

Chapter 16-131 WAC

MARIJUANA-INFUSED EDIBLES

WAC

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WAC 16-131-010 Purpose of this chapter. The purpose of this chapter is to establish rules pursuant to chapter 69.07 RCW relating to:

- (1) Procedures to obtain and maintain a marijuana-infused edible endorsement;
- (2) Requirements for marijuana-infused edible processing facilities; and
- (3) Requirements for marijuana-infused edible labeling.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-010, 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" has the same meaning as "marijuana-infused edible" in RCW 69.07.010.

"MIE processing" means the same as "marijuana-infused edible processing" 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 and bottling operations (preparing bottles, filling, and capping).

"MIE processing facility" means the room or rooms where MIEs are processed.

"MIE processor" means a person who holds an MIE endorsement.

"WSLCB" means the same as "board" in RCW 69.07-010; the state liquor and cannabis board.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-020, filed 2/8/18, effective 4/1/18.]

WAC 16-131-030 General requirements. (1) For initial authorization to produce MIEs, a person must obtain an MIE endorsement as provided under RCW 69.07.200 and WAC 16-131-040.

(2) An MIE 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.

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(3) An MIE 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 endorsement and obtain the department's approval of each MIE as provided in WAC 16-131-050 before offering the MIE for sale.

(5) All communication in connection with MIEs 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 endorsement is valid for only one location.

(7) MIE processing facilities must comply with all applicable state, county, and municipal laws and ordinances that apply to conducting business in the MIE processing facility location.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-030, filed 2/8/18, effective 4/1/18.]

WAC 16-131-040 Initial application requirements.

(1) Persons seeking to produce MIEs 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 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 processing facility as required under WAC 16-131-090;

(c) All documents required under WAC 16-131-050 for each initially proposed MIE;

(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 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 products approved for processing.

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[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-040, filed 2/8/18, effective 4/1/18.]

WAC 16-131-050 MIE approval. (1) An MIE 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.

(2) A person must obtain the department's review and approval for each MIE before offering it for sale.

(3) A person must provide the following information to the department in electronic format for each proposed MIE product:

- (a) The product name;
- (b) A complete and accurate list of ingredients;
- (c) A description of the processing steps for the MIE 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 that comply with WAC 16-131-070.

(5) Any change in the ingredients of an approved MIE 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 introduces a new type of processing in the MIE 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.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-050, filed 2/8/18, effective 4/1/18.]

WAC 16-131-060 MIE labeling. (1) MIE processors must submit a copy of the proposed ingredient label for each MIE to the department for approval. The proposed ingredient label may not be used without the department's written approval.

(2) MIE product labels must comply with the WSLCB's packaging and labeling requirements under chapter 314-55 WAC and, for the purposes of the MIE 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), Pea-

nut 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

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-060, filed 2/8/18, effective 4/1/18.]

WAC 16-131-070 MIE product types. (1) All MIEs must comply with WAC 314-55-077.

(2) The department will not approve an MIE 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 marijuana, 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 and use such for preparation of MIEs intended for sale. Retail sale of MIE 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 is prohibited (see WAC 314-55-077 and 314-55-104).

(4) The department will not approve an MIE for commercial sale if it is a potentially hazardous food. The following nonexhaustive list includes foods prohibited as MIEs:

- (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.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-070, filed 2/8/18, effective 4/1/18.]

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

(2) Processing plans for each MIE and operation of the MIE 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.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-080, filed 2/8/18, effective 4/1/18.]

WAC 16-131-090 MIE processing facilities. (1) Facilities plans. MIE processors must maintain current, to scale, and legible floor plans of the MIE processing facility. At a minimum, the plans must include:

(a) A plan showing the entire facility subject to the marijuana processor license and indicating the MIE processing facility. An applicant may use plans submitted for the marijuana processor license to meet this requirement provided the plans clearly identify the MIE 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, stand-alone 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 facility requirements. MIE processing facilities must comply with all laws applicable to food processing under chapter 69.07 RCW and the following:

(a) The MIE processing facility must be entirely enclosed (walls, ceiling, and doors) and separate from other parts of the facility subject to the marijuana processor license;

(b) Toilet room doors must not open directly into the MIE 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 processing facility.

(3) MIE processors must notify the department of any proposed significant changes to the required floor plans.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-090, filed 2/8/18, effective 4/1/18.]

(2/8/18)

WAC 16-131-100 Inspections. (1) MIE 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 facility and the entire facility subject to the marijuana processors license, including exterior of the building and grounds, to the extent that these may affect the safety of MIEs produced in the MIE 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.

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-100, filed 2/8/18, effective 4/1/18.]

WAC 16-131-110 Suspension, revocation, and denial of endorsement and penalties. (1) The department may suspend, revoke, or deny an MIE endorsement in accordance with RCW 69.07.060.

(2) The department may impose penalties on any person who processes, advertises, or distributes MIEs without an MIE endorsement. Each of the following is a distinct and separate violation:

(a) Processing MIEs without a valid MIE endorsement;

(b) Advertising or distributing MIEs processed without a valid MIE endorsement;

(c) Processing, advertising, or distributing an MIE 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 penalty assignment schedules:

Table 1. MIE Penalties for Processing, Advertising, or Distributing Without a Valid MIE Endorsement

PENALTY
\$1,000 per day per violation

Table 2. MIE Penalties for Number of Critical Violations in a 3-Year Period

VIOLATION	PENALTY	
	Risk of Adulteration	
	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

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Table 3. MIE Penalties for Number of Significant Violations in a 3-Year Period

VIOLATION	PENALTY	
	Risk of Adulteration	
	Potential	Probable
First	\$500 and 2-day suspension	\$1,000 and 4-day suspension
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 Penalties for Number of Economic or Other Violations in a 3-Year Period

VIOLATION	PENALTY	
	Unknowning	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

[Statutory Authority: RCW 69.07.020, 69.07.200, and chapter 34.05 RCW. WSR 18-05-010, § 16-131-110, filed 2/8/18, effective 4/1/18.]