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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 845
OREGON LIQUOR AND CANNABIS COMMISSION

FILED
03/27/2025 3:26 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Amend marijuana and hemp rules to extend artificially derived cannabinoid requirement deadline for CBN.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/30/2025 12:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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Filed By:
Nicole Blosse
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 04/16/2025
TIME: 9:00 AM - 10:00 AM
OFFICER: Nicole Blossé

REMOTE HEARING DETAILS
MEETING URL: Click here to join the meeting
PHONE NUMBER: 503-446-4951
CONFERENCE ID: 456312939
SPECIAL INSTRUCTIONS:
Hearing information may also be found on the OLCC web site:
https://www.oregon.gov/olcc/Pages/public_meetings.aspx.

NEED FOR THE RULE(S)

The amendments to OAR 845-025-1310 extend the exemption for artificially derived cannabinoid cannabinol (CBN) by six months. This is necessary to provide regulatory certainty to businesses that manufacture, distribute, and sell CBN products; avoid market disruption; and maintain access to these products while CBN product manufacturers determine whether they can meet the general requirements for artificially derived cannabinoids or transition to sources of CBN that are not artificially derived.

The amendments to OARs 845-026-0400 and 845-026-0410 are necessary to conform with the amendments to OAR 845-025-1310, and to comply with Section 9 of 2024 Oregon Laws, Chapter 16, which requires that rules adopted regarding industrial hemp products that contain artificially derived cannabinoids intended for retail sale be no more restrictive than the rules applicable to the sale at retail of adult use cannabis items.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2024 Oregon Laws Chapter 16 (House Bill 4121)

Permanent Administrative Order OLCC 5-2023

Temporary Administrative Order OLCC-3-2023

Permanent Administrative Order OLCC 21-2021

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

At this time, the Commission has no data to suggest that this rule will impact racial equity in the state.

FISCAL AND ECONOMIC IMPACT:

This statement takes into account the fiscal impact on (a) Marijuana Licensees; (b) Local Government; (c) State Agencies; and (d) the Public.

(a) Marijuana Licensees: The Commission expects the proposed rule amendments to have a minimal to modest impact upon some licensees. If manufacturers of artificially derived CBN are still unable to meet the general requirements for artificially derived cannabinoids by July 1, 2025, processors who made edibles with artificially derived CBN will need to change their formulation or discontinue those product lines. Retailers who still have products containing artificially derived CBN in stock will need to remove them from shelves or return them to the processor or wholesaler. However, these costs should be mitigated by giving licensees two additional years to prepare for this transition; the original deadline for artificially derived CBN to meet the same requirements as other artificially derived cannabinoids was July 2023. Some processors began transitioning to naturally derived sources of CBN in 2024.

(b) Local Government: The Commission expects the proposed amendments to have no impact upon local governments, as the rules do not apply to them.

(c) State Agencies: The Commission expects the proposed amendments to have no impact upon other state agencies, as the rules do not apply to them. The Oregon Liquor and Cannabis Commission forecasts minimal impact for the agency.

(d) The Public: The Commission anticipates the proposed rule amendments will have minimal impact on the public. If processors transition to naturally derived CBN, the unit cost of CBN edibles may increase to account for higher ingredient costs. If some processors discontinue their CBN edible lines rather than use a naturally derived source of CBN, supply could decrease relative to demand, resulting in upward price pressure. If these potential cost increases materialize, they are likely to be passed on to consumers. However, this may be mitigated to some extent because the industry has had two additional years to prepare for the transition, and some processors already began transitioning to naturally derived sources of CBN in 2024.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):
The Commission anticipates no new costs to comply with the proposed amendments for state agencies and local government.

2. Cost of compliance on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries subject to the rule:

Approximately 21 processors currently have edible products containing “CBN” in the item name and approximately 700 retailers carry edible products containing “CBN” in the item name. The Commission estimates that the majority of these licensees qualify as small businesses.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

The Commission does not anticipate these activities having any additional recordkeeping or reporting costs.

c. Equipment, supplies, labor and increased administration required for compliance:

The Commission does anticipates little to no increased costs for equipment, supplies, labor and administration to comply with these rules. A processor who transitions to naturally derived CBN in an existing edible line will need to amend their approved label and potentially order new labels. However, this should be able to happen in a non-disruptive manner given the industry has had two additional years to prepare for this change.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

OLCC held a Rules Advisory Committee meeting to assist in the development of these proposed changes and invited representatives of small businesses impacted by these rules, including licensees, retailers and permit holders.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

845-025-1310, 845-026-0400, 845-026-0410

AMEND: 845-025-1310

RULE SUMMARY: This rule details regulations for artificially derived cannabinoids.

CHANGES TO RULE:

845-025-1310
Artificially Derived Cannabinoids
(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 cannabinol (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 J~~anuar~~uly ~~2~~21, 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 cannabinol (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: 845-026-0400

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.

CHANGES TO RULE:

845-026-0400
Maximum Concentration and Serving Size Limits for Industrial Hemp Products: Definitions, Purpose, Scope and Effective Date
(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 Januar~~u~~ly ~~2~~1, 2025: ¶
(A) The ~~industrial hemp product contains~~ only artificially derived cannabinoid the industrial hemp product contains is 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 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

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

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%

AMEND: 845-026-0410

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.

CHANGES TO RULE:

845-026-0410
Adult Use Cannabinoid Concentration Level for Industrial Hemp Commodities or Products Constituting Marijuana Items: Definitions, Purpose, Scope and Effective Date
(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 J~~anuar~~uly ~~2~~1, 2025:¶
(A) The ~~industrial hemp product contains~~ only artificially derived cannabinoid the industrial hemp product contains is 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

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

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%