

# **Recreational Marijuana Program**

## **Compliance Education Bulletin**

Changes for Artificially Derived CBN Products – Extended Deadline, Approval Requirements

CE2023-02 April 27, 2023

The Oregon Liquor and Cannabis Commission (OLCC) is providing the following information to retailer, processor, and wholesaler licensees and hemp handler certificate holders.

This education bulletin is part of OLCC's compliance education. <u>It is important that you read it and understand it</u>. If you do not understand it, please contact the OLCC for help.

Marijuana licensees and certificate holders are responsible for reading, understanding, and complying with all applicable rules. This bulletin does not supersede any OLCC rule. Failure to understand and follow the rules referenced in this bulletin *could result in an OLCC administrative violation and/or civil penalty*.

This education bulletin covers changes to artificially derived cannabinoid requirements.

## Background

On April 20, 2023, the OLCC adopted amendments to OAR <u>845-025-1310.</u>¹ These changes take effect on July 1, 2023.

The rule amendments allow artificially derived CBN products an **additional 18 months** (through **January 2, 2025**) to meet the same requirements as all other artificially derived cannabinoids. The amendments also establish an approval process for manufacturers to verify that they are in compliance with current requirements in order for their artificially derived CBN to continue to be used as an ingredient in products.

The Commission previously approved the following

<u>On and after July 1, 2023,</u> processors <u>may only</u> use artificially derived CBN from manufacturers who have been approved by OLCC. Products made prior to July 1, 2023 in compliance with the rules in place at that time may continue to be sold.

These changes were adopted through temporary rulemaking, which can only last a maximum of six months and therefore would expire December 28, 2023, barring further OLCC action. OLCC anticipates completing permanent rulemaking before these changes expire to ensure continuity of the rules through January 2, 2025.

<sup>&</sup>lt;sup>1</sup> This link shows the rule language currently in effect. It will not show the amended rule language until that amendment becomes effective on July 1, 2023. Until then, you can access the amended language here: https://secure.sos.state.or.us/oard/viewReceiptPDF.action?filingRsn=53664

### Artificially Derived CBN Requirements – Products Made On or After July 1, 2023

Beginning July 1, 2023, a processor can only manufacture a product using artificially derived CBN, and retailers can only sell items containing artificially derived CBN, if:

- The product is not intended for inhalation
- The CBN was manufactured in a facility with an Oregon Department of Agriculture (ODA) food safety license;
- The CBN was manufactured under either an OLCC processor license or and ODA hemp handler license; and
- The manufacturer of the CBN has written approval from OLCC.

In order to obtain written approval from OLCC, the manufacturer needs to:

- Affirm that they have taken substantial steps toward meeting the same requirements that apply
  to other artificially derived cannabinoids: determining the cannabinoid is "generally recognized
  as safe" (GRAS) or receiving an acknowledgement with no objection from the United States
  Food and Drug Administration (FDA) in response to submitting a new dietary ingredient
  notification.
- Provide OLCC was a copy of the hazard analysis for their manufacturing process as described in the current good manufacturing practice (cGMP) regulations for food (21 CFR 117.130)
- Provide OLCC with copies of any preventative controls that minimize or prevent hazards requiring a preventative control (21 CFR 117.135)

Manufacturers can submit a request for written approval from OLCC by submitting an <u>Artificially Derived</u> <u>CBN Manufacturer Request</u> form to <u>olcc.hemp@oregon.gov</u>. OLCC will maintain a published list of approved manufacturers on the OLCC website.

Products that meet these requirements can continue to be sold until January 2, 2025. After that time, products must meet the general requirements for artificially derived cannabinoids described in OAR 845-025-1310(1).

At this time, the rules do not allow licensees to use artificially derived cannabinoids that were manufactured outside of Oregon. This issue may be revisited during permanent rulemaking on this rule.

#### Artificially Derived CBN Requirements – Products Made Before July 1, 2023

Products made prior to July 1, 2023 that contain artificially derived CBN can continue to be sold as long as they complied with the previous rule requirements. The artificially derived CBN must have been manufactured by an OLCC-licensed processor or ODA-licensed hemp handler at a facility with an ODA food safety license, and the product must not be intended for inhalation.

Products that meet these requirements can continue to be sold until January 2, 2025. After that time, products must meet the general requirements for artificially derived cannabinoids described in OAR 845-025-1310(1).

#### **Labeling Requirements**

The labeling requirements have not changed. All marijuana and hemp items that contain artificially derived CBN, or any other artificially derived cannabinoid, must have a label that complies with the requirements of OAR <u>845-025-7145</u> and the label application must be accompanied by the materials required under OAR <u>845-025-7160</u>.

#### Resources

- Questions related to artificially derived cannabinoids can be sent to olcc.hemp@oregon.gov
- Questions related to labeling can be sent to <a href="mailto:marijuana.packaging@oregon.gov">marijuana.packaging@oregon.gov</a>