



Washington State Liquor and Cannabis Board

Date: May 27, 2020

To: Jane Rushford, Board Chair
Ollie Garrett, Board Member
Russ Hauge, Board Member

From: Kathy Hoffman, Policy and Rules Manager

Copy: Rick Garza, Agency Director
Megan Duffy, Deputy Director
Justin Nordhorn, Chief of Enforcement
Becky Smith, Licensing Director

Subject: **Approval to adopt an emergency rule (CR 103E) regarding WAC 314-55-077 – Marijuana processor license – Privileges, requirements and fees: adding a new section to allow enforcement of the provisions of WAC 314-55-1065.**

On May 27, 2020, the Washington State Liquor and Cannabis Board (Board) adopted an emergency rule as WAC 314-55-1065 providing that no person including, but not limited to, a person licensed under chapter 69.50 may sell, offer for sale, or possess with intent to sell, or offer for sale vapor products containing vitamin E acetate. This emergency rule allows the Board to take disciplinary action against any processor that fails to comply with the provisions of WAC 314-55-1065 under the authority of chapter 69.50 RCW.

Process

The Policy and Rules Manager requests that the Board adopt the emergency rule described above, and requests approval to file the emergency rule described above. A CR 103E Memorandum on this rule was presented at the Board meeting on May 27, 2020, and is attached to this request.

If adopted, the timeline for the rule making process is outlined below:

May 27, 2020	Board is asked to adopt the emergency rulemaking order (CR 103E) as described above.
May 27, 2020	Emergency rule becomes effective.

_____ Approve	_____ Disapprove	_____ Jane Rushford, Chair	_____ Date
_____ Approve	_____ Disapprove	_____ Ollie Garrett, Board Member	_____ Date
_____ Approve	_____ Disapprove	_____ Russ Hauge, Board Member	_____ Date

Attachment: CR 103E Memorandum



CR 103E Memorandum

Emergency Rule Regarding Enforcement of WAC 314-55-1065 – Adding a New Section to WAC 314-55-077 – Marijuana processor license – Privileges, requirements, and fees.

Date: May 27, 2020

Presented by: Kathy Hoffman, Policy and Rules Manager

Issue:

House Bill (HB) 2826 (Chapter 133, Laws of 2020) concerning marijuana vapor products went into effect on March 25, 2020. Among other things, HB 2826 amended RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (m), providing that the Board may, by rule, prohibit any device used in conjunction with a marijuana vapor product and the prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products, when the Board determines, following a determination by the Washington State Department of Health or any other authority the Board deems appropriate, that the device, additive, solvent, ingredient, or compound may pose a risk to public health or youth access.

On November 19, 2019 and March 19, 2020, the Washington State Board of Health (SBOH) offered the following background and reasoning for its ban of vitamin E acetate:

- In July 2019 the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration, state and local health jurisdictions and other clinical and public health partners began investigation [of] outbreaks of lung injury associated with e-cigarette product use, or vaping. In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multi-state outbreak. As of February 18, 2020, CDC reported a total of two thousand eight hundred seven cases of hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases, and sixty-eight deaths in twenty-nine states and the District of Columbia. Twenty-seven cases of lung injury, including two deaths have been reported in Washington State.
- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, a recent study cited by the CDC conducted laboratory tests of fifty-one samples of fluid collected from

the lungs of patients with vaping-associated lung disease from sixteen states. Forty-nine samples contained vitamin E acetate, providing direct evidence of vitamin E acetate at the primary site of the injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. THC was identified in forty-seven of fifty samples and nicotine was identified in thirty of forty-seven samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and recommends that vitamin E acetate not be added to any vapor products.

- During the 2020 legislative session, the governor submitted request legislation (SB 6254) aimed at increasing regulation of vapor products in Washington. The bill included a ban of vitamin E acetate, however the legislature failed to pass SB 6254. Due to the clear association of vitamin E acetate with EVALI and absent legislative action to ban vitamin E acetate the SBOH determined that continuing a ban is necessary to protect the public health, safety and welfare.

Consistent with the statutory authority provided to the Board by HB 2826, and upon the determination of the SBOH that vitamin E acetate is a drug of concern and should be banned, the Board adopted an emergency rule on May 27, 2020 as WAC 314-55-1065 prohibiting the use of vitamin E acetate.

Emergency rule WAC 314-55-1065(2) provides that:

No person including, but not limited to, a person licensed under chapter 69.50 RCW, may sell, offer for sale, or possess with intent to sell, or offer for sale vapor products containing vitamin E acetate. The foregoing prohibition applies to the sale, offer for sale, or possession with intent to sell or offer for sale vapor products containing vitamin E acetate at any location or by any means in this state including, but not limited to, by means of a telephonic or other method of voice transmission, the mail or any other delivery service, or the internet or other online service.

Reasons why rules are needed:

This emergency rule allows the Board to take disciplinary action against any licensed marijuana processor that fails to comply with the provisions of it emergency rule WAC 314-55-1065 prohibiting the use of vitamin E acetate consistent with the authority of chapter 69.50 RCW.

The immediate adoption of rule that establishes provisions for both the enforcement of WAC 314-55-1065, and preservation of public health, safety and general welfare is necessary. Therefore, the immediate adoption of a rule establishing provisions for the enforcement of WAC 314-55-1065 that prohibits the use of vitamin E acetate is necessary.

Process:

Consistent with RCW 34.05.350, any agency may find that the immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule change is exempt from the filing of a CR 101, analytical, and public hearing requirements.

An emergency rule adopted under RCW 34.05.350 takes effect upon filing with the code reviser, unless a later date is specified in the order of adoption, and may not remain in effect for longer than one hundred twenty days after filing.

Notice will be sent to all who have indicated that they want to receive notice of rule activity, and posted to the Board's website.



RULE-MAKING ORDER

EMERGENCY RULE ONLY

CR-103E (December 2017) (Implements RCW 34.05.350 and 34.05.360)

Agency: Washington State Liquor and Cannabis Board

Effective date of rule:

Emergency Rules

- ☒ Immediately upon filing.
☐ Later (specify) _____

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

- ☐ Yes ☒ No If Yes, explain:

Purpose: WAC 314-55-077 – Marijuana processor license – Privileges, requirements and fees. The Washington State Liquor and Cannabis Board (Board) has adopted an emergency rule as WAC 314-55-077(16) that allows the Board to take disciplinary action against any licensed marijuana processor failing to comply with the provisions of WAC 314-55-1065 concerning prohibition of the sale of vitamin E acetate.

Citation of rules affected by this order:

New:
 Repealed:
 Amended: WAC 314-55-077
 Suspended:

Statutory authority for adoption: HB 2826 (Chapter 133, Laws of 2020), effective March 25, 2020; RCW 69.50.342; RCW 69.50.345.

Other authority:

EMERGENCY RULE

Under RCW 34.05.350 the agency for good cause finds:

- ☒ That immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.
☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: House Bill (HB) 2826 concerning marijuana vapor products went into effect on March 25, 2020. Among other things, HB 2826 amended RCW 69.50.342(1) regarding the Board's rulemaking authority by adding a new section (m), providing that the Board may, by rule, prohibit any device used in conjunction with a marijuana vapor product and the prohibit the use of any type of additive, solvent, ingredient, or compound in the production and processing of marijuana products, including marijuana vapor products, when the Board determines, following a determination by the Washington State Department of Health or any other authority the Board deems appropriate, that the device, additive, solvent, ingredient, or compound may pose a risk to public health or youth access.

On November 19, 2019 and March 19, 2020, the Washington State board of Health (SBOH) offered the following background and reasoning for its ban of vitamin E acetate:

- In July 2019 the United States Centers for Disease Control and Prevention (CDC), United States Food and Drug Administration, state and local health jurisdictions and other clinical and public health partners began investigation [of] outbreaks of lung injury associated with e-cigarette product use, or vaping. In September 2019, the CDC activated its Emergency Operations Center to aid in the investigation of the multi-state outbreak. As of February 18, 2020, CDC reported a total of two thousand eight hundred seven cases of hospitalized e-cigarette, or vaping, product use associated lung injury (EVALI) cases, and sixty-eight deaths in twenty-nine states and the District of Columbia. Twenty-seven cases of lung injury, including two deaths have been reported in Washington state.
- As part of the investigation into the multistate outbreak of lung disease associated with the use of vapor products, a recent study cited by the CDC conducted laboratory tests of fifty-one samples of fluid collected from the lungs of patients with vaping-associated lung disease from sixteen states. Forty-nine samples contained vitamin E acetate,

providing direct evidence of vitamin E acetate at the primary site of the injury in the lungs. Vitamin E acetate is a chemical that is used as an additive or thickening ingredient in vapor products. THC was identified in forty-seven of fifty samples and nicotine was identified in thirty of forty-seven samples. None of a range of other potential chemicals of concern was detected in the samples, but evidence is not yet sufficient to rule out the contribution of other chemicals, substances or product sources to the disease. The CDC has identified vitamin E acetate as a chemical of concern and recommends that vitamin E acetate not be added to any vapor products.

- During the 2020 legislative session, the governor submitted request legislation (SB 6254) aimed at increasing regulation of vapor products in Washington. The bill included a ban of vitamin E acetate, however the legislature failed to pass SB 6254. Due to the clear association of vitamin E acetate with EVALI and absent legislative action to ban vitamin E acetate the SBOH determined that continuing a ban is necessary to protect the public health, safety and welfare.

Consistent with the statutory authority provided to the Board by HB 2826, and upon the determination of the SBOH that vitamin E acetate is a drug of concern and should be banned, the Board adopted an emergency rule on May 27, 2020 as WAC 314-55-1065 prohibiting the sale of vitamin E acetate.

This emergency rule allows the Board to take disciplinary action against any licensed marijuana processor that fails to comply with the provisions of WAC 314-55-1065 prohibiting the use of vitamin E acetate.

The Board has the authority and responsibility to adopt rules for the preservation of public health. The immediate adoption of rule that establishes provisions for both the enforcement of WAC 314-55-1065, and preservation of public health, safety and general welfare is necessary. Therefore, the immediate adoption of a rule establishing provisions for the enforcement of WAC 314-55-1065 that prohibits the sale of vitamin E acetate is necessary.

**Note: If any category is left blank, it will be calculated as zero.
No descriptive text.**

**Count by whole WAC sections only, from the WAC number through the history note.
A section may be counted in more than one category.**

The number of sections adopted in order to comply with:

Federal statute:	New	____	Amended	____	Repealed	____
Federal rules or standards:	New	____	Amended	____	Repealed	____
Recently enacted state statutes:	New	____	Amended	____	Repealed	____

The number of sections adopted at the request of a nongovernmental entity:

New	____	Amended	____	Repealed	____
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The number of sections adopted on the agency's own initiative:


New	____	Amended	<u>1</u>	Repealed	____
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	____	Amended	____	Repealed	____
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The number of sections adopted using:

Negotiated rule making:	New	____	Amended	____	Repealed	____
Pilot rule making:	New	____	Amended	____	Repealed	____
Other alternative rule making:	New	____	Amended	<u>1</u>	Repealed	____

Date Adopted: May 27, 2020	Signature: 
Name: Jane Rushford	
Title: Chair	

WAC 314-55-077 Marijuana processor license—Privileges, requirements, and fees. (1) A marijuana processor license allows the licensee to process, dry, cure, package, and label useable marijuana, marijuana concentrates, and marijuana-infused products for sale at wholesale to marijuana processors and marijuana retailers.

(2) Application and license fees.

(a) The application fee for a marijuana processor license is two hundred fifty dollars. The applicant is also responsible for paying the fees required by the approved vendor for fingerprint evaluation.

(b) The annual fee for issuance and renewal of a marijuana processor license is one thousand three hundred eighty-one dollars. The board will conduct random criminal history checks at the time of renewal that will require the licensee to submit fingerprints for evaluation from the approved vendor. The licensee is responsible for all fees required for the criminal history checks.

(c) The application window for marijuana processor licenses is closed. The board may reopen the marijuana processor application window at subsequent times when the board deems necessary.

(3) Any entity and/or principals within any entity are limited to no more than three marijuana processor licenses.

(4)(a) A marijuana processor that makes marijuana-infused solid or liquid product meant to be ingested orally (marijuana edibles) must obtain a marijuana-infused edible endorsement from the department of agriculture as required under chapter 15.125 RCW and rules adopted by the department to implement that chapter (chapter 16-131 WAC). A licensee must allow the board or their designee to conduct physical visits and inspect the processing facility, recipes, and records required under WAC 314-55-087 during normal business hours or at any time of apparent operation without advance notice.

(b) A marijuana processor licensed by the board must ensure marijuana-infused edible processing facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapter 15.125 RCW and rules promulgated to implement chapters 16-131, 16-165 and 16-167 WAC.

(5)(a) A marijuana processor may blend tested useable marijuana from multiple lots into a single package for sale to a marijuana retail licensee so long as the label requirements for each lot used in the blend are met and the percentage by weight of each lot is also included on the label.

(b) A processor may not treat or otherwise adulterate useable marijuana with any organic or nonorganic chemical or other compound whatsoever to alter the color, appearance, weight, or smell of the useable marijuana.

(6) Recipes, product, packaging, and labeling approval.

(a) A marijuana processor licensee must obtain label and packaging approval from the board for all marijuana-infused products meant for oral ingestion prior to offering these items for sale to a marijuana retailer. The marijuana processor licensee must submit a picture of the product, labeling, and packaging to the board for approval. More information on the product, packaging, and label review process is available on the board's website.

(b) All recipes for marijuana-infused products meant for oral ingestion (marijuana edible products) must be approved by the department of agriculture under chapter 16-131 WAC. Licensees must obtain recipe approval from the department of agriculture prior to submitting any marijuana edible products, packages, and labels for review and approval by the board. The recipe for any marijuana-infused solid or liquid products meant to be ingested orally must be kept on file at the marijuana processor's licensed premises and made available for inspection by the board or its designee.

(c) If the board denies a marijuana-infused product for sale in marijuana retail outlets, the marijuana processor licensee may request an administrative hearing under chapter 34.05 RCW, Administrative Procedure Act.

(7) With the exception of the marijuana, all ingredients used in making marijuana-infused products for oral ingestion must be a commercially manufactured food as defined in WAC 246-215-01115.

(8) Marijuana-infused edible products in solid or liquid form must be homogenized to ensure uniform disbursement of cannabinoids.

(9) A marijuana processor may infuse food or drinks with marijuana, provided that:

(a) The product or products do not require cooking or baking by the consumer;

(b) Coatings applied to the product or products are compliant with the requirements of this chapter;

(c) The product and package design is not similar to commercially available products marketed for consumption by persons under twenty-one years of age, as defined by WAC 314.55.105 (1)(c).

(10) To reduce the risk to public health, potentially hazardous foods as defined in WAC 246-215-01115 may not be infused with marijuana. Potentially hazardous foods require time-temperature control to keep them safe for human consumption and prevent the growth of pathogenic microorganisms or the production of toxins. Any food that requires refrigeration, freezing, or a hot holding unit to keep it safe for human consumption may not be infused with marijuana.

(11) Other food items that may not be infused with marijuana to be sold in a retail store include:

(a) Any food that has to be acidified to make it shelf stable;

(b) Food items made shelf stable by canning or retorting;

(c) Fruit or vegetable juices (this does not include shelf stable concentrates);

(d) Fruit or vegetable butters;

(e) Pumpkin pies, custard pies, or any pies that contain egg;

(f) Dairy products of any kind such as butter, cheese, ice cream, or milk; and

(g) Dried or cured meats.

(h) Vinegars and oils derived from natural sources may be infused with dried marijuana if all plant material is subsequently removed from the final product. Vinegars and oils may not be infused with any other substance, including herbs and garlic.

(i) Marijuana-infused jams and jellies made from scratch must utilize a standardized recipe in accordance with 21 C.F.R. Part 150, revised as of April 1, 2013.

(12) Consistent with WAC 314-55-104, a marijuana processor may infuse dairy butter or fats derived from natural sources, and use that extraction to prepare allowable marijuana-infused solid or liquid products meant to be ingested orally, but the dairy butter or fats derived from natural sources may not be sold as stand-alone products.

The board may designate other food items that may not be infused with marijuana.

(13) Marijuana processor licensees are allowed to have a maximum of six months of their average useable marijuana and six months average of their total production on their licensed premises at any time.

(14) **Processing service arrangements.** A processing service arrangement is when one processor (processor B) processes useable marijuana or an altered form of useable marijuana (marijuana product) for another licensed processor (processor A) for a fee.

(a) Processor A is the product owner. However, processor B may handle the product under its license as provided in chapter 69.50 RCW and this chapter. Processor B is not allowed to transfer the product to a retailer and may only possess marijuana or marijuana products received from processor A for the limited purposes of processing it for ultimate transfer back to processor A.

(b) Processing service arrangements must be made on a cash basis only as provided in WAC 314-55-115 and payment for the service and return of the processed product must be made within thirty calendar days of delivery to processor B. Failure to do so as provided by the preceding sentence is a violation of this section and any marijuana or marijuana product involved in the transaction will be subject to seizure and destruction. Payment with any marijuana products, barter, trade, or compensation in any form other than cash for processing service arrangements is prohibited under processing service arrangements.

(c) Each processor that enters into a processing service arrangement must include records for each service arrangement in recordkeeping documents which must be maintained consistent with this chapter.

(15) Marijuana may not be returned by any retail licensee to any processor except as provided in this section.

(a) Every processor must maintain on the licensed premises for a period of five years complete records of all refunds and exchanges made under this section including an inventory of marijuana and marijuana products returned to the processor by any retail licensee.

(b) Marijuana may be returned by a retail licensee in the event a retailer goes out of the business of selling marijuana at retail and a cash refund, as defined by WAC 314-55-115, may be made upon the return of the marijuana or marijuana products, so long as WSLCB approval is acquired prior to returns and refunds under this subsection.

(c) Marijuana products different from that ordered by a retailer and delivered to the retailer may be returned to a processor and either replaced with marijuana products which were ordered or a cash refund, as defined by WAC 314-55-115, may be made. These incorrect orders must be discovered and corrected within eight days of the date the delivery was made to be eligible for returns and refunds under this subsection.

(d) A marijuana processor may accept returns of products and sample jars from marijuana retailers for destruction, but is not required to provide refunds to the retailer. It is the responsibility of the retailer to ensure the product or sample jar is returned to the processor.

(16) The board may take disciplinary action against any marijuana processor that fails to comply with the provisions of WAC 314-55-1065.