



**NOTICE OF PROPOSED RULEMAKING**  
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 845  
OREGON LIQUOR AND CANNABIS COMMISSION

**FILED**  
05/25/2023 12:09 PM  
ARCHIVES DIVISION  
SECRETARY OF STATE

FILING CAPTION: Extends deadline for CBN manufacturers to meet general requirements under this rule, subject to conditions.

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 06/30/2023 5:00 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:  
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HEARING(S)

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

DATE: 06/16/2023

TIME: 10:00 AM - 11:00 AM

OFFICER: Nicole Blosse

REMOTE MEETING DETAILS

PHONE NUMBER: 971-420-4763

SPECIAL INSTRUCTIONS:

This Public Hearing will be held virtually.

Meeting access will be available at [https://www.oregon.gov/olcc/Pages/public\\_meetings.aspx](https://www.oregon.gov/olcc/Pages/public_meetings.aspx) or by contacting [olcc.rulemaking@oregon.gov](mailto:olcc.rulemaking@oregon.gov).

NEED FOR THE RULE(S)

In 2021, the Oregon Legislature passed House Bill 3000, giving OLCC authority to regulate artificially derived cannabinoids in the adult use cannabis system. In December 2021, the Commission adopted OAR 845-025-1310 to implement that portion of House Bill 3000. Generally, OAR 845-025-1310 requires that artificially derived cannabinoid must either be determined to be Generally Recognized as Safe (GRAS) or be the subject of a New Dietary Ingredient notification before they can be used in marijuana or hemp items sold in the adult use system. The rule also contains an exception allowing artificially derived cannabiniol (CBN) to be used in products without meeting this requirement until July 1, 2023.

At this point, some CBN manufacturers have begun taking steps towards collecting the data and conducting the analysis needed to meet the general requirement for artificially derived cannabinoids, but none will be prepared to meet these requirements by July 1, 2023.

## DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

OLCC - Rulemaking file (Available upon request)

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

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

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### 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 proposed amendments may have either a negligible fiscal impact or a net positive fiscal impact.

The costs for a manufacturer of artificially derived CBN to comply with these requirements are negligible. These manufacturers will need to document the steps they are taking to comply with the general requirements for artificially derived cannabinoids and produce documentation that they should already have on hand showing how they have complied with certain general requirements around manufacturing food ingredients.

The amendments may have a positive fiscal impact on processors and hemp handlers who use artificially derived CBN. The amendments would allow processors and handlers to use artificially derived CBN made by out-of-state manufacturers in products intended for sale at OLCC-licensed marijuana retailers. This could potentially increase the number of manufacturers supplying the industry, resulting in greater competition and potentially reducing the wholesale price of the ingredient for this market.

#### (b) Local government:

The Commission does not anticipate that the proposed amendments will have any positive or negative fiscal impact on local governments.

#### (c) State agencies:

The processors and handlers impacted by the proposed amendments are also regulated by the Oregon Department of Agriculture Food Safety Program. At this time, the Commission cannot anticipate whether businesses manufacturing artificially derived CBN or products containing artificially derived CBN will result in any additional work for the program beyond current service levels.

The proposed amendments provide that the Commission may consult with the Oregon Department of Agriculture for the purposes of reviewing certain information related to compliance with food safety requirements. The Commission anticipates the total number of submissions on which the Oregon Department of Agriculture may be consulted will be small, and the fiscal impact of these consultations, should they occur, will be correspondingly small.

#### (d) The public:

The proposed amendments may have either a negligible fiscal impact or a net positive fiscal impact on consumers. If the current suppliers of artificially derived CBN remain unchanged, there will be no direct impact on product prices. If

increased competition from out-of-state manufacturers of artificially derived CBN reduces the cost of that ingredient, product prices may decrease slightly.

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#### 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 largely anticipates no new costs of compliance to comply with the proposed amendments for other state agencies, local governments, or the public. The Department of Agriculture may incur some costs in regulating impacted businesses.

##### 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:

As of May 12, 2023, there are approximately 181 recreational marijuana processor licenses with an edible endorsement and approximately 186 hemp handler licenses. The Commission estimates that 85% of these would qualify as small businesses. The Commission cannot estimate the number of out-of-state hemp businesses that manufacturer artificially derived CBN, but it is likely most would qualify as small businesses.

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

In order to comply with the proposed amendments, current manufacturers of artificially derived CBN for Oregon's adult use market may incur a small one-time cost to gather the documentation required for compliance. The proposed amendments would also allow out-of-state manufacturers of artificially derived cannabinoids from hemp the opportunity to supply artificially derived cannabinoids for products sold in the adult use market in Oregon. If those manufacturers do not yet meet the requirements that apply to Oregon businesses that currently manufacture artificially derived cannabinoids, there could be significant costs for those manufacturers to meet the requirements. The magnitude of the cost will vary depending on what steps the manufacturer has already taken; the cost to collect data necessary to support a generally recognized as safe (GRAS) determination or a new dietary ingredient notification can be substantial. However, it should be noted that this cost is not unique to OLCC rules and applies generally to introducing new food additives or dietary ingredients into interstate commerce.

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

The Commission anticipates costs of compliance for equipment, supplies, labor and increased administration required for compliance with the proposed amendments to be minimal. Current manufacturers of artificially derived CBN for Oregon's adult use market may incur a small one-time cost to gather the documentation required for compliance.

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#### 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 processors and hemp handlers.

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AMEND: 845-025-1310

RULE SUMMARY: Extends deadline for CBN manufacturers to meet general requirements under this rule, subject to conditions.

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 a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, and division 28;

(C) Was manufactured by a processor or an ODA Hemp Handler; laws relating to food safety;

(D) In the Commission's judgment, is not impairing or intoxicating; and

(E) 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 12, 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 cannabiol (CBN) if:

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

(b) The artificially derived cannabinoid: CBN:

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

(B) Was manufactured in a food establishment licensed by the ODA in compliance with the applicable provisions of OAR chapter 603, division 21, division 24, division 25, and division 28; and

(C) Was manufactured by a processor or an ODA Hemp Handler; laws relating to food safety.

(4) Until January 12, 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 cannabinoids cannabiol (CBN) if:

(a) The artificially derived cannabinoids were manufactured by a processor or received by a licensee from a Commission-certified 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)(a) 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 hemp handler before January 1, 2022; Commission with copies of any preventative controls, as described in 21 CFR 117.135 that minimize or prevent any hazards requiring a preventive control.

(b5) The manufacturing process did not involve treating a marijuana item or hemp item with an additive or

substance that increased the potency; and ¶

~~(e) The item otherwise complier may request written approval as described in paragraph (3)(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 (3)(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 these rules- definition of a trade secret as defined in ORS 192.501, the manufacturer must mark each document "confidential" or "trade secret." ¶~~

~~(57) 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. ¶~~

~~(68) The Commission may reevaluate the regulation of artificially derived cannabinoids on an annual basis, including establishing purity standards.~~

Statutory/Other Authority: ORS 475BC.02517

Statutes/Other Implemented: ORS 475BC.02517