

DRAFT
August 31, 2020

333-007-0310

Definitions

(X) "Standard operating procedure" for the purposes of producing kief includes but is not limited to procedures for creating the kief, purging unwanted components from the kief, thoroughly cleaning all equipment, counters and surfaces used to produce the kief, and appropriate use of any necessary safety or sanitary equipment.

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.

(d) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.

(e) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.

(2) Until DATE, Aa 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.

(c) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.

(d) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.

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

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

(6) A marijuana producer producing kief as permitted under OAR 845-025-2020 is not required to test the marijuana or usable marijuana used to produce the kief for water activity or moisture content prior to producing the kief.

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0330

Compliance Testing Requirements for Cannabinoid Concentrates and Extracts

(1) A producer, processor or processing site must test every process lot of a finished cannabinoid concentrate or extract for use by a consumer or patient prior to selling or transferring the cannabinoid concentrate or extract for the following:

Commented [FM1]: This includes inhalable cannabinoid products since they are considered a subset of cannabinoid products. This would apply to marijuana and usable marijuana being used to make an inhalable cannabinoid product such as twax joints and moonrocks

- (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.
 - (d) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.
 - (e) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.
 - (2) A **producer**, processor or processing site must test every process lot of a cannabinoid concentrate or extract intended for use by a processor or processing site to make a cannabinoid product for the following, except for a cannabinoid concentrate that meets the criteria in section (6) of this rule:
 - (a) Pesticides in accordance with OAR 333-007-0400.
 - (b) Solvents in accordance with OAR 333-007-0410.
 - (c) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.
 - (d) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.
 - (e) This subsection only applies to a processor or processing site that will be using the cannabinoid concentrate or extract to make an inhalable cannabinoid product that contain usable marijuana. If the processor or processing site will be further processing the cannabinoid concentrate or extract to create an inhalable cannabinoid product that does not contain usable marijuana in its original form, then this subsection does not apply.
 - (3) A **producer**, 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 **producer**, 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 **producer or** processor may transport batches of cannabinoid concentrates or extracts to a wholesaler licensed by the Commission under ORS 475B.100 and the wholesaler may order and arrange for the sampling and testing of the batches, in accordance with rules established by the Commission.
 - (6) A process lot of a cannabinoid concentrate that is made only using food grade animal fat or food grade plant-based oil is not required to be tested for pesticides, heavy metals or mycotoxins if:
 - (a) All marijuana or usable marijuana used to make the concentrate was tested for ~~pesticides~~ and passed:
 - (A) Pesticide testing in accordance with OAR 333-007-0400;
 - (B) On and after DATE, heavy metals testing in accordance with OAR 333-007-XXXX; and
 - (C) On and after DATE, mycotoxin testing in accordance with OAR 333-077-XXXX; and
 - (b) The concentrate itself is only used to make a cannabinoid product intended for human consumption or use but not intended for inhalation and the concentrate is not sold directly to consumers or patients.
- Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

Commented [FM2]: This includes inhalable cannabinoid products since they are considered a subset of cannabinoid products

333-007-0335

Compliance Testing Requirements for Finished Inhalable Cannabinoid products

- (1) A processor or processing site must test every process lot of a finished inhalable Cannabinoid product for use by a consumer or patient prior to selling or transferring the product for the following:
 - (a) Pesticides in accordance with OAR 333-007-0400.

Commented [FM3]: Product examples: infused pre-rolls with non-marijuana terpenes/flavorings, moonrocks/asteroids, twax, "blunts" that are wrapped in non-marijuana leaves, extract or concentrate blended with non-marijuana terpenes.

- (b) Solvents in accordance with OAR 333-007-0410.
 - (c) THC and CBD concentration in accordance with OAR 333-007-0430.
 - (d) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.
 - (e) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.
 - (2) Finished inhalable cannabinoid product containing any combination of only marijuana, usable marijuana, or cannabinoid concentrate or extract are not subject to section (1) of this rule. Marijuana or usable marijuana being used in the finished inhalable product must be tested in accordance with OAR 333-007-0320(3) and the cannabinoid concentrate or extract being used in the inhalable finished product must be tested in accordance with OAR 333-007-0330(2). The Finished Inhalable Cannabinoid Product must be tested for THC and CBD concentration in accordance with OAR 333-007-0430.
 - (3) A processor or processing site must test a process lot of an inhalable cannabinoid product for microbiological contaminants in accordance with OAR 333-007-0390, upon written request by the Authority or the Commission.
 - (4) In lieu of ordering and arranging for the sampling and testing required in this rule a processor may transport batches of inhalable Cannabinoid products 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.
 - (5) To the extent that the testing required under this rule is also required under OAR 333-007-0340, a processor or processing site is only required to comply with the testing under this rule.
- Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

333-007-XXXX

Standards for Heavy Metal Compliance Testing

- (1) A marijuana item required to be tested for heavy metals must be tested by a laboratory for the analytes listed in Exhibit A, Table X, incorporated by reference. [Table attached.]
- (2) A batch fails heavy metal testing if a laboratory detects the presence of a heavy metal above the action levels listed in Exhibit A, Table X in any sample, including a field duplicate:
 - (a) During an initial test where no reanalysis is requested; or
 - (b) Upon reanalysis as described in OAR 333-007-0450(1).

<u>Heavy Metal</u>	<u>Action Level (ug/g)</u>
	<u>marijuana, usable marijuana, cannabinoid concentrates, cannabinoid extracts, inhalable Cannabinoid products</u>
<u>Arsenic</u>	<u>0.2</u>
<u>Cadmium</u>	<u>0.2</u>
<u>Lead</u>	<u>0.5</u>
<u>Mercury</u>	<u>0.1</u>

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

333-007-XXXX

Standards for Mycotoxin Contaminants Compliance Testing

- (1) A marijuana item required to be tested for mycotoxin must be tested by a laboratory for:
 - (a) Aflatoxins B1, B2, G1, G2; and
 - (b) Ochratoxin A.

Commented [FM4]: California action levels for inhalable marijuana items

(2) A batch fails mycotoxin testing if, during an initial test where no reanalysis is requested or upon reanalysis as described in OAR 333-007-0450(1), the laboratory detects levels above the following:
(a) Total of aflatoxin B1, B2, G1, and G2 exceeds 0.02 µg/g of the marijuana item; or
(b) Ochratoxin A exceeds 0.02 µg/g of the marijuana item.
Statutory/Other Authority: ORS 475B.555
Statutes/Other Implemented: ORS 475B.555

333-007-0440

Control Study

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

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

(a) A request for a control study on a form prescribed by the Authority or Commission; and

(b) For cannabinoid products and inhalable cannabinoid products that contain usable marijuana provides:

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

(B) The amount of THC per serving the processor or processing site intends the cannabinoid product except for inhalable cannabinoid products to have per unit of sale of the product;

(C) The unit of sale and number of servings in the unit of sale-size;

(D) Product category (edible and type, tincture, topical, capsule);

(E) The final weight ~~or volume~~ of the unit of sale; and

(F) The texture of product.

(c) For cannabinoid concentrates, ~~and~~ extracts, and inhalable cannabinoid products that do not contain usable marijuana provides:

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

(B) The final weight ~~and volume if applicable~~, of the unit of sale, ~~the number of servings in the unit of sale and the serving size in the unit of sale~~;

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

(D) The texture of the concentrate or extract.

(d) A description of any variation of the product, concentrate or extract the processor or processing site intends to include under the control study that would be permitted under section (1) of this rule, including for each separate product, concentrate or extract the weight of the unit of sale, the number of servings in the unit of sale and the serving size in the unit of sale.

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

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

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

- (b) Solvents in accordance with OAR 333-007-0410; ~~and~~
- (c) THC concentration in accordance with OAR 333-007-0430 if the ~~concentrate or extract~~ marijuana item is intended to be transferred or sold directly to a consumer or patient; ~~-~~
- (d) On and after DATE, heavy metals testing in accordance with OAR 333-007-XXXX; and
- (i) On and after DATE, mycotoxin testing in accordance with OAR 333-077-XXXX.
- (4) Sample increments from a cannabinoid product, except for inhalable cannabinoid products, must be tested for THC concentration in accordance with OAR 333-007-0430, as calculated pursuant to OAR 333-064-0100.
- (5) Sample increments from an inhalable cannabinoid products that contain useable marijuana must be tested as follows:
- (a) For THC and CBD concentration in accordance with OAR 333-007-0430 if the inhalable cannabinoid product contains only any combination of marijuana or usable marijuana that passed testing under OAR 333-007-0320(3) or cannabinoid concentrate or extracts that passed testing under OAR 333-007-0330(2).
- (b) For all other inhalable cannabinoid products must be tested for:
- (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.
- (D) On or after DATE, heavy metals in accordance with OAR 333-007-XXXX.
- (E) On or after DATE, mycotoxins in accordance with OAR 333-007-XXXX.
- (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 and CBD, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch does not exceed 20 percent RSD; ~~and~~
- (B) For cannabinoid products, the amount of THC and CDB in any sample increment, as calculated pursuant to OAR 333-064-0100, does not exceed by more than 20 percent the amount of THC the processor or processing site intended the product to contain as described in section (1) of this rule, unless the target THC is below 10 mg per unit of sale in which case this paragraph does not apply; and
- (C) 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; ~~and-~~
- (d) On and after DATE, passes heavy metals testing in accordance with OAR 333-007-XXXX; and
- (e) On and after DATE, passes mycotoxin testing in accordance with OAR 333-077-XXXX.
- (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.
- (d) On and after DATE, heavy metals if applicable; and
- (d) On and after DATE, mycotoxin testing 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), or on and after DATE OAR 333-007-XXXX (Heavy Metals), or on and after DATE OAR 333-077-XXXX (Mycotoxins).

(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, OAR 333-007-XXXX (Heavy Metals), DATE OAR 333-077-XXXX (Mycotoxins) 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, OAR 333-007-XXXX (Heavy Metals), OAR 333-077-XXXX (Mycotoxins) 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 or CBD in a cannabinoid concentrate, extract or product, as calculated pursuant to OAR 333-064-0100, between sample increments taken from the batch exceeds:

(A) 20 percent RSD; or

(B) For cannabinoid products except for inhalable cannabinoid products, the amount of THC the processor or processing site intended the product to contain as described in section (1) of this rule is exceeded by more than 20 percent, unless the target THC is below 10 mg per unit of sale in which case this paragraph does not apply.

(c) The amount or percentage of THC as calculated pursuant to OAR 333-064-0100 for any sample increment, exceeds the maximum concentration limit permitted in a package by more than 10 percent as specified in 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(~~810~~)(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(~~108~~)(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 on and after January 1, 2019~~ 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 two years except as provided in section (10) of this rule:

(a) For cannabinoid concentrates and extracts and inhalable cannabinoid products that do not contain usable marijuana, 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. 3.3.

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

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

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

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

(A) To the standard operating procedures for that cannabinoid concentrate, extract or product, including changes that alter the texture, weight or volume of the unit of sale, homogeneity or for products, [except for inhalable cannabinoid products](#), expected THC potency.

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

(b) If a cannabinoid concentrate, extract or product 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 finished cannabinoid product.

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

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

(a) Reviews documentation associated with the control study;

(b) Certifies the control study; and

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

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

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

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

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

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555

333-007-0450

Failed Test Samples

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

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

(b) If a registrant or licensee has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the registrant or licensee has seven calendar days from the date the laboratory

sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 days from the date the retesting was requested.

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

(A) A request for reanalysis of a sample;

(B) The testing results of the reanalysis;

(C) A request for retesting; and

(D) The results of retesting.

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

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

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

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

(4) Except as otherwise permitted under this rule, a cannabinoid concentrate or extract that is permitted to undergo remediation cannot be further processed into a cannabinoid product during the remediation process.

(5) If a licensee or registrant is permitted under this rule to sell or transfer a batch that has failed a test, the licensee or registrant must notify the licensee or registrant to whom the batch is sold or transferred of the failed test.

(6) Failed microbiological contaminant testing.

(a) If a sample from a batch of 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 sampled and tested in accordance with these rules and must be tested if not otherwise required for that product, for microbiological contaminants, solvents and pesticides.

(d) A batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with subsection (a) or (b) of this section must be destroyed in a manner specified by the Authority or the Commission.

(7) Failed solvent testing.

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

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

(c) A batch that fails solvent testing that is not remediated or that if remediated fails testing must be destroyed in a manner specified by the Authority or the Commission.

(8) Failed water activity or moisture content testing.

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

(A) Be used to make a cannabinoid concentrate or extract if the processing method effectively sterilizes the batch; or

(B) Continue to dry or cure.

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

(9) Failed pesticide testing.

(a) If a sample from a batch of 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 Guide List for Pesticides and Cannabis and the product was applied in accordance with the label, the Authority or the Commission may permit the producer or grower to remediate the usable marijuana using procedures that would reduce the concentration of pesticides to less than the action level. A batch of usable marijuana that is permitted to be remediated must be re-sampled and re-tested for pesticides in accordance with these rules.

(d) If a processor or a processing site is only processing with usable marijuana that has passed pesticide testing under OAR 333-007-0320 and a sample from a batch of a cannabinoid concentrate or extract or inhalable cannabinoid product 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.

(10) 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.

(XX) Failed heavy metal testing.

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

(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 pesticides, solvents (if applicable), heavy metals and mycotoxins.

(c) A batch that fails heavy metal testing that if unable to be remediated must be destroyed in a manner specified by the Authority or the Commission.

(XX) Failed mycotoxin testing.

(a) If a sample from a batch fails mycotoxin testing the batch may be remediated using procedures that would reduce the concentration of mycotoxin 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 pesticides, solvents (if applicable), heavy metals and mycotoxins.

(c) A batch that fails mycotoxin testing that is unable to be remediated must be destroyed in a manner specified by the Authority or the Commission.

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

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

(13) A registrant must, as applicable:

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

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

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

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

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

Statutory/Other Authority: ORS 475B.555

Statutes/Other Implemented: ORS 475B.555