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OREGON LIQUOR AND CANNABIS COMMISSION

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RULES:

845-025-1310, 845-025-2700, 845-025-2750, 845-025-5800, 845-025-5815, 845-025-5820, 845-025-5830, 845-026-0400, 845-026-0410, 845-026-0415, 845-026-4110

AMEND: 845-025-1310

RULE TITLE: Artificially Derived Cannabinoids

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule details regulations for artificially derived cannabinoids. The changes to this rule clarify that that the commission takes into account the concentration of the cannabinoid in the product in determining whether an artificially derived cannabinoid is impairing or intoxicating.

RULE TEXT:

(1) A licensee may transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid, including an artificially derived cannabinoid created by a refinement process using a reactive material such as bleaching clay, or a marijuana or hemp item that contains an artificially derived cannabinoid if:

(a) The artificially derived cannabinoid:

(A) Is not a controlled substance under OAR chapter 855, division 80;

(B) Was manufactured in compliance with applicable laws relating to food safety;

(C) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the item; and

(D) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(b) The item is not intended for human inhalation; and

(c) The manufacturer of the artificially derived cannabinoid:

(A) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid and supplied a copy of that determination to the Commission;

(B) Has provided to the Commission a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

- (C) Has provided to the Commission an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.
- (2) The Commission will notify the licensee of acceptance of documentation received under paragraph (1)(c)(A), (B) or (C) of this rule and may apply additional labeling and concentration limit rules.
- (3) Until January 2, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured before July 1, 2023 containing the artificially derived cannabinoid cannabiniol (CBN) if:
- (a) The item is not intended for human inhalation; and
 - (b) The CBN:
 - (A) Is not a controlled substance under OAR chapter 855, division 80; and
 - (B) Was manufactured in compliance with applicable laws relating to food safety.
- (4) Until January 2, 2025, a licensee may transfer, sell, transport, purchase, possess, accept, return, or receive any marijuana or hemp item manufactured on or after July 1, 2023 containing the artificially derived cannabinoid cannabiniol (CBN) if:
- (a) The item is not intended for human inhalation; and
 - (b) The CBN:
 - (A) Is not a controlled substance under OAR chapter 855, division 80;
 - (B) Was manufactured in compliance with applicable laws relating to food safety; and
 - (C) Was manufactured by a person with written approval from the Commission affirming that the manufacturer:
 - (i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;
 - (ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN and provided the Commission with a copy of the analysis; and
 - (iii) Has provided the Commission with copies of any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring a preventive control.
- (5) A manufacturer may request written approval as described in paragraph (4)(b)(C) of this rule in a form and manner prescribed by the Commission. The Commission:
- (a) Shall publish a list of manufacturers who obtain this written approval.
 - (b) May revoke this approval if the manufacturer no longer meets the requirements described in subsection (4)(b) of this rule. If the Commission revokes approval, the manufacturer has the right to a hearing under the procedures in ORS chapter 183.
 - (c) May consult with the Oregon Department of Agriculture for the purposes of reviewing the request.
- (6) If the Commission requires a manufacturer to submit or produce documents to the Commission that the manufacturer believes falls within the definition of a trade secret as defined in ORS 192.501, the manufacturer must mark each document "confidential" or "trade secret."
- (7) A licensee may not transfer, sell, transport, purchase, possess, accept, return, or receive an artificially derived cannabinoid or a marijuana or hemp item that contains an artificially derived cannabinoid other than as provided in this rule.
- (8) The Commission may reevaluate the regulation of artificially derived cannabinoids on an annual basis, including establishing purity standards.

STATUTORY/OTHER AUTHORITY: ORS 475C.017

STATUTES/OTHER IMPLEMENTED: ORS 475C.017

AMEND: 845-025-2700

RULE TITLE: Industrial Hemp Grower Certificate Application; Denial; Revocation

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule describes the application, denial, and revocation of industrial hemp grower certificate applications. The changes to this rule enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

(1) Hemp growers may apply for an industrial hemp grower certificate to transfer industrial hemp or hemp items to a processor licensed under ORS 475C.085, a wholesaler licensed under ORS 475C.093, or a retailer licensed under ORS 475C.097.

(2) The application must:

(a) Include proof of licensure under ORS 571.281;

(b) Include the certificate and application fees specified in OAR 845-025-1060;

(c) Identify the licensed Oregon Department of Agriculture location from which the industrial hemp or hemp items will be transferred from for transport to a Commission licensee; and

(d) Include any other information identified in the application form.

(3) Incomplete Applications.

(a) The Commission must review an application to determine if it is complete. An application may be considered incomplete if an application form is not complete, the full application and certificate fee has not been paid, or some or all of the additional information required under these rules is not submitted.

(b) An applicant may submit a written request for reconsideration of a decision that an application is incomplete. Such a request must be received by the Commission within 10 days of the date the incomplete notice was mailed to the applicant. The Commission shall give the applicants the opportunity to be heard if an application is rejected. A hearing under this subsection is not subject to the requirements for contested case proceedings under ORS 183.310 to 183.550.

(4) Denial.

(a) The Commission may deny any application under this rule if:

(A) The application does not meet the requirements of section (2) of this rule;

(B) The applicant submits false or misleading information; or

(C) The Commission has reasonable cause to believe that the applicant does not have a good record of compliance with ORS 475C.005 to 475C.525 or applicable rules adopted thereunder, or with ORS 571.260 to ORS 571.348 or applicable rules adopted thereunder prior to or after certification.

(b) If the Commission denies an application, it shall issue a notice of denial in accordance with ORS 183. The applicant has the right to a hearing in accordance with ORS 183.

(5) Revocation.

(a) The Commission shall revoke any industrial hemp grower certificate if the holder no longer holds a valid industrial hemp grower license issued under ORS 571.281.

(b) The Commission may revoke any industrial hemp grower certificate if:

(A) The holder violates a provision of ORS 475C.005 to 475C.525, 475C.540 to 475C.586, 475C.600 to 475C.644 or Commission rules adopted thereunder;

(B) The holder violates a provision of ORS 571.260 to ORS 571.348 or a rule adopted thereunder; or

(C) The holder submits false or misleading information to the Commission.

(c) If the Commission revokes a certificate, the holder has a right to a hearing in accordance with ORS 183.

STATUTORY/OTHER AUTHORITY: ORS 475C.017

STATUTES/OTHER IMPLEMENTED: ORS 571.336, 571.337

AMEND: 845-025-2750

RULE TITLE: Industrial Hemp Grower Certificate Privileges; Prohibitions

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule details industrial hemp grower certificate privileges and prohibitions. The changes to this rule enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

- (1) A Commission-certified hemp grower may deliver industrial hemp or hemp items to a processor, wholesaler, or retailer that holds a license issued under ORS 475C.085, 475C.093, or 475C.097 in accordance with this rule.
- (2) If transferring, selling, or transporting to a Commission licensee, a Commission-certified hemp grower may:
 - (a) Transfer, sell, or transport harvested industrial hemp, usable hemp manufactured by the grower in compliance with OAR 603-048-0125(6), or hemp kief as defined in OAR 603-048-0010 manufactured by the grower in compliance with OAR 603-048-0125(7) to a processor licensed under ORS 475C.085 that holds an industrial hemp endorsement; or
 - (b) Transfer, sell, or transport harvested industrial hemp, usable hemp manufactured by the grower in compliance with OAR 603-048-0125(6), or hemp kief as defined in OAR 603-048-0010 manufactured by the grower in compliance with OAR 603-048-0125(7) to a wholesaler licensed under ORS 475C.093; or
 - (c) Transfer, sell, or transport usable hemp manufactured by the grower in compliance with OAR 603-048-0125(6) or hemp kief as defined in OAR 603-048-0010 manufactured by the grower in compliance with OAR 603-048-0125(7) as defined in OAR 603-048-0010 to a retailer licensed under ORS 475C.097.
- (3) When transferring, selling, or transporting pursuant to section (2) of this rule, a Commission-certified hemp grower:
 - (a) May only transfer, sell, or transport harvested industrial hemp, usable hemp, or hemp kief as defined in OAR 603-048-0010 that:
 - (A) Has been tested in accordance with OAR 845-025-5800 to 845-025-5850; and
 - (B) Otherwise complies with the requirements for marijuana items under ORS 475C.005 to 475C.525, 475C.540 to 475C.586, 475C.600 to 475C.644, and Commission rules.
 - (b) May only transfer harvested industrial hemp, usable hemp, or hemp kief as defined in OAR 603-048-0010 from the location identified in the application under OAR 845-025-2700(2)(c), and only if the Commission-certified hemp grower holds an active hemp grower license issued under ORS 571.281 at that location;
 - (c) Must:
 - (A) Hold a valid industrial hemp grower certificate issued by the Commission.
 - (B) Provide the licensee a copy of any test result conducted on the industrial hemp. Test results include, but are not limited to, any pre-harvest test result conducted under OAR 603-048-0600 and any results from research and development testing.
 - (C) Comply with CTS requirements in accordance with OAR 845-025-2775.
 - (D) Transport industrial hemp in compliance with the requirements for a licensee transporting marijuana items under OAR 845-025-7700(2), (3)(b), and (8); and
 - (d) May not transfer to a licensee:
 - (A) Any industrial hemp that has failed the testing described in OAR 603-048-0600 to 603-048-0650;
 - (B) Any batch of harvested industrial hemp, usable hemp, or hemp kief as defined in OAR 603-048-0010 that has failed a test described in OAR 845-025-5800 to 845-025-5850;
 - (C) Any living industrial hemp plants; or
 - (D) Industrial hemp seed.

STATUTORY/OTHER AUTHORITY: ORS 475C.017

STATUTES/OTHER IMPLEMENTED: ORS 475C.017, ORS 571.336, 571.337

AMEND: 845-025-5800

RULE TITLE: Definitions for Industrial Hemp and Hemp Item Testing

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule sets definitions for the purposes of industrial hemp and hemp item testing. The changes to this rule enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

For the purposes of OAR 845-025-5800 to 845-025-5850, unless otherwise specified:

(1) "Batch" means:

- (a) A quantity of industrial hemp or usable hemp from a harvest lot; or
- (b) A quantity of industrial hemp concentrate, industrial hemp extract, or hemp cannabinoid product from a process lot.

(2) "Certificate holder" means a Commission-certified hemp grower or Commission-certified hemp handler.

(3) "Finished hemp cannabinoid product"

(a) Means a hemp cannabinoid product that is in its final form ready for packaging for sale or transfer to a consumer and includes all ingredients whether or not the ingredients contain cannabinoids.

(b) For sampling and testing purposes, is equivalent to a "finished cannabinoid product" as that term is defined in OAR 333-007-0310.

(4) "Finished industrial hemp concentrate or extract"

(a) Means an industrial hemp concentrate or industrial hemp extract that is in its final form ready for packaging for sale or transfer to a consumer.

(b) For sampling and testing purposes, is equivalent to a "finished cannabinoid concentrate or extract" as that term is defined in OAR 333-007-0310.

(5) "Finished inhalable hemp cannabinoid product"

(a) Means a hemp cannabinoid product that is intended for human use via inhalation, is in its final form ready for packaging for sale or transfer to consumer and includes all ingredients whether or not the ingredients contain cannabinoids.

(b) For sampling and testing purposes, is equivalent to a "finished inhalable cannabinoid product" as that term is defined in OAR 333-007-0310.

(6) "Harvested industrial hemp"

(a) Has the meaning given that term in OAR 845-025-1015.

(b) For sampling and testing purposes, is equivalent to "marijuana" as that term is defined in OAR 333-007-0310.

(7) "Hemp cannabinoid product"

(a) Has the meaning given that term in OAR 845-025-1015.

(b) For sampling and testing purposes, is equivalent to a cannabinoid product as that term is defined in OAR 333-007-0310.

(8) "Hemp kief" has the same meaning as "kief" in OAR 603-048-0010.

(9) "Industrial hemp concentrate"

(a) Has the meaning given that term in ORS 571.269 and includes hemp kief.

(b) For sampling and testing purposes, is equivalent to a "cannabinoid concentrate or extract" as that term is defined in OAR 333-007-0310.

(10) "Industrial hemp extract"

(a) Has the meaning given that term in ORS 571.269.

(b) For sampling and testing purposes, is equivalent to a "cannabinoid concentrate or extract" as that term is defined in OAR 333-007-0310.

(11) "Usable hemp"

(a) Has the meaning given that term in OAR 845-025-1015.

(b) For sampling and testing purposes, is equivalent to “usable marijuana” as that term is defined in OAR 333-007-0310.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 571.336, 571.337

STATUTES/OTHER IMPLEMENTED: ORS 571.336, 571.337

AMEND: 845-025-5815

RULE TITLE: Ordering Tests for Industrial Hemp and Hemp Items

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule details how to order tests for industrial hemp and hemp items. The changes to this rule harmonize this rule with recent changes to OAR 333-007-0315 and enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

- (1) A certificate holder must enter a batch of industrial hemp or a hemp item into CTS prior to requesting testing under these rules.
- (2) To request a compliance test, a requestor must provide a laboratory licensee, prior to the laboratory taking samples, with at a minimum, the following information as applicable:
 - (a) The licensee's or certificate holder's license or certificate number.
 - (b) The name, address, and contact information of the licensee or certificate holder.
 - (c) Whether the item is harvested industrial hemp or a hemp item and, if the item is a hemp item, the type of hemp item.
 - (d) Harvest lot identifier that is associated with the batch, if applicable.
 - (e) Process lot number or identifier that is associated with the batch, if applicable.
 - (f) Batch numbers or identifiers to be sampled.
 - (g) Total mass of each batch to be sampled.
 - (h) For hemp cannabinoid products, all intended units 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 for quality control, research and development, or any purpose other than a compliance test.
 - (l) Whether a batch is being re-sampled because of a failed test and if so, the date the failed test result was received by the licensee and laboratory licensee's license number of the laboratory that conducted the initial test.
 - (m) Whether the hemp or hemp item was remediated, if remediation is permitted under OAR 845-025-5850.
 - (n) For tests requested by a certificate holder, whether the harvested industrial hemp or hemp item is intended to be transferred to a licensee.
 - (o) For tests requested by a processor, whether the hemp item is intended to be transferred to an unlicensed person in accordance with OAR 845-025-3320.
 - (p) If a wholesaler is requesting a test on behalf of a processor, the wholesaler must provide in addition to their own license number and name, the license number and name of that processor.
- (3) If the licensee or certificate holder informs a laboratory licensee that a batch of hemp or a hemp item is being re-sampled after a failed test, the licensee or certificate holder must provide the laboratory licensee with documentation of the failed test as applicable.
- (4) It is the responsibility of the licensee or certificate holder to order the tests necessary to comply with these rules.
- (5) Limitations on the testing that a licensee or certificate holder may request.
 - (a) A licensee may only order a compliance test for a hemp item that the licensee has processed, except a wholesaler who may order a compliance test.
 - (b) An industrial hemp grower certificate holder may order a compliance test for any harvested industrial hemp, usable hemp, or hemp kief in the certificate holder's possession at the location where the certificate is held.
 - (c) An industrial hemp handler certificate holder may order a compliance test for any harvested industrial hemp or hemp item in the certificate holder's possession at the location where the certificate is held.
- (6) More than one compliance test for the same harvested industrial hemp or hemp item may not be ordered.
- (7) It is a violation of these rules for a licensee to:

- (a) Fail to provide the information required in these rules to the laboratory licensee; or
 - (b) Submit false or misleading information to a laboratory licensee or a directed agent to submit false or misleading information to a laboratory licensee.
- (8) Once a test order has been submitted to a laboratory licensee by a licensee or certificate holder and at least one test has already been performed, the order may not be canceled unless written permission is given by the Commission, the Oregon Health Authority, or the Oregon Department of Agriculture.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 571.336, 571.337

STATUTES/OTHER IMPLEMENTED: ORS 571.336, 571.337

AMEND: 845-025-5820

RULE TITLE: Compliance Testing Requirements for Industrial Hemp and Hemp Items

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule describes compliance testing requirements for industrial hemp and hemp items. The changes to this rule enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

(1) Harvested industrial hemp.

(a) A certificate holder must have every batch from a harvest lot of harvested industrial hemp tested as required and in the same manner as marijuana under OAR 333-007-0320; and

(b) A certificate holder must have every batch from a harvest lot of harvested industrial hemp tested for adult use cannabinoid and CBD concentration as described in OAR 333-007-0430, in addition to and notwithstanding whether this test would be required for marijuana under OAR 333-007-0320.

(2) Usable hemp.

(a) A certificate holder must have every batch from a harvest lot of usable hemp tested as required and in the same manner as usable marijuana under OAR 333-007-0320; and

(b) A certificate holder must have every batch from a harvest lot of usable hemp tested for adult use cannabinoid and CBD concentration as described in OAR 333-007-0430, in addition to and notwithstanding whether this test would be required for usable marijuana under OAR 333-007-0320.

(3) Industrial hemp concentrates and industrial hemp extracts.

(a) A Commission-certified hemp handler or processor must have every process lot of industrial hemp concentrate or industrial hemp extract tested as required and in the same manner as cannabinoid concentrates and extracts under OAR 333-007-0330; and

(b) A Commission-certified hemp handler must have every process lot of industrial hemp concentrate or industrial hemp extract tested for adult use cannabinoid and CBD concentration as described in OAR 333-007-0430, in addition to and notwithstanding whether this test would be required for a cannabinoid concentrate or extract under OAR 333-007-0330.

(c) A Commission-certified hemp grower must have every process lot of hemp kief tested as required and in the same manner as cannabinoid concentrates and extracts under OAR 333-007-0330; and

(d) A Commission-certified hemp grower must have every process lot of hemp kief tested for adult use cannabinoid and CBD concentration as described in OAR 333-007-0430, in addition to and notwithstanding whether this test would be required for a cannabinoid concentrate or extract under OAR 333-007-0330.

(4) Hemp cannabinoid products.

(a) A Commission-certified hemp handler or processor must have every process lot of hemp cannabinoid product tested as required and in the same manner as cannabinoid products under OAR 333-007-0340; and

(b) A Commission-certified hemp handler must have every process lot of hemp cannabinoid product tested for adult use cannabinoid and CBD concentration in accordance with OAR 333-007-0430, notwithstanding whether this test would be required for a cannabinoid product under OAR 333-007-0340.

(5) Finished inhalable hemp cannabinoid products. A Commission-certified hemp handler or processor must have every process lot of finished inhalable hemp cannabinoid product tested as required and in the same manner as finished inhalable cannabinoid products under OAR 333-007-0340.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 571.336, 571.337

STATUTES/OTHER IMPLEMENTED: ORS 571.336, 571.337

AMEND: 845-025-5830

RULE TITLE: Batch Testing Requirements for Industrial Hemp and Hemp Items

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule details batch testing requirements for industrial hemp and hemp items. The changes to this rule enable hemp grower certificate holders to transfer usable hemp and hemp kief made by the grower to OLCC licensees, consistent with their Oregon Department of Agriculture hemp grower license privileges.

RULE TEXT:

(1) Harvested industrial hemp:

(a) A certificate holder must separate each harvest lot of harvested industrial hemp harvested before July 1, 2022 into no larger than 30 pound batches.

(b) A certificate holder must separate each harvest lot of harvested industrial hemp harvested on or after July 1, 2022 into no larger than 50.0 pound batches.

(2) Usable hemp:

(a) A processor or certificate holder must separate each harvest lot of usable hemp harvested before July 1, 2022 into no larger than 30 pound batches.

(b) A processor or certificate holder must separate each harvest lot of usable hemp harvested on or after July 1, 2022 into no larger than 50.0 pound batches.

(3) Industrial hemp concentrates or extracts:

(a) A process lot of an industrial hemp concentrate or extract is considered a batch.

(b) A batch of industrial hemp concentrate, or extract must be produced using a standard operating procedure and result in one finished industrial hemp concentrate or extract that is uniform in texture and form.

(4) Hemp cannabinoid products.

(a) A processor or Commission-certified hemp handler must separate process lots into not larger than 35,000 unit of sale batches.

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

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

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

(c) If a hemp cannabinoid product is or may be sold in different quantities in a unit of sale, then the process lot shall be sampled based on the smallest unit of sale for the purposes of sampling and testing. All proposed units of sales must meet the Commission's concentration limit rules found in OAR 845-025-2760.

(5) Finished inhalable hemp cannabinoid products.

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

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

(6) Batch identifiers.

(a) A Commission-certified hemp grower must:

(A) Assign each batch grown by the grower a unique numerical identifier as described in OAR 603-048-0500 and enter this information into CTS.

(B) Record the lot identifier or unique identifier for any harvested industrial hemp not grown by the handler as described in OAR 603-048-0500 and enter this information into CTS.

(C) Assign each batch of usable hemp or hemp kief processed by the grower a process lot identifier as described in OAR 603-048-0500 and enter this information into CTS. A grower may not reuse a process lot identifier.

(D) Record the process lot identifier or unique identifier for any usable hemp or hemp kief not processed by the grower as described in OAR 603-048-0500 and enter this information into CTS.

(b) A Commission-certified hemp handler must:

(A) Assign each batch processed by the handler a process lot identifier as described in OAR 603-048-0500 and enter this information into CTS. A handler may not reuse a process lot identifier.

(B) Record the lot identifier or unique identifier for any harvested industrial hemp or hemp item not processed by the handler as described in OAR 603-048-0500 and enter this information into CTS.

(c) A processor must assign every process lot a unique identification number and enter this information into CTS.

(7) Sampling and sample size requirements for compliance testing.

(a) Harvested industrial hemp and usable hemp must be sampled as described for marijuana or usable marijuana in OAR 333-007-0360.

(b) Industrial hemp concentrates, industrial hemp extracts, hemp cannabinoid products, and finished inhalable hemp cannabinoid products must be sampled as required in OAR 333-007-0360 for the equivalent marijuana item identified in OAR 845-025-5800.

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

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

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

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

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 571.336, 571.337

STATUTES/OTHER IMPLEMENTED: ORS 571.336, 571.337

AMEND: 845-026-0400

RULE TITLE: Maximum Concentration and Serving Size Limits for Industrial Hemp Products: Definitions, Purpose, Scope and Effective Date

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule sets the scope, definitions, purpose, and effective date for hemp item concentration and serving size limits pursuant to ORS 571.309. The changes to this rule separates limits established pursuant to ORS 475C.257 from limits established pursuant to ORS 571.309; establish a serving size limit for hemp tinctures; and establish conditions for the presence of artificially derived cannabinoids.

RULE TEXT:

(1) Applicability.

(a) Except as provided in subsection (b) of this section, this rule applies to industrial hemp products that:

(A) Contain cannabinoids and are intended for human consumption or intended for human use; and

(B) Are offered for sale, transfer, or delivery to a consumer in Oregon or imported into Oregon for delivery to a consumer.

(b) This rule does not apply to hemp items, as that term is defined in OAR 845-025-1015, that are subject to the concentration and serving size limits in OAR 845-025-2760.

(2) An industrial hemp product meets the concentration limits permitted under this rule if:

(a) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent;

(b) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum concentration of THC permitted by more than 10 percent; and

(c) The testing done in accordance with ORS 571.330 or 571.339 was performed using a method with a LOQ sufficient to demonstrate that the total delta-9-THC does not exceed the maximum amount of THC permitted in a container by more than 10 percent.

(3) The maximum concentration and amount of total delta-9-THC permitted in a container and the maximum concentration or amount of total delta-9-THC permitted in a serving is listed in Table 3, incorporated by reference.

(4) An industrial hemp product may only contain an artificially derived cannabinoid if:

(a) Until January 2, 2025:

(A) The industrial hemp product contains only artificially derived cannabinoid cannabino (CBN);

(B) The product is not intended for human inhalation; and

(C) The CBN:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety; and

(D) The manufacturer of the CBN:

(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;

(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN; and

(iii) Has documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control; or

(b) At any time:

(A) The artificially derived cannabinoid:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety;

(iii) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the product; and

(iv) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three

peer-reviewed publications.

(B) The product is not intended for human inhalation; and

(C) The manufacturer of the artificially derived cannabinoid:

(i) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid;

(ii) Has received a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(iii) Has received an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

(5) Serving size is as determined by the manufacturer and must comply with applicable serving size limits.

(6) An industrial hemp product that does not fall within a category in Table 3 must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 3.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, 475C.405, ORS 571.309, 2024 OL Ch. 16 Sec. 9

STATUTES/OTHER IMPLEMENTED: ORS 571.309, 2024 OL Ch. 16 Sec. 9

OAR 845-026-0400

Table 3

INDUSTRIAL HEMP PRODUCT THC CONCENTRATION AND SERVING SIZE LIMITS			
Type of Industrial Hemp Product	Maximum Amount of Total Delta-9-THC Per Serving	Maximum Amount of Total Delta-9-THC per Container	Maximum Concentration of Total Delta-9-THC
Hemp Edibles	2 mg	20 mg	0.3%
Hemp Topicals	N/A	N/A	0.3%
Hemp Transdermal Patches	2 mg	20 mg	0.3%
Hemp Tinctures	2 mg	100 mg	0.3%
Usable Hemp	N/A	N/A	0.3%
Industrial Hemp Concentrates or Extracts	N/A	N/A	0.3%
Cannabinoid Hemp Products Other than Hemp Edibles, Topicals, Tinctures, or Transdermal Patches	2 mg	20 mg	0.3%

ADOPT: 845-026-0410

RULE TITLE: Adult Use Cannabinoid Concentration Level for Industrial Hemp Commodities or Products Constituting Marijuana Items: Definitions, Purpose, Scope and Effective Date

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule sets the scope, definitions, purpose, and effective date for hemp item concentration and serving size limits pursuant to ORS 475C.257. The changes to this rule separates limits established pursuant to ORS 475C.257 from limits established pursuant to ORS 571.309; establish a serving concentration limit for hemp tinctures; and establish conditions for the presence of adult use cannabinoids that are artificially derived cannabinoids.

RULE TEXT:

(1) Applicability.

(a) Except as provided in subsection (b) of this section, this rule applies to industrial hemp commodities or products that:

(A) Contain cannabinoids and are intended for consumption or use by humans or animals; and

(B) Are offered for sale or transfer to a consumer in Oregon or imported into Oregon for delivery to a consumer.

(b) Hemp items, as that term is defined in OAR 845-025-1015, subject to the concentration and serving size limits in OAR 845-025-2760 must also comply with the requirements in OAR 845-025-2760.

(2) An industrial hemp commodity or product does not exceed the concentration limits established under this rule if:

(a) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum amount of THC permitted by more than 10 percent;

(b) The total delta-9-THC as calculated in accordance with OAR 333-064-0100(4) does not exceed the maximum concentration of THC permitted by more than 10 percent; and

(c) The testing done in accordance with ORS 571.330 or 571.339 was performed using a method with a LOQ sufficient to demonstrate that the total delta-9-THC does not exceed the maximum amount of THC permitted in a container by more than 10 percent.

(3) Table 4, incorporated by reference, establishes the maximum concentration and amount of total delta-9-THC for a container and the maximum concentration or amount of total delta-9-THC for a serving.

(4) An industrial hemp commodity or product may contain an adult use cannabinoid that is an artificially derived cannabinoid only if:

(a) Until January 2, 2025:

(A) The industrial hemp product contains only artificially derived cannabinoid cannabinol (CBN);

(B) The product is not intended for human inhalation; and

(C) The CBN:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety; and

(D) The manufacturer of the CBN:

(i) Has taken substantial steps towards meeting the requirements described in subsection (1)(c) of this rule, including but not limited to initiating or contracting to initiate safety studies;

(ii) Has conducted a hazard analysis as described in 21 CFR 117.130 to identify foreseeable hazards in the process of manufacturing the CBN; and

(iii) Has documented any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring preventive control; or

(b) At any time:

(A) The artificially derived cannabinoid:

(i) Is not a controlled substance under OAR chapter 855, division 80;

(ii) Was manufactured in compliance with applicable laws relating to food safety;

(iii) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the product; and

(iv) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three

peer-reviewed publications.

(B) The product is not intended for human inhalation; and

(C) The manufacturer of the artificially derived cannabinoid:

(i) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid;

(ii) Has received a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or

(iii) Has received an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

(5) Serving size is as determined by the manufacturer and must comply with applicable serving size limits.

(6) An industrial hemp commodity or product that does not fall within a category in Table 4 must meet the concentration and serving size limits applicable to a cannabinoid edible in Table 4.

(7) Civil Penalties. The Commission may impose a civil penalty of no more than \$10,000 for each violation of ORS 475C.257 against a person other than a commission-licensed marijuana retailer for selling an industrial hemp commodity or product to a consumer that exceeds the concentration and serving size limits in this rule.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 475C.257, 2024 OL Ch. 16 Sec. 9

STATUTES/OTHER IMPLEMENTED: ORS 475C.257, 2024 OL Ch. 16 Sec. 9

OAR 845-026-0410

Table 4

INDUSTRIAL HEMP PRODUCT THC CONCENTRATION AND SERVING SIZE LIMITS			
Type of Industrial Hemp Product	Maximum Amount of Total Delta-9-THC Per Serving	Maximum Amount of Total Delta-9-THC per Container	Maximum Concentration of Total Delta-9-THC
Hemp Edibles	2 mg	20 mg	0.3%
Hemp Topicals	N/A	N/A	0.3%
Hemp Transdermal Patches	2 mg	20 mg	0.3%
Hemp Tinctures	2 mg	100 mg	0.3%
Usable Hemp	N/A	N/A	0.3%
Industrial Hemp Concentrates or Extracts	N/A	N/A	0.3%
Cannabinoid Hemp Products Other than Hemp Edibles, Topicals, Tinctures, or Transdermal Patches	2 mg	20 mg	0.3%

ADOPT: 845-026-0415

RULE TITLE: Standards for Approving Industrial Hemp Products That Contain Artificially Derived Cannabinoids

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule establishes standards for approving industrial hemp products that contain artificially derived cannabinoids.

RULE TEXT:

An industrial hemp product that contains an artificially derived cannabinoid may be approved on or after January 1, 2026, if:

(1) The artificially derived cannabinoid:

- (a) Is not a controlled substance under OAR chapter 855, division 80;
- (b) Was manufactured in compliance with applicable laws relating to food safety;
- (c) In the Commission's judgment, is not impairing or intoxicating at the intended concentration in the product; and
- (d) Has been reported as a naturally-occurring component of the plant Cannabis family Cannabaceae in at least three peer-reviewed publications.

(2) The product is not intended for human inhalation; and

(3) The manufacturer of the artificially derived cannabinoid:

- (a) Has made a "Generally Recognized as Safe" (GRAS) determination for the artificial cannabinoid;
- (b) Has received a Food and Drug Administration (FDA) letter responding to a "Generally Recognized as Safe" (GRAS) notice for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses, affirming that FDA has no questions about the notice; or
- (c) Has received an FDA letter of acknowledgement with no objections in response to a New Dietary Ingredient notification for the artificially derived cannabinoid manufactured by the same method that the manufacturer uses.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, ORS 571.309, 2024 OL Ch. 16 Sec. 9

STATUTES/OTHER IMPLEMENTED: ORS 571.309, 2024 OL Ch. 16 Sec. 9

ADOPT: 845-026-4110

REPEAL: Temporary 845-026-4110 from OLCC 4-2024

RULE TITLE: Presumptive Testing

NOTICE FILED DATE: 08/28/2024

RULE SUMMARY: This rule details the procedures and requirements for presumptive testing of hemp crops.

RULE TEXT:

(1) For the purpose of this rule:

(a) "Crop" has the meaning given that term in OAR 603-048-0010.

(b) "Composite Sample" means cuttings from at least five cannabis plants removing the top five to eight inches and compositing in one receptacle for purposes of testing.

(c) "Grow site" has the meaning given that term in OAR 603-048-0010.

(d) "Presumptive test" means testing in accordance with this rule.

(e) "Production area" has the meaning given that term in OAR 603-048-0010.

(2) For the purposes of this rule:

(a) The number of production areas at a grow site is determined by a representative of the State Department of Agriculture or the Oregon Liquor and Cannabis Commission who is on-site at the time of the sampling. The representative may consider documents submitted by the licensee associated with the grow site and the number of production areas at the site actively producing cannabis at the time of the sampling.

(b) It is within the discretion of a representative of the State Department of Agriculture or the Oregon Liquor and Cannabis Commission who is on-site at the time of the sampling to determine what qualifies as different areas of the grow site.

(3) In addition to any sampling conducted under OAR 603-048-0600, a representative of the State Department of Agriculture or the Oregon Liquor and Cannabis Commission may sample from an industrial hemp grow site licensed under ORS 571.281 for the purposes of conducting a presumptive test.

(4) To conduct sampling for a presumptive test:

(a) A minimum of three composite samples from mature cannabis plants or a minimum of three composite samples from immature cannabis plants must be collected. Each composite sample must be taken from a different production area, or if the grow site has less than three production areas with growing cannabis, each composite sample must be taken from three different areas of the grow site;

(b) Grow sites with multiple production areas must have a composite sample collected from at least one out of every 10 separate production areas; and

(c) Sampling is not required to be representative of the crop, grow site, or production area.

(5) All cannabis plants at a grow site are presumptively marijuana for purposes of Section 2 of 2024 Oregon Laws Chapter 16 if sampling at the grow site meets any of the following criteria:

(a) At least 50 percent of composite samples taken from mature cannabis plants test at or above five percent total delta-9-THC;

(b) The average total delta-9-THC among the composite samples taken from mature cannabis plants tests at or above five percent;

(c) At least 50 percent of composite samples taken from immature cannabis plants test at or above a 5:1 ratio of total THC to total CBD, with total CBD calculated as described in OAR 333-064-0100, and the total THC concentration of each composite sample exceeds 0.3 percent;

(d) At least 50 percent of composite samples taken from immature cannabis plants test at or above one percent total delta-9-THC; or

(e) The average total delta-9-THC among the composite samples taken from immature cannabis plants tests at or above one percent total delta-9-THC.

STATUTORY/OTHER AUTHORITY: ORS 475C.017, 2024 OL Ch. 16 Sec. 2

STATUTES/OTHER IMPLEMENTED: 2024 OL Ch. 16 Sec. 2