



RULE-MAKING ORDER EMERGENCY RULE ONLY

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

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: January 24, 2019

TIME: 4:36 PM

WSR 19-04-010

Agency: Department of Health

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 246-70-050 - Quality assurance testing, WAC 246-70-060 - Compliant product labeling. The Department of Health (department) is temporarily repealing requirements regarding the screening of heavy metals for medical marijuana products. This emergency rule also temporarily requires the labeling of such products for sale as not having been tested for heavy metals. This measure is necessary because the single certified third-party laboratory in Washington State will no longer accept marijuana samples for cannabis heavy metal testing on January 25, 2019, and will stop all testing for heavy metals on January 31, 2019. This emergency rule will remain in effect for 120 days, or until another certified third-party laboratory is again established, whichever occurs first.

Citation of rules affected by this order:

- New: None.
- Repealed: None.
- Amended: WAC 246-70-050 and 246-70-060
- Suspended: None.

Statutory authority for adoption: RCW 69.50.375

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: RCW 69.50.375(4) provides that the department and the Washington State Liquor and Cannabis Board (LCB) adopt rules on the requirements of marijuana concentrates, useable marijuana, and marijuana products that may be sold or provided at no charge to qualifying patients or designated providers at retail outlets with a medical endorsement. RCW 69.50.375(4) (a) through (e) describe THC concentration ratios, labeling and safe handling requirements, and other requirements, such as pesticide testing.

Although heavy metal screening is not specifically required in the statute, the department included it when it adopted WAC 246-70-050(1) (b) and (c), and WAC 246-70-050(3). After January 31, 2019 there will no longer be a single LCB certified laboratory providing heavy metal screening. As a result, licensed marijuana producers and processors will be unable to get their products tested for heavy metals as required under the current rule. This will cause products to be noncompliant with the current rule. As a result, these products cannot not be sold or marketed as compliant products, reducing access and availability of safe products for qualifying patients, particularly patients with compromised immune systems.

**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	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted on the agency's own initiative:

New	<u>0</u>	Amended	<u>2</u>	Repealed	<u>0</u>
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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The number of sections adopted using:

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>0</u>	Amended	<u>2</u>	Repealed	<u>0</u>

Date Adopted: 01/24/2019

Name: Jessica Todorovich

Title: Chief of Staff

Signature:



WAC 246-70-050 Quality assurance testing. (1) Testing interval and sample size.

(a) The testing requirements of this section are in addition to the tests required under WAC 314-55-102 and shall be performed by a third-party testing lab certified by the WSLCB.

(b) Pesticide screening (~~and heavy metal screening are~~) is required at the following time(s):

(i) For all marijuana flowers, trim, leaves, or other plant matter, intended for retail sale without extraction, at the time of harvest or when placed into lots.

(ii) For all products intended for retail sale as concentrates, extracts, or for use as an intermediate product, screening is required only after extraction and is not required according to (b)(i) of this subsection.

(iii) An imported cannabinoid must be screened prior to addition to any marijuana product.

(c) Minimum sample size for pesticide screening (~~and heavy metal screening~~):

(i) For screening at harvest, three grams for every three pounds of harvested product. Harvest amounts will be rounded up to the next three-pound interval. For example, a harvest of less than three pounds requires at least three grams for testing; a harvest of three or more pounds but less than six pounds requires at least six grams for testing.

(ii) For screening a lot, three grams per lot.

(iii) For screening a batch of finished concentrates, extracts, or intermediate products, two grams per batch.

(iv) For screening imported cannabinoids, one percent of the product as packaged by the manufacturer of the imported cannabinoid but in no case shall the sample be less than two grams.

(d) Mycotoxin screening is required whenever microbial testing for any marijuana product is required by the WSLCB.

(e) Licensed marijuana producers, licensed marijuana processors, and certified third-party labs must follow the sampling protocols in chapter 314-55 WAC.

(f) At the request of the producer or processor, the WSLCB may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the retest will be borne by the producer or processor.

(2) Pesticide screening.

(a) Only allowed pesticides shall be used in the production, processing, and handling of marijuana. Pesticide use must be consistent with the manufacturer's label requirements.

(b) Certified third-party labs must screen for any pesticides that are not allowed and are designated as having the potential for misuse on a list created, maintained, and periodically updated by the department in consultation with the Washington state department of agriculture and the WSLCB. Certified third-party labs must also screen for pyrethrins and piperonyl butoxide (PBO) in samples of concentrates, extracts, intermediate products, and imported cannabinoids. Certified third-party labs may also screen for additional pesticides.

(c) For purposes of the pesticide screening, a sample of any marijuana product shall be deemed to have failed if a pesticide that is

not allowed is detected above the action level for that pesticide as determined by the WSLCB under chapter 314-55 WAC.

(d) A harvest, lot, or batch deemed to have failed pesticide screening must be destroyed according to chapter 314-55 WAC. Marijuana flowers, trim, leaves, or other plant matter deemed to have failed pesticide screening must not be used to create extracts or concentrates. Imported cannabinoids deemed to have failed pesticide screening must not be added to any marijuana product.

(e) Pesticides containing allowed pyrethrins or piperonyl butoxide (PBO) may not be applied less than seven days prior to harvest.

(f) All individuals applying pesticides shall adhere to the agricultural use requirements on the label. Pesticide applications that do not follow the pesticide product label may pose risks to public health and safety and are a violation of chapter 15.58 RCW.

~~(3) ((Heavy metal screening.~~

~~(a) For the purposes of heavy metal screening, a sample shall be deemed to have passed if it meets the following standards:~~

Metal	Limit, µg/daily dose (5 grams)
Inorganic arsenic	10.0
Cadmium	4.1
Lead	6.0
Mercury	2.0

~~(b) A harvest, lot, or batch deemed to have failed heavy metal screening must be destroyed according to chapter 314-55 WAC. Marijuana flowers, trim, leaves, or other plant matter deemed to have failed heavy metal screening must not be used to create extracts or concentrates. Imported cannabinoids deemed to have failed heavy metal screening must not be added to any marijuana product.~~

~~(4)) For purposes of mycotoxin screening, a sample shall be deemed to have passed if it meets the following standards:~~

Test	Specification
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2	<20 µG/kg of substance
Ochratoxin A	<20 µG/kg of substance

~~((+5))~~ (4) Terpenes.

(a) Terpene analysis is not required. If terpene content is listed on product packaging or label, a terpene analysis from a certified third-party lab must be available for review by the consumer upon request.

(b) The addition of any terpene to useable marijuana is prohibited. Only the following terpenes may be added to a marijuana product other than useable marijuana.

(i) Terpenes naturally occurring in marijuana; or

(ii) Terpenes permitted or generally recognized as safe by, and used in accordance with, 21 C.F.R., Chapter I, subchapter B.

WAC 246-70-060 Compliant product labeling. (1) Products meeting the requirements of this chapter must be readily identifiable to the consumer by placement on the product's label of the appropriate logo found in WAC 246-70-090. A logo must be used in compliance with this chapter and any guidance for use developed by the department. A logo may not be used on any object or merchandise other than a compliant marijuana product. A logo used in accordance with this chapter must be printed in either black or dark blue.

(2) Labels for compliant products must not:

(a) Use any word(s), symbol, or image commonly used in or by medical or pharmaceutical professions including, but not limited to: Depiction of a caduceus, staff of Asclepius, bowl of Hygieia, or mortar and pestle; or use of the word "prescription" or letters "RX";

(b) State or imply any specific medical or therapeutic benefit; or

(c) Mimic a brand of over-the-counter or legend drug.

(3) The label must prominently display the following statements:

(a) "This product is not approved by the FDA to treat, cure, or prevent any disease."; and

(b) "Not tested for heavy metals."

(4) Only marijuana products complying with this chapter may use a logo found in WAC 246-70-090. Marijuana products that use a logo but do not meet the requirements in this chapter will be reported to the WSLCB.