



## ADMINISTRATIVE RULES OF MONTANA



### 42.39.102 DEFINITIONS

The following definitions apply to this chapter:

- (1) "Act" means the Marijuana Regulation and Taxation Act, codified at 16-12-101, MCA, et. seq.
- (2) "Authorized employee" means:
  - (a) an employee of the department who has received written authorization from the department director or the director's designee to obtain individual names and other identifying information from the marijuana registry;
  - (b) an employee of a state or local law enforcement agency who is authorized to obtain marijuana registry information through the Montana Criminal Justice Information Network (CJIN)/marijuana registry interface; or
  - (c) an employee of a state or local government agency, including a state or local law enforcement agency, who has received authorization to obtain marijuana registry information.
- (3) "Batch" means:
  - (a) a quantity of usable marijuana from a harvest lot; or
  - (b) a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.
- (4) "CBD" means cannabidiol.
- (5) "CBDA" means cannabidiolic acid.
- (6) "Certificate of analysis" means the report prepared by a marijuana testing laboratory about the analytical testing performed and the results obtained by the laboratory.
- (7) "Chemical manufacturing" means the use of chemical compounds such as, but not limited to, hydrocarbon solvents or food grade nonhydrocarbon solvents to separate cannabinoids or marijuana analytes of interest from marijuana.
- (8) "Child resistant" means packaging designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly. The standard for child-resistant packaging is set by the federal consumer product safety commission (CPSC) and the testing procedures found in 16 CFR 1700.20 (2012).
- (9) "Compliance audit" means a department review of aspects of a licensee's business without conducting a physical on-site inspection, including but not limited to website compliance checks,

review of seed-to-sale tracking system records, permit compliance checks, and local ordinance compliance checks.

- (10) "Cultivate" means to grow, propagate, clone, or harvest marijuana for use by registered cardholders or consumers.
- (11) "Customer" means, collectively, adult use consumers and registered cardholders.
- (12) "Edible marijuana-infused product" or "edible" means an ingestible marijuana-infused product that is intended to be taken by mouth, swallowed, and primarily absorbed through the gastrointestinal tract. Edible marijuana-infused products may be psychoactive when used as intended. Without limitation, edible marijuana-infused products may be in the form of a food, beverage, capsule, tablet, or tincture.
- (13) "Employee" as defined in 16-12-102, MCA, includes an independent contractor that performs work for any aspect of a marijuana business.
- (14) "Existing outdoor cultivation space" means outdoor space used to grow live marijuana plants in an area exposed to natural sunlight and environmental conditions including variable temperature, precipitation, and wind, licensed on or before November 3, 2020.
- (15) "Exit package" means a sealed container or package provided at the retail point of sale, in which any marijuana item already within a container is placed.
- (16) "Fee" means the mandatory fees required by the department.
- (17) "Fingerprint card" means an FD-258 fingerprint card utilized to facilitate a Federal Bureau of Investigation (FBI) fingerprint and background check.
- (18) "Food-Grade" means the processing and packaging has been done with clean equipment and can be safely eaten.
- (19) "Green county" means a county where the majority of voters voted to approve Initiative Measure No. 190 in the November 3, 2020 general election or where the local government approval provisions of 16-12-301, MCA, have been satisfied. This definition does not include a municipality that has approved or disapproved a category or categories of marijuana businesses, as authorized in 16-12-301, MCA.
- (20) "Ingestible marijuana-infused product" or "ingestible" means a product that contains marijuana and at least one other ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended to be taken into the body, and is either categorized as an edible marijuana-infused product or a transmucosal marijuana-infused product.
- (21) "Ingredient" means any substance that is added to marijuana items that changes its final form including but not limited to flavorings, aromatic oils, colorants, food items, spices, sweeteners, and preservatives.
- (22) "Label" or "labeling" means the printed analytical information pertaining to the marijuana flower or marijuana product displayed on the packaging in which marijuana or a marijuana product is dispensed or displayed to a customer.
- (23) "Licensee" means any person licensed by the department.

- (24) "Limited access area" means a building, room, or other contiguous area upon the licensed premises where marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under the control of the licensee.
- (25) "Major food allergen" or "allergen" means milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat, sesame, soybeans, any additional ingredient identified by the United States Food and Drug Administration, and any ingredient containing a protein derived from these foods.
- (26) "Manufacture" means the act of preparing and processing usable marijuana into a marijuana-infused product. A marijuana-infused product must be labeled as to indicate that it contains marijuana.
- (27) "Marijuana" means the same as the definition in 16-12-102, MCA, and includes the biomass of the marijuana plant which contains greater than 0.3% total THC concentration and appreciable concentrations of other cannabinoids of interest including flower, bud, shake, trim, and manicure.
- (28) "Marijuana concentrate and extract" or "concentrate and extract" means the same as the definition in 16-12-102, MCA, and includes a substance obtained by separating and/or concentrating naturally occurring chemical constituents of marijuana, such as, but not limited to, cannabinoids, from marijuana plant material by mechanical, physical, chemical, or other processes that may:
- (a) contain solvents in allowable amounts and ingredients used to promote a desired physical state, texture, or flavor in the marijuana concentrate, but no other ingredients; or
  - (b) be intended for use in the production of marijuana-infused products; or
  - (c) be a finished product intended for consumption or use.
- (29) "Marijuana-infused product" means the same as the definition in 16-12-102, MCA, and includes the infusion of cannabinoids of interest using marijuana or marijuana concentrate or extract into existing products, substances, or consumer goods, and as an ingredient in the production of consumer goods that would not naturally or ordinarily contain cannabinoids of interest.
- (30) "Marijuana items" means:
- (a) marijuana;
  - (b) usable marijuana;
  - (c) dried leaves and flowers of the marijuana plant;
  - (d) marijuana derivatives, concentrates, extracts, resins, infused products, edible products, ointments, tinctures, suppositories, topicals; and
  - (e) other marijuana-related products.
- (31) "Marijuana laws" for the purposes of these rules, means any combination of regulatory authority pursuant to the Montana Marijuana Regulation and Taxation Act (Title 16, chapter 12, MCA), rules of the department, or local ordinances applicable to marijuana businesses.
- (32) "Marijuana product category" means a defined group of marijuana products that are in the same form. Marijuana product categories are:
- (a) marijuana flower;
  - (b) marijuana concentrates; and

- (c) marijuana-infused products, including the following subcategories:
  - (i) ingestible marijuana-infused products, including the following subcategories:
    - (A) edible; and
    - (B) transmucosal;
  - (ii) non-ingestible marijuana-infused products, including the following subcategories:
    - (A) topical; and
    - (B) transdermal.
- (33) "Mechanical manufacturing" means the use of mechanical methods to produce or refine marijuana concentrates and extracts, such as but not limited to a press, centrifuge, or evaporation.
- (34) "Mixed strain" means multiple strains of marijuana.
- (35) "Monthly" means, for purposes of determining a registered cardholder's maximum monthly amount of usable marijuana, a period of 30 consecutive days.
- (36) "Motor vehicle," for purposes of these rules, means a vehicle propelled by its own power and designed or used to transport persons or property on the highways of the state with an interior passenger compartment.
- (37) "Non-ingestible marijuana-infused product" or "non-ingestible" means a product that contains marijuana and at least one other ingredient, is intended for consumption or use other than by smoking or vaporizing, is intended for external use only, and is either a topical marijuana-infused product or a transdermal marijuana-infused product.
- (38) "Opaque" means packaging that does not allow the contents to be seen when unopened. Packaging may be opaque by virtue of the specific properties of the material of which it is composed, including any coating applied to it, or by means of a secondary opaque covering, such as a sticker.
- (39) "Package" or "packaging" means the immediate container in which a finished marijuana product is placed for retail sale to consumers and any outer container or wrapping used in the retail display of the marijuana or marijuana product to customers, and includes graphics, logos, and design elements.
- (40) "Performing work on behalf of any aspect of a marijuana business" means and includes:
  - (a) possessing, handling, producing, propagating, processing, securing, or selling marijuana or marijuana products at the licensed premises;
  - (b) recording of the possession, handling, production, propagation, processing, securing, or selling of marijuana or marijuana products at the licensed premises; and
  - (c) the direct supervision of a person described in (a) or (b).
- (41) "Physician statement" means a written statement by a Montana licensed physician on department forms certifying the registered cardholder applicant's debilitating condition. Physician statement forms include:
  - (a) Physician Statement for Debilitating Condition; or
  - (b) Physician Statement for Minors.

- (42) "Property owner permission form" means a completed, signed, and notarized form which gives an applicant or licensee who is renting or leasing the property where marijuana will be cultivated and manufactured permission to do so by the property owner. The form must be provided by the department.
- (43) "Psychoactive" means capable of affecting mental processes or cognition when used as intended. A marijuana product is considered *per se* psychoactive if it is not a topical marijuana-infused product and the labeled potency is greater than .3% THC.
- (44) "Reconcile" for purposes of seed-to-sale tracking means to ensure that what is recorded in the seed-to-sale tracking system is consistent with what is physically located at the licensed premises.
- (45) "Red county" means a county where the majority of voters voted against approval of Initiative Measure No. 190 in the November 3, 2020 general election or where the local government has voted to prohibit all marijuana businesses pursuant to 16-12-301, MCA. This definition does not include a municipality that has approved or disapproved a category or categories of marijuana businesses, as authorized in 16-12-301, MCA.
- (46) "Registered premises" has the same meaning as "licensed premises."
- (47) "Registry" means the department's confidential record identifying registered cardholders.
- (48) "Resident" means a person determined to be a resident of Montana for tax purposes, pursuant to ARM 42.15.109.
- (49) "Safety data sheet (SDS)" means a summary document that provides information about the hazards of a product and advice about safety precautions written by the manufacturer or supplier of the product. An SDS must be provided by a supplier of a hazardous product at the time of sale.
- (50) "Seed-to-sale tracking system" means the system provided in 16-12-105, MCA, for tracking inventory of marijuana, marijuana concentrate, and marijuana-infused products from either the seed or the seedling stage until the marijuana or marijuana product is sold to a consumer.
- (51) "Standard operating procedure (SOP)" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action.
- (52) "Strain" means a pure breed or hybrid variety of cannabis reflecting similar or identical combinations of properties such as appearance, taste, color, smell, cannabinoid profile, and potency.
- (53) "Test Batch" means a portion of a harvest or process lot that has been submitted for quality assurance testing.
- (54) "THC" means delta-9 tetrahydrocannabinol.
- (55) "THCA" means tetrahydrocannabinolic acid.
- (56) "Topical marijuana-infused product" or "topical" means a non-ingestible marijuana-infused product that is not psychoactive when used as intended. Topicals include but are not limited to creams, salves, bath soaks, and lotions.
- (57) "Total potential psychoactive THC" or "Total THC" means the highest theoretical concentration of psychoactive THC available in a marijuana item achievable only through the complete conversion of THCa to THC with the application of heat during administration/consumption. Total potential

psychoactive THC is the sum of THC and THCa calculated using the following equation: Total potential psychoactive THC = (THCa x 0.877) + THC.

- (58) "Transdermal marijuana-infused product" or "transdermal" means a non-ingestible marijuana-infused product that contains at least one skin-permeation-enhancing ingredient to facilitate absorption through the skin into the bloodstream, and may be psychoactive when used as intended. Transdermal products include but are not limited to adhesive patches applied to the skin.
- (59) "Transmucosal marijuana-infused product" means an ingestible marijuana-infused product that is intended to be placed in a body cavity and absorbed through the mucosal lining of the cavity, and may be psychoactive when used as intended.

**Authorizing statute(s):** 16-12-112, MCA

**Implementing statute(s):** 16-12-101, 16-12-102, 16-12-104, 16-12-105, 16-12-112, 16-12-201, 16-12-207, 16-12-208, 16-12-210, 16-12-301, 16-12-501, 16-12-503, 16-12-508, 16-12-515, 16-12-533, MCA

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