

## **DIVISION 7**

### **MARIJUANA LABELING, CONCENTRATION LIMITS, AND TESTING**

#### **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, patient or designated primary caregiver. 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 475B.400 to 475B.525 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.

(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 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, patient or designated primary caregiver at the point of sale.

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

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

#### **333-007-0020**

##### **Definitions**

For the purposes of OAR 333-007-0010 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) For purposes of labeling "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" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.
- (11) "Container"
- (a) Means a sealed, hard or soft-bodied receptacle in which a marijuana item is placed.
  - (b) Does not mean inner wrapping or packaging that is not intended to display the marijuana item for sale to a consumer.
- (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) "Licensee" has the meaning given that term in ORS 475B.015.
- (20) "Major food allergen" means an ingredient that is one of the five foods listed in subsections (a) to (e) of this section, or from one of the three food groups listed in subsections (f) to (h) of this section, or is an ingredient that contains protein derived from one of the following:
- (a) Milk;
  - (b) Egg;

- (c) Fish;
  - (d) Crustacean shellfish;
  - (e) Tree nuts;
  - (f) Wheat;
  - (g) Peanuts; and
  - (h) Soybeans.
- (21)(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.
- (22) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product, or a cannabinoid concentrate or extract.
- (23) "Medical grade cannabinoid product, cannabinoid concentrate or cannabinoid extract" means a cannabinoid product, cannabinoid concentrate or cannabinoid extract that has a concentration of THC that is permitted under ORS 475B.625 in a single serving of the cannabinoid product, cannabinoid concentrate or cannabinoid extract for a patient.
- (24) "Medical grade symbol" means the image established by the Authority and made available to licensees indicating the cannabinoid product, concentrate or extract may only be sold or transferred to a designated primary caregiver or patient, for use only by a patient.
- (25) "Medical marijuana dispensary" means a facility registered under ORS 475B.450.
- (26) "Net weight" means the gross weight minus the tare weight of the packaging.
- (27) "Package unique identification number" mean the unique identification number that was generated by the Commission's seed to sale tracking system at the time the marijuana item was packaged and labeled for sale to the consumer, patient, or designated primary caregiver.
- (28) "Patient" has the same meaning as "registry identification cardholder."
- (29) "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."
- (30) "Place of address" means the name, mailing address, city, state and zip code of the processor who made the cannabinoid edible.
- (31) "Principal display panel" means the part of a label on a package or container that is most likely to be displayed, presented, shown or seen under customary conditions of display for sale or transfer.
- (32) "Processor" means a person:
- (a) Licensed by the Commission to process marijuana under ORS 475B.090; or
  - (b) Registered with the Authority under ORS 475B.435 as a processing site and who is not exempt from labeling requirements under ORS 475B.605
- (33) "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.
- (34) "Producer" means a person:
- (a) Licensed by the Commission to produce marijuana under ORS 475B.070; and

(b) Registered with the Authority under ORS 475B.420 as a grower and who is not exempt from labeling requirements under ORS 475B.605.

(35) "Product identity" means a truthful or common name of the product that is contained in the package.

(36) "Registrant" means a person registered with the Authority under ORS 475B.400 to 475B.525.

(37) "Registry identification cardholder" means a person to whom a registration card has been issued under ORS 475B.415.

(38)(a) "Test batch" means 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.

(39) "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.

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

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

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

(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.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0030**

#### **Marijuana Plant Labeling Requirements**

Prior to a marijuana plant being sold or transferred to a consumer, patient or designated primary caregiver 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) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;

(3) Name of the strain; and

(4) Universal symbol.

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0040**

#### **Marijuana Seed Labeling Requirements**

Prior to marijuana seeds being sold or transferred to a consumer, patient or designated primary caregiver 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) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;
- (3) Name of the strain of seed;
- (4) Date of harvest;
- (5) Number of seeds or net weight in U.S. customary and metric units as appropriate; and
- (6) Universal symbol.

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0050**

#### **Usable Marijuana Labeling Requirements**

Prior to usable marijuana being sold or transferred to a consumer, patient or designated primary caregiver 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) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the producer;
- (3) For licensees, package unique identification number and for registrants, harvest lot number;
- (4) Date of harvest;
- (5) Name of strain;
- (6) Net weight in U.S. customary and metric units;
- (7) Concentration of THC and CBD, as calculated under OAR 333-064-0100;
- (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 usable marijuana for sale to a consumer 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."
- (12) For usable marijuana for use by a patient 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.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0060**

#### **Cannabinoid Topical Labeling Requirements**

Prior to a cannabinoid topical product being sold or transferred to a consumer, patient or designated primary caregiver 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) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) For licensees, package unique identification number and for registrants, process lot number;
- (4) Product identity (common or usual name);
- (5) Date the product was made;

- (6) Net weight or volume in U.S. customary and metric units;
  - (7) Amount suggested for use by the consumer or patient at any one time;
  - (8) Concentration or amount by weight or volume of THC and CBD in the container;
  - (9) List of ingredients in descending order or predominance by weight or volume used to process the cannabinoid topical;
  - (10) Activation time, expressed in words or through a pictogram;
  - (11) Name of the lab that performed any test, any associated test batch number and any test analysis date;
  - (12) Universal symbol;
  - (13) For licensees, a medical grade symbol if applicable;
  - (14) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
  - (15) For cannabinoid topicals for sale to a consumer warnings that state:
    - (a) "For use only by adults 21 and older. Keep out of reach of children."
    - (b) "DO NOT EAT" in bold, capital letters.
  - (16) For cannabinoid topicals for use by a patient 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.: ORS 475B.605  
 Stats. Implemented: ORS 475B.605

### **333-007-0070**

#### **Cannabinoid Edible Labeling Requirements**

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

- (1) Processor's business or trade name, place of address, and licensee or registrant number;
- (2) Business or trade name and place of address of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) Product identity (common or usual name);
- (4) For licensees, package unique identification number and for registrants, process lot number;
- (5) Date the edible was made;
- (6) Net weight or volume in U.S. customary and metric units;
- (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 major food allergens:
  - (a) Using a "contains" statement to summarize the major food 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 per serving;
- (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;
  - (16) For licensees, a medical grade symbol if applicable;
  - (17) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
  - (18) For cannabinoid edibles for sale to a consumer 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."
  - (19) For cannabinoid edibles for use by a patient 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.: ORS 475B.605  
 Stats. Implemented: ORS 475B.605

### **333-007-0080**

#### **Labeling Requirements for Cannabinoid Concentrates and Extracts**

Prior to a cannabinoid concentrate or extract being sold or transferred to a consumer, patient or designated primary caregiver 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) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
- (3) For licensees, package unique identification number and for registrants, process lot number;
- (4) Product identity (concentrate or extract);
- (5) Date the concentrate or extract was made;
- (6) Net weight or volume in U.S. customary and metric units;
- (7) If applicable, serving size and number of servings per container or amount suggested for use by the consumer or patient at any one time;
- (8) Concentration or amount by weight or volume of THC and CBD in each amount suggested for use and in the container;
- (9) Activation time, expressed in words or through a pictogram;
- (10) Name of the lab that performed any test, any associated test batch number and any test analysis date;
- (11) Universal symbol;
- (12) For licensees, a medical grade symbol if applicable;
- (13) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
- (14) For cannabinoid concentrates and extracts for sale to a consumer 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.

(15) For cannabinoid concentrates and extracts for use by a patient 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.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **333-007-0083**

#### **Cannabinoid Tincture Labeling Requirements**

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

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

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

(3) Product identity (common or usual name);

(4) For licensees, package unique identification number and for registrants, process lot number;

(5) Date the tincture was made;

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

(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) For licensees, a medical grade symbol if applicable;

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

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

(15) For cannabinoid tinctures for sale to a consumer 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."

(16) For cannabinoid tinctures for use by a patient 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.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **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, patient or designated primary caregiver the container holding the product must have a label that has the following information:



- (1) Processor's business or trade name and licensee or registrant number;
  - (2) Business or trade name of licensee or registrant that packaged or distributed the product, if different from the processor;
  - (3) Place of address for the processor and packager, if applicable;
  - (4) Product identity (common or usual name);
  - (5) For licensees, package unique identification number and for registrants, process lot number;
  - (6) Date the product was made;
  - (7) Net weight or volume in U.S. customary and metric units;
  - (8) Serving size and number of servings per container;
  - (9) Concentration or amount by weight or volume of THC and CBD in each serving and in each container;
  - (10) List of all ingredients in descending order of predominance by weight or volume used to process the cannabinoid product;
  - (11) Name of the lab that performed any test, any associated test batch number and any test analysis date;
  - (12) Universal symbol;
  - (13) For licensees, a medical grade symbol if applicable;
  - (14) Activation time expressed in words or through a pictogram;
  - (15) A statement that reads: "This product is not approved by the FDA to treat, cure, or prevent any disease";
  - (16) For cannabinoid products for sale to a consumer warnings that state:
    - (a) "For use only by adults 21 and older. Keep out of reach of children."
    - (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."
  - (17) For cannabinoid products for use by a patient 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.: ORS 475B.605  
 Stats. Implemented: ORS 475B.605

### **333-007-0090**

#### **General Label Requirements; Prohibitions; Exceptions**

- (1) Principal Display Panel.
  - (a) Every container that contains a marijuana item for sale or transfer to a consumer, patient or designated primary caregiver must have a principal display panel, as that term is defined in OAR 333-007-0020.
  - (b) If a container is placed within packaging for purposes of displaying the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver, the packaging must have a principal display panel as that term is defined in OAR 333-007-0020.
  - (c) The principal display panel must contain the product identity, net weight, and universal symbol, if applicable.
  - (d) If the product is a medical grade cannabinoid product, concentrate or extract processed by a licensee the principal display panel must include the medical grade symbol.
- (2) A label required by these rules must:
  - (a) Be placed on the container and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver.

- (b) Comply with the National Institute of Standards and Technology (NIST) Handbook 130 (2016), Uniform Packaging and Labeling Regulation, incorporated by reference.
  - (c) Be in no smaller than 8 point Times New Roman, Helvetica or Arial font;
  - (d) Be in English, though it can be in other languages; and
  - (e) Be unobstructed and conspicuous.
- (3) A marijuana item may have one or more labels affixed to the container or packaging.
- (4) A marijuana item that is in a container that because of its size does not have sufficient space for a label that contains all the information required for compliance with these rules:
- (a) May have a label on the container that contains a marijuana item and on any packaging that is used to display the marijuana item for sale or transfer to a consumer, patient or designated primary caregiver that includes at least the following:
    - (A) Information required on a principal display panel, if applicable for the type of marijuana item;
    - (B) Licensee or registrant business or trade name and licensee or registrant number;
    - (C) For licensees, package unique identification number and for registrants, batch or process lot number;
    - (D) Concentration of THC and CBD; and
    - (E) Required warnings; and
  - (b) Must include all other required label information not listed in subsection (4)(a) of this rule on an outer container or package, or on a leaflet that accompanies the marijuana item.
  - (c) May:
    - (A) Use a peel-back or accordion label with the information required in subsection (4)(b) of this rule, if the peel-back or accordion label can be easily identified by a patient or consumer as containing important information.
    - (B) Use 6 point font for the information listed in paragraph (4)(a)(A) to (D) of this rule.
- (5) A marijuana item in a container that is placed in packaging that is used to display the marijuana item for sale or transfer to a consumer, patient, or designated primary caregiver must comply with the labeling requirements in these rules, even if the container qualifies for the exception under section (4) of this rule.
- (6) 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](http://www.healthoregon.org/marijuana).
- (7) Medical grade symbol. The medical grade symbol must be at least 0.35 inches in diameter.
- (8) A label may not:
- (a) 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; or
  - (b) Be attractive to minors, as that is defined in OAR 845-025-7000.
- (9) 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 is intended for human consumption or the "BE CAUTIOUS" warning if the effects of the product are customarily felt immediately.

- (10) The THC and CBD amount required to be on a label must be based on the value calculated by the laboratory that did the testing in accordance with OAR 333-064-0100, plus or minus ten percent, except that a label may not have a THC value that exceeds the applicable maximum concentration limit. A registrant or licensee that has more than one laboratory test result for THC or CBD from the same batch may either express the THC or CBD amounts on the label:
- (a) As a range, based on the high and low THC and CBD values for each sample that was tested; or
  - (b) As an average of all the THC values for each sample or an average of all the CBD values for each sample.
- (11) 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.
- (12) 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.
- (13) A licensee or registrant must have documentation that demonstrates the validity of the calculation of the amount of sodium, sugar, carbohydrates and total fat in a cannabinoid edible and must make that documentation available to the Commission or the Authority upon request.
- (14) Exit packaging must contain a label that reads: "Keep out of the reach of children."
- (15) A cartridge containing a cannabinoid concentrate, extract or product intended for use with an inhalant delivery system as that is defined in ORS 431.840 is not required to be labeled in accordance with these rules except that the cartridge must have a label with the universal symbol. All the remaining label requirements must be included on the packaging that is used to display the cartridge for sale or transfer.

Stat. Auth.: ORS 475B.605

Stats. Implemented: ORS 475B.605

### **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.: ORS 475B.610

Stats. Implemented: ORS 475B.610

### **333-007-0200**

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

- (1) In accordance with ORS 475B.625, the Authority must establish, for marijuana items sold or transferred to a consumer, patient or designated primary caregiver through a Commission licensed marijuana retailer or medical marijuana dispensary:
- (a) The maximum concentration of THC permitted in a single serving of a cannabinoid product or cannabinoid concentrate or extract; and
  - (b) The number of servings permitted in a cannabinoid product container or cannabinoid concentrate or extract container.
- (2) OAR 333-007-0200 through 333-007-0220 apply to:

- (a) A Commission licensee as that is defined in OAR 845-025-1015; and
  - (b) A person registered with the Authority under ORS 475B.400 to 475B.525 who is not exempt under ORS 475B.630.
  - (3) The concentration of THC permitted under OAR 333-007-0210 through 333-007-0220 must take into account both the amount of Delta-9 THC in the cannabinoid product or cannabinoid concentrate or extract and the amount of tetrahydrocannabinolic acid (THCA) in the cannabinoid product or cannabinoid concentrate or extract that if heated would convert THCA to THC. A cannabinoid product or cannabinoid concentrate or extract that contains a high amount of THCA must meet the concentration limits established in OAR 333-007-0200 through 333-007-0220 even if heated.
  - (4) 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, patient or designated primary caregiver.
  - (5) A marijuana item received or transferred by a dispensary must meet the concentration and serving size limits in OAR 333-007-0220.
  - (6) For purposes of OAR 333-007-0200 through 333-007-0220:
    - (a) The definitions in OAR 333-007-0020 apply unless otherwise specified.
    - (b) "Cannabinoid capsule" means a small soluble container, usually made of gelatin, that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.
    - (c) "Cannabinoid edible" means a food or potable liquid into which a cannabinoid concentrate or extract or the dried leaves or flowers of marijuana have been incorporated.
    - (d) "Cannabinoid suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina containing a cannabinoid product, concentrate or extract.
    - (e) "Cannabinoid transdermal patch" means an adhesive substance applied to human skin that contains a cannabinoid product, concentrate or extract for absorption into the bloodstream.
    - (f) "Medical marijuana item" is a marijuana item for sale or transfer to a patient or designated primary caregiver and includes medical grade cannabinoid products, cannabinoid concentrates and cannabinoid extracts.
    - (g) "Retail adult use marijuana item" is a marijuana item for sale to a consumer.
    - (h) "Scored" means to physically demark a cannabinoid edible in a way that enables a reasonable person to:
      - (A) Intuitively determine how much of the product constitutes a single serving; and
      - (B) Easily physically separate the edible into single servings either by hand or with a common utensil, such as a knife.
- Stat. Auth.: ORS 475B.625  
Stats. Implemented: ORS 475B.625

### **333-007-0210**

#### **Retail Marijuana Item Concentration and Serving Size Limits**

- (1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a retail adult use marijuana item is listed in Table 1. [Table not included. See ED. NOTE.]
- (2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:
  - (a) Sold and packaged with a measuring device that measures single servings; or

- (b) Placed in packaging that clearly enables a consumer to determine when a single serving has been consumed.
- (3) Serving size is as determined by the processor.
- (4) A retail adult use marijuana item that does not fall within a category in Table 1 such as cannabinoid suppositories and transdermal patches or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 1.

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

Stat. Auth.: ORS 475B.625

Stats. Implemented: ORS 475B.625

### **333-007-0220**

#### **Medical Marijuana Item Concentration Limits**

- (1) The maximum concentration or amount of THC permitted in a container and the maximum concentration or amount of THC permitted in a serving of a medical marijuana item is listed in Table 2.
- (2) A cannabinoid edible must be scored unless it is not capable of being scored in which case the cannabinoid edible must be:
  - (a) Sold and packaged with a measuring device that measures single servings; or
  - (b) Placed in packaging that clearly enables a patient to determine when a single serving has been consumed, as that serving size is determined by the processor.
- (3) Serving size is as determined by the processor.
- (4) A medical marijuana item that does not fall within a category in Table 2 or is a cannabinoid product intended for human consumption that is not specifically categorized must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 2.

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

Stat. Auth.: ORS 475B.625

Stats. Implemented: ORS 475B.625

### **333-007-0300**

#### **Marijuana Testing: Purpose and Effective Date**

- (1) The purpose of these rules is to establish the minimum compliance testing standards for marijuana items. These rules are applicable to:
  - (a) A licensee; and
  - (b) A registrant who is not exempt from the testing requirements.
- (2) The testing requirements do not apply to:
  - (a) A grower if the person is transferring usable marijuana or an immature marijuana plant to:
    - (A) A patient who designated the grower to grow marijuana for the patient; or
    - (B) A designated primary caregiver 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.
  - (c) Immature plants or seeds.

(3) A person registered with the Authority under ORS 475B.400 to 475B.525 who is subject to these rules may not:

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

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

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0310**

#### **Definitions**

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

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

(2) "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.

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

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

(5) "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.

(6)(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.

(7) "Cannabinoid capsule":

(a) Means a small soluble container, usually made of gelatin that encloses a dose of a cannabinoid product, concentrate or extract intended for human ingestion.

(b) Does not mean a cannabinoid suppository.

(8) "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.

(9) "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.

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

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

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

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

- (14) "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.
- (15) "Chain of custody form" means a form completed by laboratory personnel that documents the collection, transport, and receipt of samples by the laboratory.
- (16) "Commission" means the Oregon Liquor Control Commission.
- (17) "Compliance test" means a laboratory test required by these rules in order to allow the transfer or sale of a marijuana item.
- (18) "Consumer" has the meaning given that term in ORS 475B.015 and does not include a patient or designated primary caregiver.
- (19) "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.
- (20) "Delta-9 THC" is the principal psychoactive constituent (the principal cannabinoid) of cannabis, Chemical Abstracts Service Number 1972-08-3.
- (21)(a) "Designated primary caregiver" means an individual 18 years of age or older who has significant responsibility for managing the well-being of a person who has been diagnosed with a debilitating medical condition, who is designated as such on that person's application for a registry identification card or in other written notification to the Authority, and who has been issued an identification card by the Authority under ORS 475B.415(5)(b).
- (b) "Designated primary caregiver" does not include the person's attending physician.
- (22) "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.
- (23) "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.
- (24) "Grower" has the same meaning as "person responsible for a marijuana grow site."
- (25) "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.420.
- (26) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72-hour period at the same location and cured under uniform conditions.
- (27) "Homogeneous" means a cannabinoid product, concentrate or extract has uniform composition and properties throughout each process lot.
- (28) "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.
- (29) "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.
- (30) "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.
- (31) "Licensee" has the meaning given that term in ORS 475B.015.
- (32)(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.
- (33) "Marijuana item" means marijuana, usable marijuana, a cannabinoid product or a cannabinoid concentrate or extract.
- (34) "Marijuana processing site" means a marijuana processing site registered under ORS 475B.435.
- (35) "Medical marijuana dispensary" or "dispensary" means a medical marijuana dispensary registered under ORS 475B.450.
- (36) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.
- (37) "Patient" has the same meaning as "registry identification cardholder."
- (38) "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.420.
- (39) "Process lot" means:
- (a) Any amount of cannabinoid concentrate or extract 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 as defined in subsection (a) of this section.
- (40) "Processing" means the compounding or conversion of marijuana into cannabinoid products or cannabinoid concentrates or extracts.
- (41) "Processing site" means a processor registered with Authority under ORS 475B.435.
- (42) "Processor" has the meaning given that term in OAR 845-025-1015.
- (43) "Producer" has the meaning given that term in OAR 845-025-1015.
- (44) "Producing" means:
- (a) Planting, cultivating, growing, trimming or harvesting marijuana; or
- (b) Drying marijuana leaves and flowers.
- (45) "Registrant" means a grower, marijuana processing site, or a medical marijuana dispensary registered with the Authority under ORS 475B.420, 475B.435 or 475B.450.
- (46) "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 475B.415(5)(a).
- (47) "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..
- (48) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.
- (49) "Sample" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee and provided to a laboratory for testing.
- (50) "Sample increment" means an amount of a marijuana item collected by laboratory personnel from a registrant or licensee that may be combined into a sample for purposes of testing or, in the case of a control study, is tested individually.
- (51) "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.



- (52) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.
- (53) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.
- (54) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.
- (55) "These rules" means OAR 333-007-0300 through 333-007-0500.
- (56) "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 consensus standards for accrediting environmental laboratories.
- (57) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab 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.
- (58) "Total THC" means the molar sum of THC and THCA.
- (59) "Unit of sale" means an amount of a marijuana item commonly packaged for transfer or sale to a consumer, patient or designated primary caregiver, or capable of being packaged for transfer or sale to a consumer, patient or designated primary caregiver.
- (60)(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.: ORS 475B.555
- Stats. Implemented: ORS 475B.555

### **333-007-0315**

#### **Ordering Tests**

- (1) A registrant or licensee must provide a laboratory, prior to laboratory taking samples, with at a minimum, the following information:
- (a) The registrant or licensee's registrant or license number.
- (b) The name, address and contact information of the registrant or licensee.
- (c) Type of marijuana item.
- (d) Harvest lot number that is associated with the batch numbers, if applicable.
- (e) Process lot number that is associated with the batch numbers, if applicable.
- (f) Batch numbers to be sampled.
- (g) Total mass or volume of each batch to be sampled.
- (h) For cannabinoid products, the unit of sale.
- (i) Identification of the test or tests the laboratory is being requested to conduct.
- (j) Whether the test or tests being requested are compliance tests.
- (k) Whether the test or tests being requested are quality control or research and development tests.
- (l) 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.
- (m) Whether the marijuana item has a certified control study.

- (2) If the registrant or licensee informs a laboratory that a marijuana 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.
- (3) It is the responsibility of the registrant or the licensee to order the tests necessary to comply with these rules.
- (4) 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.
- (5) A registrant or licensee may not order more than one compliance test for the same marijuana item.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **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) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid concentrate or extract for water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (3) A producer or grower must test every batch from a harvest lot of marijuana or usable marijuana intended for use by a processor or processing site in making a cannabinoid product for the following:
  - (a) Pesticides in accordance with OAR 333-007-0400.
  - (b) Water activity and moisture content in accordance with OAR 333-007-0420 unless the processor or processing site uses a method of processing that results in effective sterilization.
- (4) A producer or grower must test one or more batches from a harvest lot of marijuana or usable marijuana for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a producer may transport batches of marijuana or usable marijuana to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0330**

#### **Compliance Testing Requirements for Cannabinoid Concentrates and Extracts**

- (1) A processor or processing site must test every process lot of 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) THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following:
  - (a) Pesticides in accordance with OAR 333-007-0400.
  - (b) Solvents in accordance with OAR 333-007-0410.
- (3) A processor or processing site is exempt from testing for solvents under this rule if the processor or processing site:
  - (a) Did not use any solvent listed in OAR 333-007-0410, Table 4; and
  - (b) Only used a mechanical extraction process to separate cannabinoids from the marijuana; or
  - (c) Used only water, animal fat or vegetable oil as a solvent to separate the cannabinoids from the marijuana.
- (4) A processor or processing site must test a process lot of a cannabinoid concentrate or extract for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (5) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0340**

#### **Compliance Testing Requirements for Cannabinoid Products Intended for Human Consumption or Ingestion and Cannabinoid Suppositories**

- (1) A processor or processing site must test every process lot of a cannabinoid product intended for human consumption or ingestion, including cannabinoid edibles, capsules, and tinctures, and cannabinoid suppositories for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test a process lot for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0345**

#### **Compliance Testing Requirements for Cannabinoid Topicals and Cannabinoid Transdermal Patches**

- (1) A processor or processing site must test every process lot of a cannabinoid topical or transdermal patch for use by a consumer or patient prior to selling or transferring the cannabinoid product for THC and CBD concentration in accordance with OAR 333-007-0430.
- (2) A processor or processing site must test a process lot of a cannabinoid topical or transdermal patch for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
- (3) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of cannabinoid products references in section (1) of this rule to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0350**

#### **Batch Requirements for Compliance Testing**

(1) Usable marijuana.

A producer or grower must separate each harvest lot into no larger than 15 pound batches.

(2) Cannabinoid concentrates and extracts.

(a) A process lot 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, extract or product for purposes of sampling and testing after a control study has been certified.

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

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

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

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

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

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

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0360**

#### **Sampling and Sample Size Requirements for Compliance Testing**

(1) Usable marijuana.

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

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

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

(2) Cannabinoid concentrates, extracts and products.

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

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

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

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

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

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0370**

#### **Sampling Personnel Requirements; Sampling Recordkeeping**

(1) Only individuals employed by a laboratory with an ORELAP accredited scope item for sampling under these rules may take samples.

(2) Sampling may be conducted at a licensee's or registrant's premises or the licensee or registrant may transport the batch to a laboratory with an ORELAP accredited scope item for sampling under these rules.

(3) If a producer or wholesaler transports marijuana or usable marijuana to a laboratory for compliance testing for pesticides all the batches from the harvest lot must be transported so the laboratory can choose which batches to sample from.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0380**

#### **Grower and Processing Site Requirements for Labeling, Storing, and Securing Pre-Tested Marijuana Items; Recordkeeping**

(1) Following samples being taken from a harvest or process lot batch a grower or processing site must:

(a) Label the batch with the following information:

- (A) The registrant's registration number;
  - (B) The harvest or process lot unique identification number;
  - (C) The name and accreditation number of the laboratory that took samples and the name and accreditation number of the laboratory responsible for the testing, if different;
  - (D) The test batch or sample unique identification numbers supplied by the laboratory personnel;
  - (E) The date the samples were taken; and
  - (F) In bold, capital letters, no smaller than 12 point font, "PRODUCT NOT TESTED."
- (b) Store and secure the batch in a manner that prevents the product from being tampered with or transferred prior to test results being reported.
  - (c) Be able to easily locate a batch stored and secured under section (1)(b) of this rule and provide that location to the Authority or a laboratory upon request.
- (2) If the samples pass testing the product may be sold or transferred in accordance with the applicable Authority rules.
  - (3) If the samples do not pass testing the grower or processing site must comply with OAR 333-007-0450.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0390**

#### **Standards for Microbiological Contaminants Compliance Testing**

- (1) A marijuana item required to be tested for microbiological contaminants under OAR 333-007-0320 to 333-007-0345 must be sampled using appropriate aseptic technique and tested by a laboratory for total coliform count.
- (2) If a laboratory detects the presence of any coliforms the sample must be assessed for *Escherichia coli* (*E. coli*).
- (3) A batch fails microbiological contaminant testing if the laboratory detects the presence of *E. coli* at more than 100 colony forming units per gram in a sample:
  - (a) During an initial test where no reanalysis is requested; or
  - (b) Upon reanalysis as described in OAR 333-007-0450(1).

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0400**

#### **Standards for Pesticides Compliance Testing**

- (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) 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 a sample:
  - (a) During an initial test where no reanalysis is requested; or
  - (b) Upon reanalysis as described in OAR 333-007-0450(1). [Table not included. See ED. NOTE.]
- (3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 3, at least every two years.

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

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0410**

#### **Standards for Solvents Compliance Testing**

(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.

(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 [Table not included. See ED. NOTE.]

(b) Calculates a RPD of more than 20 percent between the field primary result and the field duplicate result if the mean result is greater than half the action level for any analyte listed in Exhibit A, Table 4.

(3) The Authority will review and update, if necessary, the analytes listed in Exhibit A, Table 4, at least every two years

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

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0420**

#### **Standards for Water Activity and Moisture Content Compliance Testing**

(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.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0430**

#### **Standards for THC and CBD Compliance Testing**

(1) A laboratory must test for the following when testing a marijuana item for potency:

(a) THC.

(b) THCA.

(c) CBD.

(d) CBDA.

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

(a) The amount of THC, as calculated pursuant to OAR 333-064-0100, between samples taken from the batch exceeds 30 percent RSD; or

(b) The amount or percentage of THC, as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limits permitted in package by over 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.

(3) A process lot of a cannabinoid concentrate, extract or product 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 THC, as calculated pursuant to OAR 333-064-0100, between the sample and the field duplicate exceeds 20 percent RPD; or

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

(4) A sample cannot fail CBD testing.

(5) Notwithstanding section (2)(a) and (3)(a) of this rule, a sample that has less than 5 mg of THC as calculated pursuant to OAR 333-064-0100 does not fail potency testing based on exceedance of the RSD or RPD as described in section (2)(a) or (3)(a) of this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0440**

#### **Control Study**

(1) A laboratory may perform a control study on a process lot of cannabinoid concentrates, extracts or products for a processor or processing site if the processor or processing site informs the laboratory, in writing:

(a) That sampling and testing is for the purposes of a control study; and

(b) For cannabinoid products, the expected THC range for the product.

(2) Sample increments taken for purposes of a control study may not be combined.

(3) Sample increments from a cannabinoid concentrate or extract must be tested for:

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

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

(c) On and after July 1, 2017, THC concentration in accordance with OAR 333-007-0430 if the concentrate or extract is intended to be transferred or sold directly to a consumer or patient.

(4) Sample increments from a cannabinoid product must be tested for THC 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) THC concentration testing if:

(A) The amount of THC, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch does not exceed 30 percent RSD; and

(B) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100 for any sample increment does not exceed the maximum concentration limit permitted in a package by more than 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.



- (6) A laboratory must identify on a form prescribed by the Authority if a batch undergoing a control study has passed for any of the following, and must send the form at the client's request to the Authority or the Commission:
- (a) Pesticides, if applicable.
  - (b) Solvents, if applicable.
  - (c) THC concentration as calculated pursuant to OAR 333-064-0100, if applicable.
- (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 or 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 THC in a cannabinoid concentrate, extract or product, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch exceeds 30 percent RSD.
  - (c) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100, exceeds the maximum concentration limit permitted in a package by more than 10 percent as specified in OAR 333-007-0200 to 333-007-0220, as applicable.
    - (A) A batch that has a sample increment fail under subsections (b) or (c) of this section may not be re-mixed or re-packaged under OAR 333-007-0450(8)(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(8)(a) or (b), but sample increments from that batch may not be resubmitted for a control study.
- (8) A process lot sampled and tested for purposes of a control study may be sold or transferred if the sample increments pass all the required tests.
- (9) If a cannabinoid concentrate, extract or product successfully passes a control study and the control study has been certified by the Authority or the Commission, as applicable, the following applies to sampling and testing of future batches for one year:
- (a) For cannabinoid concentrates and extracts, 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. 3.1.
  - (b) For cannabinoid products, at a minimum, one unit of sale must be collected, at random, for the primary sample, and one unit of sale must be collected at random for the field duplicate sample.
  - (c) Both the primary sample and the field duplicate sample must be prepared and analyzed individually.
- (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 product.
    - (B) In the type of ingredient in the product.
  - (b) If a cannabinoid concentrate, extract or product fails a THC 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 product.
  - (12) A processor or processing site does not qualify for reduced sampling and testing under a control study until either the Authority or Commission:
    - (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 Exhibit B, Tables 5 and 6 and the sample increments prepared and analyzed separately.
- Stat. Auth.: ORS 475B.555  
 Stats. Implemented: ORS 475B.555

**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 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.
- (4) 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 CO<sub>2</sub> 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 CO<sub>2</sub> closed loop system.
  - (c) A batch that is sterilized in accordance with subsection (a) or (b) of this section must be sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.
  - (d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.
- (5) Failed solvent testing.
- (a) If a sample from a batch fails solvent testing the batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level.
  - (b) A batch that is remediated in accordance with subsection (a) of this section must be re-sampled and re-tested in accordance with these rules and must be tested if not otherwise required for that product under these rules, for solvents and pesticides.
  - (c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.
- (6) 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) 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.
- (7) Failed pesticide testing.
- (a) If a sample from a batch of 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 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 Guidelist 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 usable marijuana that has passed pesticide testing under OAR 333-007-0320 and a sample from a batch of a cannabinoid concentrate or extract fails pesticide testing the batch may be remediated using procedures that would reduce the concentration of pesticides to less than the action level.

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

(8) Failed potency testing.

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

(9) 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.

(10) 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.

(11) 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.

(12) 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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0470**

#### **Tentative Identification of Compounds**

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

(2) The Authority 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.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **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 registrant's choosing to be tested in order to determine whether a registrant is in compliance with OAR 333-007-0300 through 333-007-0500.

(2) A laboratory doing audit testing under section (1) of this rule must comply with these rules.

(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) Other contaminants that may pose a risk to public health and safety.

(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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-0500**

#### **Quality Control and Research and Development Testing**

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

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

(3) A registrant or licensee that submits a marijuana item 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 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) 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.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555

### **333-007-2000**

#### **OLCC Licensee Pesticide Testing Requirements**

(1) Notwithstanding OAR 333-007-0320, the Commission may establish the frequency of pesticide testing required by a producer or wholesaler as long as at least one-third of the batches in a harvest lot are tested. The producer or wholesaler must permit the laboratory that conducts the sampling to choose the batches to sample from and may not direct the laboratory to sample from specific batches.

(2) If any sample taken from a batch in accordance with section (1) of this rule fails a pesticide test, every batch from the harvest lot must be tested for pesticides.

(3) If all samples from each randomly chosen batch of a harvest lot pass pesticide testing, the entire harvest lot is considered to have passed pesticide testing and may be transferred or sold.

(4) A laboratory cannot be considered to be in violation of any accreditation standard for reporting test results in accordance with this rule.

Stat. Auth.: ORS 475B.555

Stats. Implemented: ORS 475B.555