) A dispensary may not accept the transfer of a marijuana item on or after June 1, 2016, that was not tested in accordance with these rules. A dispensary may transfer a marijuana item to a patient or caregiver that was transferred to the dispensary before June 1, 2016, and that was not

tested in accordance with these rules but that item must contain the following label placed on the package where it can easily be seen by the patient or caregiver, in 12 point font, and in bold, capital letters that reads "DOES NOT MEET NEW TESTING REQUIREMENTS".

(6) Nothing in these rules prevents a registrant or licensee from having marijuana items tested in accordance with these rules by an accredited and licensed laboratory prior to June 1, 2016.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0310

Definitions

For purposes of OAR 333-007-0300 through 333-007-0490:

(1) "Batch" means:

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

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

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

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

(4) "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.

(5)(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.

(b) "Cannabinoid product" does not include:

(A) Usable marijuana by itself;

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

(C) Industrial hemp, as defined in ORS 571.300.

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

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

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

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

(10) "Consumer":

(a) Has the meaning given that term in section 1, chapter 614, Oregon Laws 2015; or

(b) Means a patient or designated primary caregiver receiving a transfer from a medical marijuana dispensary.

(11) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service Number 1972-08-3.

(12)(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 and who is designated as such on that person's application for a registry identification card or in other written notification to the Authority.

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

- (13) "Field duplicate sample" means two samples taken in an identical manner from and representative of the same marijuana item being sampled.
- (14) "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, or chewing gum.
- (15) "Grower" has the same meaning as "person responsible for a grow site".
- (16) "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.
- (17) "Harvest lot " means a specifically identified quantity of marijuana that is uniform in strain, cultivated utilizing the same growing practices, harvested at the same time at the same location and cured under uniform conditions.
- (18) "Laboratory" means a laboratory that is accredited under ORS 438.605 to 438.620 to conduct tests on marijuana items and licensed by the Oregon Liquor Control Commission under section 93, chapter 614, Oregon Laws 2015.
- (19)(a) "Marijuana" means the plant Cannabis family Cannabaceae, any part of the plant Cannabis family Cannabaceae and the seeds of the plant Cannabis family Cannabaceae.
- (b) "Marijuana" does not include industrial hemp, as defined in ORS 571.300.
- (20) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.
- (21) "Marijuana processing site" means a marijuana processing site registered under section 85, chapter 614, Oregon Laws 2015.
- (22) "Medical Cannabis Producer" has the same meaning as "person designated to produce marijuana by a registry identification cardholder".
- (23) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475.314.
- (24) "Patient" has the same meaning as "registry identification cardholder."
- (25) "Person designated to produce marijuana by a registry identification cardholder" has the same meaning as "medical cannabis producer" and means a person designated to produce marijuana by a registry identification cardholder under ORS 475.304 who produces marijuana for a registry identification cardholder at an address:
- (a) Other than the address where the registry identification cardholder resides; or
- (b) Where more than 12 mature marijuana plants are produced.
- (26) "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 475.304.
- (27) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extracts.
- (28) "Processor" has the meaning given that term in OAR 845-025-1015.
- (29) "Producer" has the meaning given that term in OAR 845-025-1015.
- (30) "Producing" means:
- (a) Planting, cultivating, growing, trimming or harvesting marijuana; or
- (b) Drying marijuana leaves and flowers.
- (31) "Process lot" means:
- (a) Any amount of cannabinoid concentrate or extract of the same type and processed at the same time 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 at the same time 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 as defined in subsection (a) of this section.

(32) "Registrant" means a medical cannabis producer, grower, marijuana processing site, or a medical marijuana dispensary.

(33) "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.

(34) "Representative sample" means a sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionately represented.

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

(36) "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.

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

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

(39) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.

(40) "These rules" means OAR 333-007-0300 through 333-007-0490.

(41) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish mutually acceptable standards for accrediting environmental laboratories.

(42) "TNI Standards" means the adopted 2009 TNI Standards (© 2009 The NELAC Institute), which describe the elements of laboratory accreditation developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies.

(43)(a) "Usable marijuana" means the dried leaves and flowers of marijuana.

(b) "Usable marijuana" 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.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0320

Usable Marijuana Testing Requirements

(1) Every batch of usable marijuana prior to being sold or transferred to a consumer must be tested for the following:

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

(b) Microbiological contaminants in accordance with OAR 333-007-0390.

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

- (d) THC and CBD concentration in accordance with OAR 333-007-0430.
 - (2) Every batch of usable marijuana prior to being used by a processor to make a cannabinoid edible must be tested for pesticides in accordance with OAR 333-007-0400.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0330

Cannabinoid Concentrate and Extract Testing Requirements

- (1) Every process lot of cannabinoid concentrate or extract, prior to being sold or transferred to a consumer 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) THC and CBD concentration in accordance with OAR 333-007-0430.
 - (2) Every process lot of a cannabinoid concentrate or extract prior to being used by a processor must be tested for the following:
 - (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
 - (3) A cannabinoid extract or concentrate that is processed in a manner that does not provide effective sterilization must be tested for microbiological contaminants in accordance with OAR 333-007-0390.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0340

Cannabinoid Product Testing Requirements

- (1) Cannabinoid products except for products applied to skin or hair. All process lots of a cannabinoid product, except for a product intended to be applied to a person's skin or hair prior to being sold to a consumer must be tested for the following:
 - (a) THC and CBD concentration in accordance with OAR 333-007-0430.
 - (b) Homogeneity in accordance with OAR 333-007-0440.
 - (2) Cannabinoid products intended to be applied to skin or hair. All process lots of a cannabinoid product intended to be applied to a person's skin or hair must be tested for:
 - (a) THC and CBD concentration in accordance with OAR 333-007-0430.
 - (b) Solvents in accordance in OAR 333-007-0410.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0350

Batch Size

- (1) Usable marijuana. A harvest lot must be separated into no larger than 10 pound batches.
 - (2) Cannabinoid concentrates and extracts and cannabinoid products. A process lot is a batch.
 - (3) Batches must be assigned a unique batch number.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0360

Sampling

- (1) All samples must be taken in accordance with ORELAP approved policies and procedures as specified in OAR 333-061-0100.
 - (2) Usable marijuana.
 - (a) Usable marijuana may only be sampled after it is cured.
 - (b) Samples taken must in total represent a minimum of 0.5 percent of the batch.
 - (3) Cannabinoid concentrates and extracts and cannabinoid products.
 - (a) Samples must be taken from random locations within each batch.
 - (b) The sample size of a cannabinoid edible is a whole unit (a serving size).
 - (c) Only a single sample of appropriate size necessary to run the required analyte tests and a field duplicate must be taken from a process lot regardless of the process lot size, if:
 - (A) A process lot passed a homogeneity test in accordance with OAR 333-007-0440; and
 - (B) The processor used the exact same procedures for making the process lot that passed the homogeneity tests as were used for making the process lot from which samples are to be taken.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0370

Sampling Personnel Requirements; Sampling

- (1) Only laboratory personnel may take samples.
 - (2) Laboratory personnel that perform sampling must:
 - (a) Follow ORELAP approved policies and procedures as specified in OAR 333-064-0100;
 - (b) Follow chain of custody procedures consistent with TNI Standard VIM2 5.8;
 - (c) After taking samples, record in the Commission's seed to sale system under the licensee or registrant number:
 - (A) A description of the samples taken (for example, flower, concentrate, brownies);
 - (B) Size of sample (amount of material comprising the sample);
 - (C) Date the samples were collected;
 - (D) The field identification numbers of the samples; and
 - (E) Where and when they will be transported.
 - (d) Comply with record keeping requirements in OAR 333-061-0100.
- Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015
Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0380

Labeling, Storage, and Security of Pre-Tested Marijuana Items

- (1) Following samples being taken from a harvest or process lot batch, the batch must be:
 - (a) Labeled with the following information:
 - (A) The laboratory doing the samples;
 - (B) The test batch samples numbers, once known;
 - (C) The date the samples were taken;
 - (D) The harvest or process lot number;
 - (E) The registrant's registrant number; and
 - (F) In bold, capital letters, no smaller than 12 point font, "PRODUCT NOT TESTED".
 - (b) Stored and secured in a manner that prevents the product from being tampered with or transferred prior to test results being reported.

(2) If the samples pass testing the product may be sold in accordance with the applicable Authority rules.

(3) If the samples do not pass testing the registrant must comply with OAR 333-007-0450.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0390

Standards for Testing Microbiological Contaminants

(1) A marijuana item required to be tested for microbiological contaminants must be tested by a laboratory for:

(a) *E. coli*; and

(c) *Salmonella*.

(2) If a laboratory detects the presence of *E.coli* at more than 100 colony forming units per gram or *Salmonella* at more than 0 colony forming units per gram the sample fails.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0400

Standards for Testing Pesticides

(1) A marijuana item required to be tested for pesticides must be tested by a laboratory for the analytes listed in Exhibit A, Table 3, incorporated by reference. [Table not included. See ED. NOTE.]

(2) If a laboratory detects the presence of a pesticide above the action levels listed in Exhibit A, Table 3 the sample fails. [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0410

Standards for Testing Solvents

(1) A marijuana item required to be tested for solvents must be tested by a laboratory for the analytes listed in Exhibit A, Table 4 incorporated by reference. [Table not included. See ED. NOTE.]

(2) If a laboratory detects the presence of a solvent above the action level listed in Exhibit A, Table 4 the sample fails. [Table not included. See ED. NOTE.]

[ED. NOTE: Tables referenced are not included in rule text. Click here for PDF copy of table(s).]

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

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) If a sample has a water activity rate of more than 0.65 A_w the sample fails.
- (3) If a sample has a moisture content of more than 15 percent the result must be reported to the licensee but the sample does not fail.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0430

Standards for Testing THC and CBD Concentration

A laboratory must test for the following when testing a marijuana item for THC and CBD:

- (1) THC.
- (2) THCA.
- (3) CBD.
- (4) CBDA.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0440

Homogeneity

- (1) Cannabinoid edibles.

(a) Samples from a batch of cannabinoid edibles must show that the cannabinoid edible batch is homogeneous.

(b) In order to be considered homogenous the samples from five consecutive process lots of the same product must not exceed a 30 percent relative percentage difference in THC.

(c) Samples of cannabinoid edibles that have greater than a 30 percent relative percentage difference in THC fail.

- (2) Cannabinoid concentrates, extracts and cannabinoid products other than edibles.

(a) At least 20 representative samples must be taken from random locations in a process lot to test for homogeneity.

(b) In order to be considered homogeneous samples must have a relative standard deviation (RSD) of less than 20 percent with no sample identified as an outlier using the Grubb's outlier test evaluated with a significance level of 0.05 (only a 5 percent chance of an error).

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0450

Failed Test Samples

(1) If a sample fails any initial test a registrant may have samples retested in accordance with OAR 333-007-0460.

- (2) Failed microbiological contaminant testing.

(a) If a sample from a batch of usable marijuana fails microbiological contaminant testing the batch may be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO₂ closed loop system.

(b) If a sample from a batch of a cannabinoid concentrate or extract fails microbiological contaminant testing the batch may be further processed if the processing method effectively

sterilizes the batch, such as a method using a hydrocarbon based solvent or a CO2 closed loop system.

(c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be resampled and retested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(3) Failed solvent testing.

(a) If a sample from a batch fails solvent testing the batch may be re-processed using procedures that would reduce the concentration of solvents to less than the action level.

(b) A batch that is re-processed in accordance with subsection (a) of this section must be resampled and retested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(4) Failed water activity testing.

(a) If a sample from a batch of usable marijuana fails for water activity the batch from which the sample was taken may:

(A) Be used to make a cannabinoid concentrate or extract; or

(B) Continue to dry or cure.

(b) Cannabinoid concentrates or extracts made using a batch that failed a water activity test must be tested in accordance with OAR 333-007-0330.

(c) A batch that undergoes additional drying or curing as described in paragraph (a)(B) of this section must be resampled and retested in accordance with these rules.

(5) Failed pesticide testing.

(a) If a sample from a batch fails pesticide testing the batch must be:

(A) Destroyed in a manner approved by the Authority; or

(B) Re-tested in accordance with OAR 333-007-0460.

(b) The Authority must report to the Oregon Department of Agriculture all test results that show that a sample failed a pesticide test or retest.

(6) If a sample fails a retest required under sections (2), (3) or (5) of this rule for microbiological contaminants, solvents or pesticides a registrant must destroy or dispose of the batch.

(7) An Authority representative must witness the destruction or disposal of a batch if destruction or disposal is required by this rule.

(8) A registrant must inform a laboratory prior to samples being taken that the batch is being resampled and retested after an initial failed test.

(9) 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 resampling, retesting, sterilization, re-processing, remediation and destruction or disposal.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0460

Retesting

(1) If a sample fails an initial test a licensee or registrant may:

(a) Instruct the lab that did the initial test to send a portion of the sample that failed to two other laboratories of the licensee's or registrant's choice, for retesting; or

(b) Have two other laboratories of the licensee's or registrant's choice resample and retest the new sample or samples.

(2) If a sample passes all of the retesting done by both the other laboratories, the sample is considered compliant with these rules.

(3) If a sample fails a registrant must comply with OAR 333-007-0450 and a licensee must comply with OAR 845-025-5740.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0470

Tentative Identification of Compounds

(1) Tentatively Identified Compounds (TICs) are compounds detected in a sample that are not among the target analytes for that method.

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

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0480

Audit Testing

(1) The Authority may require a registrant to submit samples identified by the Authority to a laboratory to be tested in order to determine whether a registrant is in compliance with OAR 333-007- 0300 through 333-007-0490, and may require additional testing that is not required by these rules.

(2) A laboratory doing audit testing must comply with these rules, to the extent they are applicable, and if conducting testing not required by these rules, may only use Authority approved methods.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

333-007-0490

Waiver of Pesticide Testing Requirements

(1) The Commission or the Authority may, upon receipt of a written request from a licensee or registrant, waive a requirement that every batch be tested for pesticides, if the licensee or registrant can demonstrate that none of the batches from any of the harvest lots tested in the last 12 months have failed a pesticide test.

(2) If the waiver is granted the Commission or Authority must provide notice, in writing, to the registrant or licensee, what the new requirement will be and how long the waiver will be in effect.

(3) If the Commission or the Authority waives the testing requirement the licensee or registrant is subject to random testing and the Commission or the Authority shall notify the licensee or registrant when a harvest lot must be tested in accordance with these rules.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015

DIVISION 64

ACCREDITATION OF LABORATORIES

Oregon Environmental Laboratory Accreditation Program (ORELAP)

333-064-0100

Marijuana Item Sampling Procedures and Testing

(1) Sampling.

(a) A laboratory must prepare sampling policies and procedures that contain all of the information necessary for collecting and transporting samples in a manner that does not endanger the integrity of the sample for any analysis required by this rule. These procedures must be appropriate to the matrix being sampled.

(b) Sampling policies and procedures must be submitted to the accrediting body for approval prior to any marijuana samples being taken.

(c) Care should be taken 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) A sufficient sample size must be taken for analysis of all requested tests, quality control, and for a re-test of sample if necessary.

(2) Sample identification.

(a) Records must contain the location of each sample and subsample taken.

(b) The samples, subsamples and field duplicates must be assigned a field identification number the field identification numbers must have an unequivocal link to the laboratory analysis identification.

(c) The test batch must be assigned a unique identifier in accordance with TNI standard V1M2 5.8.5 and that information must be provided to the licensee or registrant.

(d) The following must be entered into the Commission's seed to sale tracking system or the Authority's database under the licensee or registrant number:

(A) The sample test batch numbers;

(B) Date and time samples were received; and

(C) A description of the marijuana item being tested.

(3) Combining subsamples.

(a) Subsamples collected from the same batch must be combined into a single sample by a laboratory prior to testing.

(b) Subsamples and samples collected from different batches may not be combined.

(c) Field duplicates may not be combined with the other samples.

(4) THC and CBD testing validity. When testing a sample for THC and CBD a laboratory must comply with additional method validation as follows:

(a) Run a laboratory control standard in accordance with TNI standards requirements within passing control limits of 70 percent to 130 percent recovery.

(b) Analyze field duplicates of samples within precision control limits of plus or minus 30 percent relative percent difference.

(5) Calculating total THC and total CBD.

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

$$M_{\text{total delta-9 THC}} = M_{\text{delta-9 THC}} + 0.877 \times M_{\text{delta-9 THCA}}$$

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

$$M_{\text{total CBD}} = M_{\text{CBD}} + 0.877 \times M_{\text{CBDA}}$$

(c) Each test report must include the total THC and total CBD.

(6) Report total THC and total CBD as Dry Weight. A laboratory must report total THC and Total CBD content by dry weight calculated as follows:

$$P_{\text{total THC(dry)}} = P_{\text{total THC(wet)}} / [1 - (P_{\text{moisture}}/100)]$$

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

(7) Tentative Identification of Compounds (TIC).

(a) When testing cannabinoid concentrates or extracts, if a laboratory determines that a sample may contain compounds that are not included in the list of analytes the laboratory is testing for the laboratory must attempt to achieve tentative identification.

(b) Tentative identification is achieved by searching NIST 2014 (>250,000 compounds) or an equivalent database. Match scores for background subtracted or deconvoluted spectra must exceed 90 percent compared to library spectrum. The top five matches over 90 percent should be considered by the analyst for reporting.

(c) TIC quantitation is estimated by comparing analyte area to closest internal standard area. All chromatographic peaks from total (reconstructed) ion chromatogram estimated to have a concentration greater than 1ppm should have representative spectra (background subtraction or deconvolution) searched for possible library matches and tentative identification or quantitation.

(d) A laboratory shall report to the licensee or registrant and the Authority or the Commission, depending on which agency has jurisdiction, up to five tentatively identified compounds (TICS) that have the greatest apparent concentration using the response factor (RF) = 1.

(8) A laboratory must provide 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.

Stat. Auth.: ORS 448.150(1), 448.131, 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, section 92 and 94, chapter 614, Oregon Laws 2015.

Stats. Implemented: ORS 448.280(1)(b) & (2), 438.605, 438.610, 438.615 & 438.620, section 92 and 94, chapter 614, Oregon Laws 2015.

333-064-0110

Reporting Marijuana Test Results

(1) A laboratory must report all required test results within 24 hours of completion of validation:

(a) Into the Commission's seed to sale tracking system; and

(b) To the licensee or registrant.

(2) A laboratory must determine and include on each test report its limit of quantification (LOQ) for each analyte.

(3) When reporting pesticide testing results the laboratory must report any target compound that falls below the LOQ that has a signal to noise ratio of greater than 3:1 and meets identification criteria with a result of "detected".

(4) A test report must include any associated test batch numbers and the date each test was completed.

Stat. Auth.: Section 91 and 92, chapter 614, Oregon Laws 2015

Stats. Implemented: Section 91 and 92, chapter 614, Oregon Laws 2015