#### Washington State Register

### WSR 24-01-035 PERMANENT RULES

#### DEPARTMENT OF AGRICULTURE

[Filed December 11, 2023, 9:43 a.m., effective January 11, 2024]

Effective Date of Rule: Thirty-one days after filing. Purpose: This rule-making order amends chapter 16-131 WAC, Marijuana-infused edibles, by replacing all occurrences of the word "marijuana" with "cannabis" and all references to MIE (marijuana infused edibles) with CIE (cannabis infused edibles) in alignment with SSHB 1210 (chapter 16, Laws of 2022).

Citation of Rules Affected by this Order: Amending WAC 16-131-010, 16-131-020, 16-131-030, 16-131-040, 16-131-050, 16-131-060, 16-131-070, 16-131-080, 16-131-090, 16-131-100, and 16-131-110.

Statutory Authority for Adoption: RCW 69.07.020; chapter 16, Laws of 2022.

Adopted under notice filed as WSR 23-19-069 on September 18, 2023.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 11, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 0, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 0, Repealed 0. Date Adopted: December 8, 2023.

> Derek I. Sandison Director

OTS-4926.1

### Chapter 16-131 WAC ((MARIJUANA)) CANNABIS-INFUSED EDIBLES

- WAC 16-131-010 Purpose of this chapter. The purpose of this chapter is to establish rules pursuant to chapter 69.07 RCW relating
- (1) Procedures to obtain and maintain a ((marijuana)) cannabisinfused edible endorsement;

- (2) Requirements for ((marijuana)) cannabis-infused edible processing facilities; and
- (3) Requirements for ((marijuana)) cannabis-infused edible labeling.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

- WAC 16-131-020 Definitions. In addition to the definitions in RCW 69.07.010, the following definitions apply to this chapter:
- "((MIE)) CIE" has the same meaning as "((marijuana)) cannabis-infused edible" in RCW 69.07.010.
- "((MIE)) CIE processing" means the same as "(( $\frac{marijuana}{marijuana}$ ))  $\frac{canna-bis}{marijuana}$  in RCW 69.07.010. The term includes all activities covered by "food processing" under RCW 69.07.010. The term also includes packaging of ((MIEs)) CIEs and bottling operations (preparing bottles, filling, and capping).
- "((MIE)) CIE processing facility" means the room or rooms where ((MIEs)) <u>CIEs</u> are processed.
- "((MIE)) CIE processor" means a person who holds ((an MIE)) a CIE endorsement.
- "WSLCB" means the same as "board" in RCW 69.07.010; the state liquor and cannabis board.

- WAC 16-131-030 General requirements. (1) For initial authorization to produce ((MIEs)) CIEs, a person must obtain ((an MIE)) a CIE endorsement as provided under RCW 69.07.200 and WAC 16-131-040.
- (2) ((An MIE)) A CIE processor must comply with all laws to which other food processors are subject including, but not limited to, chapter 69.07 RCW, Washington Food Processing Act, chapter 16-165 WAC, Food inspection, and chapter 16-167 WAC, Intrastate commerce in foods.
- (3) ((An MIE)) A CIE processor in good standing may renew an endorsement through the department of revenue as provided in RCW 69.07.200.
- (4) A person must hold ((an MIE)) a CIE endorsement and obtain the department's approval of each ((MIE)) CIE as provided in WAC 16-131-050 before offering the ((MIE)) <u>CIE</u> for sale.
- (5) All communication in connection with ((MIEs)) CIEs from an applicant or endorsement holder to the department must reference the applicant or endorsement holder's WSLCB license number and the name under which the WSLCB license is held.
  - (6) ((An MIE)) A CIE endorsement is valid for only one location.
- (7) ((MIE)) CIE processing facilities must comply with all applicable state, county, and municipal laws and ordinances that apply to conducting business in the ((MIE)) CIE processing facility location.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

- WAC 16-131-040 Initial application requirements. (1) Persons seeking to produce ((MIEs)) CIEs must apply to the department of revenue as required under RCW 69.07.200. The initial endorsement is not valid until the department approves the applicant's submittals required under this section, inspects the ((MIE)) CIE processing facility, and determines that the applicant and facility substantially complies with applicable laws and regulations.
- (2) Once the department receives the endorsement application from department of revenue's business licensing service, the department will contact the applicant and provide electronic copies of required forms for the applicant to complete.
- (3) Before the department will begin evaluation of an initial application, the applicant must submit the following:
  - (a) Full facility plans as required under WAC 16-131-090;
- (b) A detailed floor plan or diagram of the ((MIE)) CIE processing facility as required under WAC 16-131-090;
- (c) All documents required under WAC 16-131-050 for each initially proposed ((MIE)) CIE;
- (d) Documentation verifying that the water supply meets standards in WAC 16-165-130.
- (4) Once the department determines that an initial applicant's submittal is complete and satisfactory, the department will contact the applicant to schedule an inspection. The ((MIE)) CIE processing facility must be production ready at the time of inspection; perishable ingredients are not required to be in stock.
- (5) Following the inspection, the department will notify the applicant of its decision to approve or deny the endorsement. If approving the endorsement, the department will identify the ((MIE)) CIE products approved for processing.

- WAC 16-131-050 ((MIE)) <u>CIE</u> approval. (1) ((An MIE)) <u>A CIE</u> is specific to its form, formulation and ingredients, including color and flavor. The same formulation and ingredients in different forms (for example, powder and solid forms) are different ((MIEs)) CIEs.
- (2) A person must obtain the department's review and approval for each ((MIE)) CIE before offering it for sale.
- (3) A person must provide the following information to the department in electronic format for each proposed ((MIE)) CIE product:
  - (a) The product name;
  - (b) A complete and accurate list of ingredients;
- (c) A description of the processing steps for the ((MIE)) CIE product;
  - (d) A description of the packaging; and
- (e) A copy of the proposed ingredient label conforming to WAC 16-131-060.
- (4) The department will approve only the types of ((MIEs)) CIES that comply with WAC 16-131-070.

- (5) Any change in the ingredients of an approved ((MIE)) CIE requires department review and approval as provided in subsection (2) of this section.
- (6) The department may require another facility inspection if a newly proposed or reformulated ((MIE)) CIE introduces a new type of processing in the ((MIE)) CIE processing facility. For example, the department will require a new inspection if a facility that previously produced baked goods proposes to add a bottled beverage ((MIE)) CIE.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

- WAC 16-131-060 ((MIE)) CIE labeling. (1) ((MIE)) CIE processors must submit a copy of the proposed ingredient label for each ((MIE)) <u>CIE</u> to the department for approval. The proposed ingredient label may not be used without the department's written approval.
- (2) ((MIE)) CIE product labels must comply with the WSLCB's packaging and labeling requirements under chapter 314-55 WAC and, for the purposes of the ((MIE)) CIE endorsement, additionally display:
- (a) A statement of ingredients as specified under 21 C.F.R. 101.4 (2017). The ingredient statement must identify sulfites, if present, as required under 21 C.F.R. 101.100 (2017) and the names of Food and Drug Administration certified color additives such as FD&C Yellow 5 and the like, if present.
- (b) Allergens (milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans) as specified under the Food Allergen Labeling and Consumer Protection Act of 2004 (P.L. 108-282, Title II).
- (3) The following sample label illustrates the ingredient and allergen labeling requirements:

## Chocolate Peanut Butter Walnut Brownie

Ingredients: Brown Sugar (Sugar, Invert sugar, Cane molasses), All-purpose flour (Wheat flour, Niacin, Reduced iron, Thiamine mononitrate, Riboflavin, Folic acid), Milk chocolate (Sugar, Whole milk powder, Cocoa butter, Cocoa mass, Soy lecithin, Vanilla), Peanut Butter (Peanuts, Sugar, Molasses, Hydrogenated vegetable oil, Mono and diglycerides, Salt), Chopped Walnuts, Dextrose, Salt, Artificial Flavoring, Leavening (Sodium bicarbonate), Cannabis Extract.

CONTAINS: Milk, Peanuts, Soy, Walnuts, Wheat

- WAC 16-131-070 ((MIE)) CIE product types. (1) All ((MIEs)) CIEs must comply with WAC 314-55-077.
- (2) The department will not approve ((an MIE)) a CIE for commercial sale unless it complies with WAC 314-55-077 and is a low hazard food that typically does not support bacterial or toxigenic growth. Such foods include, but are not limited to:
- (a) Baked goods that do not require refrigeration such as cookies, brownies, fruit pies and fruit tarts;
  - (b) Candies and chocolates;

- (c) Stove top treats, which are candies or confections made from sugar or syrup to which flavorings and/or colorants are added such as molded chocolates, fruit rolls, roasted coated nuts, and nonbaked bars or granola products;
- (d) Flavored water beverages (like vitamin style waters), carbonated beverages, and lemonade style beverages. Product safety is formulation dependent; the department may reject some formulations as potentially hazardous;
- (e) Dry mixes such as coffee granules, leaf tea, soup mixes, beverage mixes, and seasonings;
- (f) Jams, jellies, and related products made in accordance with 21 C.F.R. Part 150;
- (g) Roasted nut butters, such as peanut butter, almond butter, etc;
  - (h) Honey and syrups;
- (i) Vinegars, tinctures, and tonics. If infused with dried ((mariguana)) cannabis, the processor must strain and entirely remove all plant parts and particulates from the final product. Use of other plant parts and particulates for infusion, such as herbs and garlic, is prohibited (see WAC 314-55-077);
  - (j) Tablets and capsules.
- (3) A processor may infuse oils or fats (canola oil, olive oil, coconut oil, butter, etc.) with ((marijuana)) cannabis and use such for preparation of ((MIEs)) CIEs intended for sale. Retail sale of ((MIE)) CIE oils and fats is prohibited. Use of other plant parts and particulates for infusion in oils and fats, such as herbs and garlic, that is intended for use in production of retail ((MIEs)) CIEs is prohibited (see WAC 314-55-077 and 314-55-104).
- (4) The department will not approve ((an MIE)) <u>a CIE</u> for commercial sale if it is a potentially hazardous food. The following nonexhaustive list includes foods prohibited as ((MIES)) <u>CIEs</u>:
- (a) Any food that must be temperature controlled (frozen, refrigerated, hot holding) for food safety (see WAC 314-55-077);
- (b) Foods that required acidification to assure food safety (for example, ready-to-drink tea and barbecue sauce) (see WAC 314-55-077);
- (c) Foods that must be retorted or pasteurized to assure food safety (see WAC 314-55-077);
- (d) Dairy products of any kind such as butter, cheese, ice cream, or milk (see WAC 314-55-077);
- (e) Fruit or vegetable juices, except shelf stable concentrates (see WAC 314-55-077);
  - (f) Oils and vegetable butters (see WAC 314-55-077);
- (g) Pies containing egg such as pumpkin or custard (see WAC 314-55-077);
  - (h) Dried or cured meats (see WAC 314-55-077);
- (i) Jams, jellies, and related products with sugar to fruit ratio less than provided by 21 C.F.R. Part 150.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

WAC 16-131-080 ((MIE)) CIE processing. (1) All ((MIE)) CIE processing must take place in the ((MIE)) CIE processing facility. ((An MIE)) A CIE intended for retail sale must leave the ((MIE)) CIE processing facility in sealed consumer packaging.

- (2) Processing plans for each ((MIE)) CIE and operation of the ((MIE)) CIE processing facility must comply with all laws applicable to food processing under chapter 69.07 RCW.
- (3) All ingredients must be from approved sources, meaning the food ingredients are from a source that a regulatory authority routinely and regularly inspects. Whole raw agricultural commodities are exempt from approved source requirements.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

- WAC 16-131-090 ((MIE)) CIE processing facilities. (1) Facilities plans. ((MIE)) CIE processors must maintain current, to scale, and legible floor plans of the ((MIE)) CIE processing facility. At a minimum, the plans must include:
- (a) A plan showing the entire facility subject to the (( $\frac{marijua-na}{na}$ )) cannabis processor license and indicating the (( $\frac{MIE}{na}$ )) CIE processing facility. An applicant may use plans submitted for the (( $\frac{mari-juana}{na}$ )) cannabis processor license to meet this requirement provided the plans clearly identify the (( $\frac{mari-na}{na}$ )) CIE processing facility.
- (b) A detailed floor plan, which may be a hand drawn diagram if to scale and legible, showing room dimensions, fixtures (sinks, counters, etc.), equipment (refrigeration units, range/stove, oven, standalone processing equipment, etc.), storage shelves/racks (for edible ingredients, utensils, packaging supplies, cleaning supplies), and floor drain, if required. Applicant must identify the finished surfaces of the ceiling, walls, and floor on the floor plan/diagram or in a separate document.
- (2) ((MIE)) <u>CIE</u> facility requirements. ((MIE)) <u>CIE</u> processing facilities must comply with all laws applicable to food processing under chapter 69.07 RCW and the following:
- (a) The ((MIE)) <u>CIE</u> processing facility must be entirely enclosed (walls, ceiling, and doors) and separate from other parts of the facility subject to the ((marijuana)) cannabis processor license;
- cility subject to the ((marijuana)) cannabis processor license; (b) Toilet room doors must not open directly into the ((MIE)) CIE processing facility or adjacent air space. This requirement may be met with double doors or with an air management system;
- (c) Hand sinks and equipment sinks required of all processors must be located inside the ((MIE)) CIE processing facility.
- (3) ((MIE)) <u>CIE</u> processors must notify the department of any proposed significant changes to the required floor plans.

AMENDATORY SECTION (Amending WSR 18-05-010, filed 2/8/18, effective 4/1/18)

WAC 16-131-100 Inspections. (1) ((MIE)) CIE processors must allow access to the department for inspections and to collect samples as required under RCW 69.07.080 and as otherwise authorized by law. The department must have access to the ((MIE)) CIE facility and the entire facility subject to the ((marijuana)) cannabis processors license, including exterior of the building and grounds, to the extent that these may affect the safety of ((MIEs)) CIEs produced in the ((MIE)) CIE facility.

(2) The department will use the same inspection procedures and protocols used for inspections of all food processors licensed under chapter 69.07 RCW. This includes unscheduled and unannounced inspections.

- WAC 16-131-110 Suspension, revocation, and denial of endorsement and penalties. (1) The department may suspend, revoke, or deny ( $\frac{1}{1}$  MIE)) a CIE endorsement in accordance with RCW 69.07.060.
- (2) The department may impose penalties on any person who processes, advertises, or distributes (( $\frac{MIES}{}$ ))  $\underline{CIES}$  without (( $\frac{ANDE}{}$ ))  $\underline{a}$   $\underline{CIE}$  endorsement. Each of the following is a distinct and separate violation:
- (a) Processing (( $\underline{\text{MIEs}}$ ))  $\underline{\text{CIEs}}$  without a valid (( $\underline{\text{MIE}}$ ))  $\underline{\text{CIE}}$  endorsement;
- (b) Advertising or distributing ((MIEs)) <u>CIEs</u> processed without a valid ((MIE)) <u>CIE</u> endorsement;
- (c) Processing, advertising, or distributing (( $\frac{an MIE}{a}$ )) a CIE that has not received department approval under WAC 16-131-050.
- (3) For violations under an endorsement, the department may impose civil penalties in conformance with the penalty assignment schedules in this section and chapter 16-139 WAC, excluding WAC 16-139-020, 16-139-030, and 16-139-040.
  - (4) ((MIE)) <u>CIE</u> penalty assignment schedules:

PENALTY	
\$1,000 per day per violation	

Table 2. ((MHE)) <u>CIE</u> Penalties for Number of Critical Violations in a 3-Year Period

	PENALTY		
	Risk of Adulteration		
VIOLATION	Potential	Probable	
First	\$1,000 and 4-day suspension	\$5,000 and 14- day suspension	
Second	\$2,000 and 8-day suspension	\$5,000 and 30- day suspension	
Third	\$4,000 and 16- day suspension	\$5,000 and revocation	

Table 3. ((MIE)) <u>CIE</u> Penalties for Number of Significant Violations in a 3-Year Period

	PENALTY	
	Risk of Adulteration	
VIOLATION	Potential	Probable
First	\$500 and 2-day suspension	\$1,000 and 4-day suspension

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	PENALTY	
	Risk of Adulteration	
VIOLATION	Potential	Probable
Second	\$1,000 and 4-day suspension	\$2,000 and 8-day suspension
Third	\$2,000 and 8-day suspension	\$4,000 and 16- day suspension

Table 4. ((MIE)) <u>CIE</u> Penalties for Number of Economic or Other Violations in a 3-Year Period

	PENALTY		
VIOLATION	Unknowing	Knowing	
First	\$500 and 2-day suspension	\$1,000 and 4-day suspension	
Second	\$1,000 and 4-day suspension	\$2,000 and 6-day suspension	
Third	\$1,500 and 6-day suspension	\$5,000 and 20- day suspension	