



Adult-Use Hemp Product Regulation Act

Model Legislation: “Adult-Use Hemp Product Regulation Act”

Summary:

The federal Agriculture Improvement Act of 2018, also known as the “2018 Farm Bill,” defined cannabis containing less than 0.3% delta-9 tetrahydrocannabinol (THC) as hemp and removed hemp from the auspices of the Controlled Substances Act. This includes “all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not.” In the wake of this federal change, a significant interstate market has emerged for hemp extracts and cannabinoids.

Many of these extracts and cannabinoids are non-intoxicating, but some are THC variants that have an intoxicating effect similar to delta-9 THC or can be chemically modified into an intoxicating THC variant. Courts have interpreted federal statute to mean that even chemically modified hemp extracts are federally legal hemp products because the dispositive factor for this determination is the provenance of the material and not the method of manufacture.

The federal Food and Drug Administration has not established clear product standards or manufacturing protocols for consumable hemp-derived products. Likewise, many states have not established these standards nor established regulations governing the sale of potentially intoxicating hemp products. This model legislation would require a manufacturer of adult-use hemp products to register with state authorities and adhere to certain manufacturing and testing standards, require retailers of these products to procure a license and remit excise taxes on the retail sale of these products, and would restrict to sale of these products to adults over the age of 21.

ADULT-USE HEMP PRODUCT REGULATION ACT

1. Definitions. As used in this section:

- a. “Adult-use hemp product,” means any finished product cultivated, derived, or manufactured from hemp or hemp materials that contains a total THC concentration of greater than 0.5 milligrams per serving AND greater than 2.5 milligrams per package, OR which exceeds the ratio limitation of nonintoxicating cannabinoids to intoxicating cannabinoids (15:1 CBD:THC).
- b. “Approved source” means
 - i. a [state] adult-use hemp product manufacturer, processor, or wholesaler permitted with [the state regulatory agency]; OR
 - ii. an out-of-state manufacturer, processor, or distributor duly authorized to produce or distribute adult-use hemp products under the laws of their applicable jurisdiction;
- c. “Cannabinoid” means any hemp-derived phytocannabinoid, including, but not limited to: Tetrahydrocannabinol (THC), Tetrahydrocannabinolic acid (THCA), cannabidiol (CBD), cannabidiolic acid (CBDA), cannabinol (CBN), and cannabigerol (CBG).
- d. “Child-resistant” means packaging that is
 - i. Designed or constructed to be significantly difficult for children under five (5) years of age to open and not difficult for adults to use properly; AND
 - ii. Resealable to maintain this effectiveness for children through multiple openings for any product containing multiple servings.
- e. “Consumable hemp product” or “hemp product” means:
 - i. a finished product derived from industrial hemp that contains any cannabinoid, including cannabidiol, and is intended for consumption or topical use with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent; AND
 - ii. "Consumable hemp product" shall include commercial feed, pet products, and hemp floral material.
- f. “Hemp” or "Industrial hemp" means the plant *Cannabis sativa* L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a total delta-9 THC concentration of not more than 0.3 percent on a dry weight basis;
 - i. Hemp and hemp-derived cannabinoids, including cannabidiol, shall be considered an agricultural commodity and not a controlled substance due the presence of hemp or hemp-derived cannabinoids.
- g. “Hemp product” means a finished product with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis;
 - i. Hemp products shall not be considered controlled substances due to the presence of hemp or hemp-derived cannabinoids;
- h. “Hemp product class” means a group of cannabinoid products that:
 - i. Have all ingredients in common; and
 - ii. Are produced by or for the same company.
- i. “Non-intoxicating hemp product” means a product:

- i. with non-psychoactive properties that does not result in alteration of perception, cognition, or behavior;
 - ii. contains a total THC concentration of not more than 0.5 milligrams per serving or 2.5 milligrams per package;
 - iii. does not exceed a ratio of fifteen (15) non-intoxicating cannabinoids to one (1) intoxicating cannabinoid; or
 - iv. is deemed a non-intoxicating hemp product or hemp product class by [Department/Agency].
 - j. "Package" means a container or wrapping in which any consumer commodity is enclosed for the purpose of delivery or display of that commodity to retail purchasers and contains one or more servings.
 - k. "Remote retailer" means a person or entity who offers any consumable hemp product for sale at retail, or for any transaction of products in lieu of a sale, through a digital application, catalog, or the internet, that can be purchased and delivered directly to a consumer in [State]. "Retail sale" or "sale at retail" means the sale or any transaction in lieu of a sale of products to the public for use or consumption but does not include the sale or any transaction in lieu of a sale of products for resale.
 - l. "Retailer" means a person or entity who offers any consumable adult-use hemp product for sale at retail.
 - m. "Serving" means the total amount of individual units or amount of liquid of a product recommended by the manufacturer to be consumed at a single time.
- 2. Permit to process, manufacture, warehouse, or distribute adult-use hemp products.**
- a. It is an offense for a person or entity to engage in the business of manufacturing, producing, or distributing adult-use hemp products without a valid permit required by this act.
 - b. All qualifying applicants seeking a permit to process, manufacture, store, or distribute adult-use hemp products shall be granted a permit by [Department/Agency] so long as they:
 - i. Complete the application process
 - ii. Adhere to the regulations in this act; and
 - iii. Pay the fee required in subsection (c).
 - c. The permit shall be:
 - i. Nontransferable with regard to the person (or entity) or address;
 - ii. Posted in a conspicuous place in the facility;
 - iii. Renewed every five (5) years;
 - iv. Include the product registration fee required by subsection X of this section; and
 - v. Include the permitting fees as follows:
 - 1. For an adult-use hemp processor or manufacturer the permit the fee is: \$__.
 - 2. For an adult-use hemp wholesale warehouse or distributor the permit fee is: \$__.
 - d. Application for a permit or registration to process, manufacture, warehouse, or distribute adult-use hemp products shall be made to the [Department/Agency] in a

form provided by the [Department/Agency] and shall include the following information:

- i. The name and address of the applicant;
- ii. The name and address of the brand or company whose name shall appear on the label, if other than the applicant; and
- iii. The permit fee.
- iv. Application to register as an out-of-state processor, manufacturer, or distributor of adult use hemp products shall include the additional information:
 1. A copy of the current, valid permit to process or manufacture adult-use hemp products issued from their state regulatory authority; and
 2. A copy of the relevant state regulation pertaining to the production of adult-use hemp products.
 3. The product registration fee required by subsection (c) of this section.
- v. A new in-state processor or manufacturer permit or out-of-state processor or manufacturer registration shall be required for any changes to the requirements of [subsection d] this section.

3. Adult-use hemp product registration, regulation.

- a. Any adult-use hemp product or adult-use hemp product class sold in [state name] and intended for human consumption must be registered with [Department/Agency]. Products that do not meet the definition of adult-use hemp product shall be regulated in accordance with the [the State's Food, Drug, and Cosmetic Law]. For the purposes of this rule, non-intoxicating hemp products shall:
 - i. Have a ratio of at least fifteen (15) non-intoxicating cannabinoids to one (1) intoxicating cannabinoid; or
 - ii. Contain 2.5 milligrams or less of intoxicating cannabinoids per package.
- b. All in-state or out-of-state processors, manufacturers, or distributors permitted by the [Department/Agency] seeking to register new products shall submit:
 - i. The name of the applicant;
 - ii. The name and address of the brand or company whose name shall appear on the label, if other than the applicant;
 - iii. The name of the product;
 - iv. The name and address of the origin of the adult-use hemp with which the final product was manufactured;
 - v. A complete copy of the front and back of the label that will appear on the product; and
 - vi. The product registration fee.
- c. Every batch of a registered adult-use hemp product shall contain a certificate of analysis from an accredited third-party laboratory, including the following information:

- i. The batch identification number, date received, date of completion, and the method of analysis for each test conducted.
 - ii. Test results identifying:
 - 1. Solvents, pesticides, microbials, and heavy metals;
 - 2. The cannabinoid profile by percentage of weight; and
 - 3. A potency test of the final product indicating the serving size, total THC per serving, total number of servings, and total THC per package, identified as milligrams per grams.
- d. A new in-state processor or manufacturer permit or out-of-state processor or manufacturer permit shall be required for any changes to the requirements [of the above subsection] of this section.
- e. Product registration fee.
 - i. A product registration fee of \$__ shall be paid for each adult-use hemp product or adult-use hemp product class sold in [State Name].
 - ii. The fee shall be paid to [Department/Agency] by check or money order made payable to [the state treasurer].
- f. For the purpose of establishing a product's ratio of intoxicating to nonintoxicating cannabinoids:
 - i. Intoxicating cannabinoids shall include:
 - 1. Delta-10 THC;
 - 2. Delta-9 THC;
 - 3. Delta-8 THC; or
 - 4. Any additional cannabinoid deemed to be intoxicating by [Department/Agency].
 - ii. Non-intoxicating cannabinoids shall include:
 - 1. Cannabidiol (CBD)
 - 2. Cannabidiolic acid (CBDA)
 - 3. Cannabidivarin (CBDV); or
 - 4. Any additional cannabinoid deemed non-intoxicating by [Department/Agency].
- g. A new product registration shall be required for changes:
 - i. In the chemical composition or formula of the cannabinoid product; or
 - ii. To the serving size or directions for use.

4. Manufacturing, processing, storage, and distribution of adult-use hemp products.

- a. All processors and manufacturers shall meet:
 - i. [Applicable state laws regarding Hazard Analysis and Critical Control Point systems]; and
 - ii. [state requirements regarding permits, plans, construction/maintenance, water supply, and plumbing standards for food or cosmetic manufacturing or processing plant, packaging plant, storage warehouse, or distribution warehouse]
- b. A business that processes, manufactures, warehouses, distributes, sells, or serves adult-use hemp products shall not employ any person who is under twenty-one (21) years of age unless that person employed is at least eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.

- c. The serving size of an ingestible adult-use hemp product shall be:
 - i. As a whole unit where one (1) unit equals one (1) serving; and
 - ii. Equal the maximum amount recommended, as appropriate, on the label for consumption per occasion in whole units.
- d. Only permitted adult-use hemp processing facilities shall perform cannabinoid extraction, conversion, catalyzation, distillation, hydrogenation, or other refinement processes for adult-use hemp products registered with [the State].
- e. An adult-use hemp product processing or manufacturing facility shall not treat or otherwise adulterate a cannabinoid product with:
 - i. Any non-cannabinoid additive that increases toxicity or addictive potential, excluding caffeine;
 - ii. Alcohol;
 - iii. Nicotine; or
 - iv. Other chemicals that may increase carcinogenicity or cardiac effects.
- f. All products shall be homogenized to ensure uniform distribution of cannabinoids throughout the product.
- g. An adult-use hemp product processor or manufacturer shall only use the following solvents: water, glycerin, vegetable oils, animal fats, butane, propane, carbon dioxide, ethanol, isopropanol, acetone, heptane, ethyl acetate, and pentane;
OR
 - i. any other solvent pre-approved by the [Department/Agency].
- h. An adult-use hemp product processor or manufacturer using hydrocarbon-based solvents shall use only such solvents of ninety-nine (99) percent or greater purity. Nonhydrocarbon-based solvents shall be food grade.
- i. Processors and manufacturers of adult-use hemp products shall retain on file for two (2) years:
 - i. A current copy of the safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process; and
 - ii. A certificate of analysis (COA) from the original manufacture with purity and impurity limits and results for all solvents used.
- j. Extraction processes shall take place in an environment properly ventilated to control all sources of ignition where a flammable atmosphere is, or could be, present.
- k. Cannabinoid processing facilities shall not use pressurize canned flammable fuel, such as butane intended for use in outdoor activities, handheld torch devices and refillable cigarette lighters.
- l. Cannabinoid processing facilities using carbon dioxide shall have equipment and facilities approved by local fire code officials, if applicable.
- m. Processes using flammable gas or flammable liquid shall have leak or gas detection measures, or both.
- n. An adult-use hemp product manufacturer shall not use dimethylsulfoxide (DMSO) in the manufacture of adult-use hemp products, and possession upon the permitted premises is prohibited.
- o. An adult-use hemp product manufacturer may use terpenes or other hemp essential oil but shall not use non-cannabinoid derived inactive ingredients not

listed in the Food and Drug Administration inactive ingredient database in the manufacture of inhalable adult-use hemp products; AND

- i. Any non-cannabinoid derived inactive ingredients used shall be less than or equal to the concentration listed in the database.
- p. The following substances shall be prohibited in extraction processes for adult-use hemp products intended for inhalation:
 - i. Acetates;
 - ii. Medium-chain triglycerides (MCT);
 - iii. Diketones:
 - 1. 2,3-butanedione (Diacetyl);
 - 2. 2,3-pentanedione (acetylpropionyl); AND
 - 3. 3-hydroxybutanone (acetoin);
 - iv. Myclobutanil;
 - v. Artificial food coloring; and
 - vi. Benzoic acid.

5. Product Testing

- a. An adult-use hemp product manufacturer or processor may submit representative samples of each batch of the final product equivalent to an independent, accredited laboratory to certify that the product complies with standards adopted by [the agency]. Testing must be consistent with generally accepted industry standards and, at a minimum, must confirm the product:
 - i. Contains the amount or percentage of cannabinoids that is stated on the product label, within an allowable variance of 20 percent of the stated amount;
 - ii. Does not contain more than trace amounts of any mold, residual solvents or other catalysts, pesticides, fertilizers, or heavy metals.
- b. Infused cannabinoid products may not require additional testing for microbial impurities, mycotoxins, residual pesticides, heavy metals, or residual solvents if the cannabinoid distillate used in the infused product was:
 - i. Previously tested in compliance with this regulation; and
 - ii. Test results indicate the batch or process lot was within established limits.
- c. Infused cannabinoid products shall be tested if the addition of ingredients or processing practices create reasonable or foreseeable hazards related to microbial impurity, mycotoxin, pesticides, heavy metals, or residual solvents.
 - i. All hemp cannabinoid batches intended for inhalation shall be tested for acetates.
 - ii. In accordance with [section] all applicable certificates of analysis shall accompany the final product.
- d. Testing facility requirements.
 - i. Testing facilities used by adult-use hemp processors or manufacturers shall be independent, third-party, accredited to the standard established by the International Organization for Standardization (ISO) 17025 by an International Laboratory Accreditation Cooperation recognized by the accreditation body.
 - ii. The testing facility shall:

1. Maintain ISO 17025 accreditation; and
2. Comply with all required analytes standards for the relevant test methods of:
 - a. Cannabinoids;
 - b. Microbial impurities;
 - c. Mycotoxins;
 - d. Residual pesticides;
 - e. Heavy metals; and
 - f. Residual solvents, if applicable.
- iii. The testing facility shall:
 1. Generate a COA for each representative sample tested; and
 2. Ensure the COA contains the results of all required analyses performed for the representative sample.
- iv. The COA shall contain, at a minimum:
 1. The facility name;
 2. The facility address,
 3. License number;
 4. Batch or lot number;
 5. Sample history;
 6. Analytical methods and instrumentation used;
 7. Analytes detected that are unknown; and
 8. Chromatograph of cannabinoid test results.

6. Product Packaging and Labeling requirements.

- a. Each container of an adult-use hemp product shall:
 - i. Have a temper-evident seal;
 - ii. Be in child-resistant packaging; AND
 - iii. Be labeled in compliance with [State code on labeling consumable products] and the requirements of this law.
- b. Adult-use hemp product packaging shall not include:
 - i. [child-appealing packaging]
- c. An adult-use hemp product regulated under this section must bear a label that contains, at a minimum:
 - i. The name, location, and contact information of the manufacturer or distributor of the product;
 - ii. The name and address of the independent, accredited laboratory used by the manufacturer to test the product;
 - iii. The batch number;
 - iv. A list of all ingredients, ordered by weight, including direct and indirect additives;
 - v. An accurate statement of the amount or percentage of cannabinoids found in each unit of the product for consumption. Such statement shall:
 1. be listed per serving and the total amount per serving;
 2. accurately reflect testing results; and

3. shall not contain less than eighty (80) percent or more than one hundred and twenty (120) percent of the concentration of total cannabinoid content as listed on the product label.
- vi. A warning statement that the product contains THC;
- vii. A warning that the product may cause intoxicating effects, including drowsiness or impairment, those intoxicating effects may be delayed up to two hours, and users should not operate machinery while using the product;
- viii. A statement that the product is only intended for use by adults twenty-one (21) years and older and should be kept out of reach of children and pets;
- ix. a statement that the product does not claim to diagnose, cure, or prevent any disease and has not been evaluated or approved by the FDA unless the product has been so approved; and
- x. An FDA major allergen warning if applicable.
- d. The information in paragraph [above] may be provided on the outer package if the immediate container of the product is too small to contain all of the required information.
- e. The information required in [this subparagraph] may be provided through the use of a scannable barcode or matrix barcode that links to a page on the manufacturer's website if that page contains all the information required by this subdivision.

7. Retail sale of adult-use hemp products.

- a. Retail establishments and food service establishments offering adult-use hemp products shall be permitted by the [Department/Agency] in accordance with this Act.
- b. The permit shall be:
 - i. Nontransferable to any person, entity, or address;
 - ii. Renewed annually; and
 - iii. Include a \$__ annual permit fee.
- c. A business that distributes, sells, or serves adult-use hemp products shall not employ any person under twenty-one (21) years of age, unless that person is eighteen (18) years of age and under the direct supervision of a person twenty-one (21) years of age or older.
- d. All adult-use hemp products sold in a retail establishment shall:
 - i. Be from an approved source;
 - ii. Be registered with [Department/Agency] in accordance with this Act;
 - iii. Be pre-packaged and labeled in accordance with this Act; and
 - iv. Have a valid printed certificate of analysis available upon request.
- e. A retailer shall ensure that all adult-use hemp products are properly registered with [Department/Agency];
- f. A retailer may register a product in lieu of the processor or manufacturer.
- g. Retailers of adult-use hemp products shall maintain records of wholesale product purchase, including invoices:

- i. clearly indicating the name and location of the approved source as the supplier; and
 - ii. transfer manifests or bills of lading.
 - h. Adult-use hemp products for sale at retail shall:
 - i. Be secured in the retail setting to prevent theft or other access to persons under the age of twenty-one (21); and
 - ii. Not be sold, gifted, or otherwise transferred to any person under the age of twenty-one (21).
 - i. Any person who sells adult-use hemp products at retail shall:
 - i. Require proof of age of the buyer; and
 - ii. May deliver or ship adult-use hemp products to consumers over the age of twenty-one (21) years in packages clearly marked “adult-use only”.
 - j. All persons located outside of the state who deliver, ship, or cause to be delivered or shipped adult-use hemp products directly to any consumer in [the state] shall hold a valid adult-use hemp product wholesaler or distributor permit issued by [the state].

8. Adult-use hemp product retail at food service establishments.

- a. Only consumable hemp products or hemp product classes approved in accordance with this Act may be sold in retail and food service establishments.
- b. Retail food service establishment may register an adult-use hemp product or consumable hemp product in lieu of the process or manufacturer.
- c. Consumable adult-use hemp products sold at food service establishments shall be:
 - i. pre-packaged adult-use hemp products from an approved source; and
 - ii. registered with the state.
- d. Adult-use hemp products shall not be added to an ingestible food product at a food service establishment.

9. Uniform Cannabis Excise Tax

- a. Any retailer licensed to sell adult-use hemp products shall procure a Uniform Cannabis Excise Tax Certificate from the [Taxation Department] prior to retailing any adult-use hemp products.
- b. The [Taxation Department] shall issue a Uniform Cannabis Excise Tax Certificate to a licensed retailer of adult-use hemp products within three (3) business days of receiving a completed application on a form prescribed by the [Taxation Department]. The Uniform Cannabis Excise Tax Certificate will indicate a unique account number in the name of the licensed retailer of adult-use hemp products.
- c. A licensed retailer of adult-use hemp products shall report to the [Taxation Department], on a form prescribed by the [Taxation Department], the total value of its gross retail sales of adult-use hemp products across all retail locations for the preceding quarter within 30 days of every March 31, June 30, September 30, and December 31. A retailer’s obligation to report the gross retail sales of adult-use hemp products begins for the quarter in which the retailer has received a Uniform Cannabis Excise Tax Certificate.

- d. There is hereby levied a Uniform Adult-Use Cannabis Excise Tax at a rate of X percent of the total value of gross retail sales of adult-use hemp products. The excise tax imposed pursuant to this subsection:
 - i. Is the obligation of the retailer of adult-use hemp products but may be recovered from the purchaser.
 - ii. Is separate from and in addition to any general state and local sales and use taxes that apply to retail sales of tangible personal property.
 - iii. Is due and payable for holders of a Uniform Cannabis Excise Tax Certificate within 30 days of every March 31, June 30, September 30, and December 31.
- e. A local government shall not levy an excise tax on adult-use hemp products.
- f. The revenues collected from the excise tax imposed pursuant to subsection d must be distributed:
 - i. To the [Department/Agency] to the extent of its costs for regulating adult-use hemp processors, manufacturers, retailers, and products.
 - ii. If any money remains after the revenues are distributed pursuant to paragraph (i), to the Economic Stabilization Fund.
- g. A person shall not, with intent to defraud the State or evade payment of the excise tax on cannabis or any part of the tax:
 - i. Make, cause to be made or permit to be made any false or fraudulent return or declaration or false statement in any return or declaration.
 - ii. Make, cause to be made or permit to be made any false entry in books, records or accounts.
 - iii. Keep, cause to be kept or permit to be kept more than one set of books, records or accounts.
- h. Any person who violates the provisions of subsection g is guilty of a gross misdemeanor.