



Hemp-Derived Cannabinoid Products Guidance August 24, 2022

INTRODUCTION

Pursuant to Minnesota Statutes section 214.108, the Board of Pharmacy is authorized to provide guidance to licensees about the application of the statutes and rules that the Board enforces. Such guidance is not binding in any court or other adjudicatory body. While the comments below are recommendations that do not have the force of law, some of the comments state the actual requirements of various statutes and rules. Please see Minnesota Statutes section 151.72 for the statutory requirements to manufacture, dispense, and sell Hemp-Derived Cannabinoid products in Minnesota.

This document has been approved by the Minnesota Board of Pharmacy and offers guidance to wholesalers, manufacturers, retailers, and other interested parties that are seeking to comply with Minnesota Statutes section 151.72. You may also review the Board's Hemp-Derived Cannabinoid Products Frequently Asked Questions (FAQ) document, which is also available on the Board's Web site. In addition to the Board's regulatory authority under Minnesota Statutes section 151.72, other state and federal agencies, including the Minnesota Departments of Agriculture and Health and the U.S. Food and Drug Administration, may have regulatory authority.

Note, the Board cannot provide legal advice. Individuals or companies involved in the manufacture, distribution, or sale of such products are encouraged to seek the advice of appropriate consultants and legal counsel. Individuals or companies should also review the recently enacted updates to Minnesota Statutes section 151.72.

GENERAL REQUIREMENTS

What is Permissible to Sell under 151.72

Only products that meet **all** the requirements of Minnesota Statutes section 151.72 are permissible to sell under Minnesota law.

Depending on the substances involved, products that do not meet all the requirements of that section may be misbranded or adulterated. It is a misdemeanor-level crime to sell misbranded or adulterated products. (See Minn. Stat. §§ 151.29 and 151.30). Products that do not meet all the requirements of Minnesota Statutes section 151.72 may also be schedule 1 controlled substances, depending on the substance and quantity involved. It can be a felony-level crime to sell or possess controlled substances. (See Minn. Stat. §§ 152.02 – 152.025).

Even if products fully meet all the requirements of Minnesota Statutes section 151.72, they may still be illegal to sell under federal law. The United States Food and Drug Administration (FDA) has provided information about the legality of substances derived from hemp on the FDA's [FAQ webpage](#).

Geographical Considerations

Products containing substances derived from hemp that are shipped **into** Minnesota from **outside** of the state must meet all the requirements of Minnesota Statutes section 151.72. Likewise, products containing substances derived from hemp that are manufactured **within** Minnesota even if they are intended for sale **outside** of Minnesota must meet all the requirements of Minnesota Statutes section 151.72. Additionally, the Board reminds manufacturers, wholesalers, and retailers located within Minnesota to **not** ship, sell, or deliver products into another state where the product would be prohibited by that state's law.

Hemp Considerations

The hemp used to derive the cannabinoids that are used to manufacture products must meet the requirements of Minnesota Statutes chapter 18K and Minnesota Rule 1565.

PRODUCT GUIDANCE

Application of Minnesota Statutes section 151.72's Tetrahydrocannabinol (THC) Limits

Minnesota Statutes section 151.72 applies to **all** cannabinoid products including edible and nonedible cannabinoid products.

Edible cannabinoids are defined in section 151.72, subdivision 1(c), as products that are intended to be eaten, or consumed as a beverage, by humans, that contain a cannabinoid in combination with food ingredients, and are not drugs. Accordingly, to be considered an edible cannabinoid, **no claim can be made or implied** that the product can prevent, treat, or cure a disease, or alter the structure or function of a human or animal body. A product for which such claims are made would fall under the definition of the word "drug" found in Minnesota Statutes section 151.01, subdivision 5, and would be regulated as a drug. (See Minn. Stat. chs. 151 & 152.)

Minnesota Statutes section 151.72 contains three limitations on the amount of THC an edible cannabinoid product may contain. Please note that these limitations apply to all THC combined in a cannabinoid product regardless of whether the product contains more than one type of THC. The three limitations are as follows:

- 1) Edible cannabinoid products must not contain more than five (5) milligrams of any and all THC's per single serving.
- 2) Edible cannabinoid products must not contain more than a total of fifty (50) milligrams of any and all THC's per package.
- 3) Edible cannabinoid products must not contain more than 0.3% of any and all THC's. This limitation applies to any and all units, whether servings, packages, or other.

In addition to the limitations described above for edible cannabinoids, all cannabinoid products, regardless of the route of administration, must not contain more than 0.3% of any and all THC's.

Examples include, but are not limited to tablets, capsules, solutions, tinctures, or other products meant for oral administration/ingestion; creams, lotions, ointments, salves, or other products meant for topical administration; products meant to be inhaled, smoked, vaped, sprayed into nostrils, or insufflated (sniffed); and hemp flowers and buds.

Cannabinoid products that exceed the THC limitations described above may not be manufactured or sold in Minnesota and may subject the manufacturer and seller to criminal enforcement.

Other Substances Derived from Hemp

The Board is aware of products that contain other substances derived from hemp. ***No intoxicating substances derived from hemp, other than tetrahydrocannabinols within the specified limits, can be legally sold in Minnesota.***

Combining Hemp-Derived Cannabinoids with Over-the-Counter Drug Ingredients

The FDA has warned companies that products that contain cannabinoids derived from hemp, that are combined with over-the-counter drugs, would be unapproved new drugs, making them illegal to sell under federal law.

Manufacturing Edible Cannabinoids

As noted above, edible cannabinoids must not contain more than 0.3% of all THC's combined **and** must not contain more than five (5) mg of all THC's combined per single serving and fifty (50) mg of all THC's combined per package.

Food ingredients that will be combined with substances derived from hemp, to make an edible cannabinoid product, must meet requirements for food manufacturing. Prior to being combined with substances derived from hemp, food ingredients fall under the definition of "food" found in Minnesota Statutes section 34A.01, subdivision 4, and are under the jurisdiction of the Minnesota

Department of Agriculture. Additional information can be found at the [Minnesota Department of Agriculture Manufactured Food Regulations website](#).

Minnesota Statutes section 151.72, subdivision 5a, states that an edible cannabinoid product must not “be made by applying an extracted or concentrated hemp-derived cannabinoid to a commercially available candy or snack food item.” The Board interprets the word “applying” to include adding the cannabinoid to a commercially available food product in any manner. Accordingly, edible cannabinoid products cannot be made by combining an extracted or concentrated hemp-derived cannabinoid with a commercially produced candy, snack food item, or other food.

Minnesota Statutes section 151.72 only allows for the sale of manufactured and prepackaged products that contain substances derived from hemp. It does not allow for food service or other food preparation activities using products which contain substances derived from hemp. Accordingly, products that contain substances derived from hemp cannot be added to foods or beverages by restaurants, bars, or other businesses that prepare food and beverages for onsite or take-away consumption.

Prior to licensing in Minnesota, alcoholic beverages must adhere to the federal requirements under the U.S. Department of Treasury Alcohol, Tobacco, Tax and Trade Bureau (TTB), which require the submission and approval of the formulation and brand labels. For more information, visit the [TTB’s hemp policy for alcoholic beverages webpage](#).

TESTING GUIDANCE

The minimum statutory testing standards, as set forth in Minnesota Statutes section 151.72, subdivision 4(a)(1),(2), and (3), are now in effect and apply to all manufacturers.

Products that do not meet all the requirements of that section may be misbranded or adulterated. As noted above, it is a misdemeanor-level crime to sell misbranded or adulterated products. (See Minn. Stat. §§ 151.29 and 151.30). Products that do not meet all the requirements may also be schedule 1 controlled substances, depending on the substance and quantity involved. As noted above, it can be a felony-level crime to sell or possess controlled substances.

Applying the Testing Requirements

The testing requirements found in Minnesota Statutes section 151.72, subdivision 4, apply to the product itself, they do **not** apply to the hemp from which cannabinoids and THCs are derived. A manufacturer of a product regulated under Minnesota Statutes section 151.72 must submit representative samples of **each** batch or lot of the products that will be sold to consumers to an independent, accredited laboratory in order to certify that the product complies with requirements

in that section. A certificate of analysis for the hemp from which a cannabinoid is derived, or for an extract that is used to make the product sold to the consumer, does **not** meet the testing requirement. A manufacturer's internal testing results **cannot** be used to establish compliance with these requirements.

The testing required by Section 151.72 must be completed and certified **before** a manufacturer's product is offered for sale in Minnesota. Manufacturers are required to provide the Board with test results certifying their product complies with Section 151.72, upon request.

Laboratory Requirements

Minnesota Statutes section 151.72, subdivision 4, states that "[t]esting must be consistent with generally accepted industry standards for herbal and botanical substances." It is the responsibility of the manufacturer to identify an independent, accredited laboratory that is capable of conducting the required testing. The Minnesota Department of Health, Office of Medical Cannabis (OMC), has a process in place to approve laboratories. The Board considers the laboratories approved by the OMC to be acceptable for conducting the testing required under Minnesota Statutes section 151.72, to the extent the product is derived from hemp. Laboratories must be accredited to ISO/IEC 17025:2017 standards by an accreditation organization.

PACKAGING AND LABELING GUIDANCE

Packaging and labeling must comply with the requirements of Minnesota Statutes section 151.72, subdivision 5.

Child-Resistant Packaging

One of the requirements is that packaging be child-resistant. Packages that have been certified as child-resistant under the requirements of the Poison Prevention Packaging Act (PPPA) at 16 CFR 1700.15(b)(1) will meet this requirement. Additional information can be found at the [Consumer Product Safety Commission website](#).

When investigating packaging complaints, the Board may take into consideration whether the packaging meets the child-resistant requirements, adopted by other states, for the packaging of hemp-derived products.

The requirement that packaging be child-resistant does not apply to an edible cannabinoid product that is intended to be consumed as a beverage.

Targeting or Appealing to Children

Edible cannabinoid products must not be marketed to or target children. Such products **must not** bear the likeness or contain characteristics of persons, animals, or fruit that appeal to children.

Such products also **must not** be modeled after a brand of products primarily consumed by or marketed to children.

Deceptive Packaging

Edible cannabinoid products **must not** be packaged in a way that resembles the trademark, characteristic, or product-specialized packaging of a commercially available food product. Edible cannabinoid products also **must not** be packaged in a container that includes a statement, artwork, or design that could reasonably mislead any person to believe the package contains anything other than an edible cannabinoid product.