



CR103 Memorandum

Regarding New Rule Section WAC 314-55-560 – Evaluation of additives, solvents, ingredients or compounds used in the production of marijuana products.

Date: January 5, 2022
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Background

In mid-2020, WSLCB became aware of products entering the regulated market with labeling noting the presence of cannabinoids other than delta-9 tetrahydrocannabinol (THC). In early 2021, the agency also became aware of the conversion of CBD, hemp, or both to delta-8 THC, delta-9 THC, and other marijuana compounds not currently identified or defined in the Revised Code of Washington (RCW), the Washington State Administrative Code (WAC), or both. These products include, but are not limited to marijuana infused edibles and marijuana concentrates. WSLCB also became aware of products with labeling noting the presence of THC compounds other than delta-9 THC in markets it does not regulate.

WSLCB issued Policy Statement PS-21-01 on April 28, 2021 concerning tetrahydrocannabinol (THC) compounds other than delta-9 and the conversion of CBD, hemp, or both to delta-8 THC, delta-9 THC, or any other cannabis compound not currently identified or defined in the Revised Code of Washington (RCW), the Washington Administrative Code (WAC), or both. Based on questions received concerning the policy statement, and the agency voluntarily issued a clarifying statement on May 3, 2021. Both of these communications were issued as part of an agency initiated strategic, iterative and transparent process designed to leverage the Board's limited regulatory authority concerning THC compounds, maximize stakeholder engagement, and assure that the rule development process could be meaningfully and effectively used to inform future legislation while being grounded in verifiable data, fact, and science.

Stakeholder Engagement

The agency's stated goal of grounding this work in science and verifiable data was realized in extensive stakeholder engagement that began by hosting two Deliberative Dialogue sessions on cannabis plant chemistry. Deliberative Dialogue is a stakeholder engagement model designed to engage participants in facilitated policy discussion rather than responding to conceptual draft rules. The

first session occurred on June 3, 2021 and was empaneled by experts from the University of Washington, Washington State University, the sole cannabis research licensee in Washington State, a cannabis lab director, and doctoral level industry representative. This session was attended by well over 120 individuals, including the FDA, CDC, Health Canada, and the agency's national partners.

Based on this initial panel discussion and its subsequent question/answer session, themes and points of clarification emerged, suggesting that a follow up session may be appropriate. As a result, WSLCB hosted a second Deliberative Dialogue session on July 20, 2021, reassembling the original panel with the exception of one individual. This session was as well attended as the first, and both sessions informed the development of conceptual draft rules that eventually became the rule text of this proposal.

The WSLCB hosted one virtual Listen and Learn session on September 9, 2021 to provide an opportunity for licensees and other interested parties to respond to conceptual draft rules for the evaluation of THC compounds. Participants were invited to speak to what they liked, didn't like and offer proposed language during the session and after the session. Few substantive concepts were offered, and two revised language offerings provided. The majority of the session occurred in the chat, and consisted largely of debate around the legality of delta-8 derived from various sources rather than the substance of the conceptual draft rules. The chat, as well as a table linking rule language offerings to the conceptual draft rules are provided here as Attachments B and C.

It is important to note that attendees requested a definition for "synthetic" and "synthetic cannabinoid" in rule when the agency released potential legislation for stakeholder review the week before, placing these more complex definitions for consideration in statute. A webinar concerning that potential legislation and those specific definitions was held on September 27, 2021.

Rule Necessity

As noted above, WSLCB became aware of products entering the regulated market with labeling noting the presence of cannabinoids other than delta-9 THC, and later became aware of the conversion of CBD, hemp, or both to delta-8 THC, delta-9 THC, and other marijuana compounds not currently identified or defined in statute or regulation. The agency's regulatory authority is limited to marijuana products as defined in statute. As a result, products containing cannabinoids other than delta-9 THC, and products that are the result of the conversation of CBD, hemp, or both to delta-8 THC or delta-9 THC are not subject to that same rigorous regulatory and quality standards that marijuana edibles, concentrates and other products defined in statute are.

For example, delta-8 THC is a psychoactive substance found in the *Cannabis sativa* plant, of which marijuana and hemp are two varieties. Delta-8 THC is one of over 100 cannabinoids produced naturally by the cannabis plant but is not found in significant amounts in the cannabis plant. Concentrated amounts of delta-8 THC are typically manufactured from hemp-derived cannabidiol (CBD). The Washington State Department of Agriculture (WSDA) has explicit regulatory authority over hemp.

Delta-8 products derived from hemp have not been evaluated or approved by the FDA, WSDA, or WSLCB for safe use, and may be marketed in ways that put public health at risk. As of September 14, 2021, the FDA reported an increase in adverse event reporting involving delta-8 THC-containing products. Specifically, From December 2020 through July 2021, the FDA received adverse event reports from both consumers and law enforcement describing 22 patients who consumed delta-8 THC products; of these, 14 presented to a hospital or emergency room for treatment following the ingestion. Of the 22 patients, 19 experienced adverse events after ingesting delta-8 THC-containing food products (e.g., brownies, gummies). Adverse events included vomiting, hallucinations, trouble standing, and loss of consciousness.

National poison control centers received 661 exposure cases of delta-8 THC products between January 2018 and July 31, 2021, 660 of which occurred between January 1, 2021, and July 31, 2021. Of the 661 exposure cases:

- 41% involved unintentional exposure to delta-8 THC and 77% of these unintentional exposures affected pediatric patients less than 18 years of age.
- 39% involved pediatric patients less than 18 years of age
- 18% required hospitalizations, including children who required intensive care unit (ICU) admission following exposure to these products.

Although the Board has statutory authority to engage in emergency rulemaking under certain conditions described in RCW 34.05.350 generally, this rule proposal provides a specific framework for the Board to evaluate additives, solvents, ingredients or compounds used in the production of marijuana products and prohibit use of substances determined to pose a risk to public health or youth access. The framework provides that such prohibition may occur by either emergency or permanent rule, providing an additional layer of oversight for substances that may pose risk to public health or youth access.

Description of Rule Changes

New Section. WAC 314-55-560 – Evaluation of additives, solvents, ingredients or compounds used in the production of marijuana products.

Creates a new section of rule to provide the Board with a framework to evaluate products other than marijuana vapor products as described in WAC 314-55-550.

New Subsection. WAC 314-55-560(1) – Purpose and scope. Describes the purpose and scope of the section, directly referencing the Controlled Substances Act (chapter 69.50 RCW), and more specifically, RCW 69.50.342 (1)(m) that provides that the Board may prohibit the use of any type of additive, solvent, ingredient, or compound used in the production and processing of marijuana products.

New Subsection. WAC 314-55-560(2) – Definitions. Provides definitions for terms that are referenced in statute, but for which there is no statutory definition, such as “additive,” “compound,” “ingredient,” “nonmarijuana additive,” and “solvent.”

New Subsection. WAC 314-55-560(3) – Procedure. Establishes procedures for the Board to evaluate and prohibit additives, solvents, ingredients, or compounds in the production or use of marijuana products that may pose a risk to public health. Establishes process to determine if additives, solvents, ingredients, or compounds in the production or use of marijuana vapor products should no longer be prohibited.

Variance between proposed rule (CR102) and final rule:

There is no variance between the proposed rule and the final rule.

Rule Implementation

Informing and Educating Persons Impacted by the Rule

To help inform and educate persons impacted by the rule, the WSLCB will:

- Email notice with the adoption materials to the rule making and licensee distribution lists, and the general WSLCB GovDelivery list;
- Post rule adoption materials, including final rule language, final analysis (Concise Explanatory Statement), and any other relevant documents on the rulemaking webpage for public access.
- Provide information and training on request.

Promoting and Assisting Voluntary Compliance

WSLCB will promote and assist voluntary compliance through technical assistance.

- WSLCB staff are available to respond to phone and email inquiries about the rule.
- Agency leadership and staff have actively participated in rule development, and are familiar with the final product. Internal and external

education efforts to share knowledge and assure consistent application of rule have will be supported.

- Rule and guidance documents will be available on the WSLCB website.
- WSLCB will use available and customary resources to disseminate materials and information to all persons impacted by the rules.

These actions are designed to inform and educate all persons impacted by the rule.

Training and Informing WSLCB Staff

Several WSLCB staff responsible for implementing these adopted rules work directly with impacted parties and are already familiar with the nuances of the rule changes. Additional internal guidance documents may be prepared as necessary. The WSLCB will also consider:

- Provision of internal and external training and education, as needed, potentially including webinars, training, and videos if appropriate;
- Coordinating and centrally locating decisions to assure consistency between agency, staff, and industry.

Rule Effectiveness Evaluation

The WSLCB will evaluate the effectiveness of these rules in the following ways, including but not limited to:

- Monitoring questions received after the effective date of these rules, and adjusting training and guidance accordingly;
- Monitoring requests for rule language revisions or changes;
- Monitoring requests for rule interpretation;
- Monitoring licensee feedback including, but not limited to, requests for assistance.