



Product and Dosage Requirements

Orally-Consumed Cannabis Products

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The following guidance is provided by the Maryland Cannabis Administration (MCA) to assist cannabis businesses to comply with state laws and regulations governing: (1) Categorization of cannabis-infused products and edible cannabis products, and (2) Restrictions on product form and dosage.

This document is not legal advice. It is meant to assist licensed cannabis businesses with understanding product and dosage requirements, and to comply with State statutes and regulations. Please consult an attorney if you have any questions regarding the legal requirements that apply.

I. Product Categories

Edible Cannabis Product

An edible cannabis product is a cannabis product intended for human consumption by oral ingestion, in whole or in part, including cannabis products that dissolve or disintegrate in the mouth. (See COMAR 14.17.01.01 B(21))

Infused Non-Edible Cannabis Product

An infused non-edible cannabis product is an ointment, salve, suppository, dermal patch, cartridge, or any other product containing cannabis that has been processed so that the dried leaves and flowers are integrated into other material that is not intended for human consumption by inhalation or oral ingestion. (See COMAR 14.17.01.01B(29))

Table 1. Infused Non-Edible Cannabis Product versus Edible Cannabis Product

Infused Non-Edible Cannabis Product	Edible Cannabis Product
<ul style="list-style-type: none"> • A topically-applied cannabis product, such as an oil, a wax, an ointment, or a salve • Suppository • Dermal patch • Vaporizer cartridge • Any orally-consumed capsule that does not contain natural or artificial flavor or sweetener • Tincture (as defined in COMAR 14.17.01.01) • Any other dosage form that is recognized by the United States Pharmacopeia, the National Formulary, or the Food and Drug Administration AND approved by the MCA 	<ul style="list-style-type: none"> • A cannabis product intended for human consumption by oral ingestion, in whole or in part, including cannabis products that dissolve or disintegrate in the mouth • Includes: <ul style="list-style-type: none"> ○ Solid, powdered, and liquid edibles ○ Capsules with flavors or sweeteners ○ Vegetable oil tinctures • Does not include: <ul style="list-style-type: none"> ○ Cannabis concentrates ○ Infused Non-Edible Cannabis Products ○ Dried leaves and flowers of the cannabis plant

Tinctures

Pursuant to COMAR 14.17.01.01B(54) and COMAR 14.17.13.06, a tincture is a solution that is dissolved in alcohol, glycerin, or vegetable oil and distributed in a dropper bottle of 4 ounces or less. A tincture shall contain no additional non-cannabis ingredients except potable water, unless approved by the Administration.

Note: Any tincture containing vegetable oil must be manufactured in accordance with the regulation of edible cannabis products under COMAR 14.17.13.05E—H and COMAR 14.17.11.05—14, but is exempt from the requirements under COMAR 14.17.11.05B. Vegetable oils are a food ingredient and have the potential of containing foodborne hazards. Therefore, tinctures that are made with vegetable oils are expected to be manufactured in accordance with all applicable edible cannabis product regulations related to manufacturing and sanitation.

Edible Cannabis Regulation Exemptions

The following orally-ingested products are exempt from the definition of edible cannabis products and the edible cannabis product regulations:

1. An orally-ingested cannabis-infused product indicated in Table 1; and
2. A dosage form recognized by the United States Pharmacopeia, the national formulary, or the Food and Drug Administration if the licensed processor:
 - i. Is certified by an accredited third-party certification body in an alternative pharmaceutical or dietary supplement certification approved by the MCA, and
 - ii. Submits an application in a form prescribed by the MCA to exempt the product.

II. Acceptable Edible Cannabis Products

Pursuant to COMAR 14.17.11.13, all permittees must establish standard operating procedures to ensure consistent and safe production of edible cannabis products and ensure that manufacturing processes reduce or eliminate microorganisms. Additionally, solid finished products must have a water activity level (aw) of 0.85 or less to help reduce the potential for microbial contamination during transport and storage (see the MCA's Technical Authority for Cannabis Testing).

Solid edible cannabis products

Pursuant to COMAR 14.17.13.05B(2), each single serving contained in a package of a multiple-serving edible cannabis product shall be physically separated in a way that enables an individual to determine how much of the edible cannabis product constitutes a single serving.



An intact product form containing multiple servings **does not** meet the requirements of §B(2) of this regulation if it has demarcations or delineations on the product to indicate individual servings.



Non-solid edible cannabis products

Pursuant to COMAR 14.17.18.05D, a package containing more than one serving of a non-solid (such as a liquid or powder) edible cannabis product shall:

1. Have a resealing cap or closure; and
2. Include within the package a measuring device that is appropriate for the product form, such as a dropper for liquids or a measuring spoon for powders.

Non-solid edible cannabis product packaging must contain a suitable device that allows a patient to easily identify a single serving.

Product Restrictions

COMAR 14.17.13.05C establishes specific product standards for edible cannabis products. These product standards include appearance and ingredient restrictions.

Appearance

A solid edible cannabis product may only be manufactured or distributed in geometric shapes.

An edible cannabis product may not:

1. Due to its shape, design, or flavor, be likely to appeal to minors.
2. Bear any likeness or contain characteristics to a human, animal, or fruit.
3. Contain characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings.
4. Resemble a commercially available food or beverage product that targets, or is primarily marketed to, minors.



Ingredients

An edible cannabis product may not:

1. Contain meat, seafood, unpasteurized eggs, or unpasteurized dairy of any type.
2. Be an alcoholic beverage, as defined in the Alcoholic Beverage Article, §1-101, Annotated Code of Maryland.
3. Contain any non-cannabis additive that would increase potency or toxicity, or that would create an unsafe combination with other psychoactive substances.

Note: Prohibited additives include but are not limited to, nicotine and caffeine. This prohibition does not apply to products containing naturally-occurring caffeine, such as coffee, tea, or chocolate.

Dosage Requirements

Homogeneity and stability studies must be conducted to demonstrate that a cannabis infused product or edible cannabis product is homogenous between servings, packages, and production lots, and the content of therapeutic compounds remains stable throughout the manufacturer-suggested shelf life (See the MCA's Technical Authority for Cannabis Testing).

Edible cannabis products may not have more than 10 milligrams (mg) of Delta-9 tetrahydrocannabinol (D9-THC) in a single serving, or 100mg of D9-THC per package.

Example:

- 10 single servings with 10mg D9-THC in each serving
- 20 single servings with 5mg D9-THC in each serving
- 40 single servings with 2.5mg D9-THC in each serving