

R68. Agriculture and Food, Plant Industry.

R68-25. Industrial Hemp Program - Cannabinoid Product Processors.

R68-25-1. Authority and Purpose.

Pursuant to Subsection 4-41-103(4), this rule establishes the standards, practices, procedures, and requirements for participation in the Utah Industrial Hemp Program for the processing and handling of cannabinoid products.

R68-25-2. Definitions.

- 1) "CBD" means cannabidiol (CAS #13956-29-1).
- 2) "Cannabinoid" means any:
 - a) naturally occurring derivative of cannabigerolic acid (CAS #25555-57-1); or
 - b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.
- 3) "Cannabinoid concentrate" means:
 - a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass; and
 - b) any amount of a natural, derivative, or synthetic cannabinoid in the synthetic cannabinoid's purified state.
- 4) "Cannabinoid product" means a product that:
 - a) contains one or more cannabinoids;
 - b) contains less than the cannabinoid product THC level by dry weight; and
 - c) after December 1, 2022, contains a combined amount of total THC and any THC analog that does not exceed 10% of the total cannabinoid content.
- 5) "Cannabinoid product THC level" means a combined concentration of total THC and any THC analog of less than 0.3% on a dry weight basis if laboratory testing confirms a result within a measurement of uncertainty that includes the combined concentration of 0.3%.
- 6) "Community location" means a public or private elementary or secondary school, a church, a public library, a public playground, or a public park.
- 7) "Department" means the Utah Department of Agriculture and Food.
- 8) "Derivative cannabinoid" means any cannabinoid that has been intentionally created using a process to convert one cannabinoid into another.
- 9) "Final product" means a reasonably homogenous cannabinoid product in its final packaged form created using the same standard operating procedures and the same formulation.
- 10) "Industrial Hemp" means any part of a cannabis plant, whether growing or not, with a concentration of less than 0.3% tetrahydrocannabinol by weight.
- 11) a) "Key participant" means any person who has a financial interest in the business entity, including members of a limited liability company, sole proprietor, partners in a partnership, and incorporators or directors of a corporation.
 - b) "Key participant" includes an:
 - i) individual at an executive level, including a chief executive officer, chief operating officer, or chief financial officer; and
 - ii) an operation manager, site manager, or any employee who may present a risk of diversion.
- 12) "Handle" or "Handling" means possessing, transporting, or storing industrial hemp for any period.
- 13) "Processing" means any action taken to prepare industrial hemp, or material derived from industrial hemp, for market.
- 14) "Processor" means a person licensed by the department to process industrial hemp or a material derived from industrial hemp.
- 15) "Manufacturing" means storing, preparing, packaging, or labeling of industrial hemp or cannabinoid products.
- 16) "Non-compliant material" means:
 - a) a hemp plant or plant material that does not comply with this rule, including a cannabis plant with a concentration of 0.3% tetrahydrocannabinol or greater by dry weight; and
 - b) a cannabinoid product, chemical, or compound with a concentration that exceeds the cannabinoid product THC level.
- 17) "Raw plant material" or "Raw concentrate" means industrial hemp plant material or concentrate that is not in final product form.
- 18) "Synthetic cannabinoid" means any cannabinoid that:
 - a) was chemically synthesized from starting materials other than a naturally occurring cannabinoid; and
 - b) is not a derivative cannabinoid.
- 19) "Tetrahydrocannabinol" or "THC" means delta-9-tetrahydrocannabinol, the cannabinoid identified as CAS #1972-08-3.
- 20) "Third-party laboratory" means a laboratory that has no direct interest in a grower or processor of industrial hemp or cannabinoid products that is capable of performing mandated testing utilizing validated methods.

R68-25-3. Industrial Hemp Processor Licenses.

- 1) The department shall issue the following industrial hemp processor licenses:

- a) a Tier One license, which allows a licensee to receive, store, extract, transport, and sell raw plant material or raw concentrate, and manufacture finished cannabinoid product;
 - b) a Tier Two license, which allows a licensee to receive raw plant material and extract it into raw concentrate to store, sell, or transport;
 - c) a Tier Three license, which allows a licensee to receive cannabinoid concentrate under 0.3% THC concentration, and manufacture, store, package, and label finished cannabinoid product; and
 - d) a Tier Four license, which allows a licensee to receive, store, transport, or sell raw concentrate, raw plant material, or finished cannabinoid product, and perform minimal processing for the purpose of storage only.
- 2) A Tier One processor may accept industrial hemp derived cannabinoid concentrate with greater than 0.3% THC concentration from another Tier One processor or a Tier two processor.

R68-25-4. Application Requirements.

- 1) The applicant shall be a minimum of 18 years old.
- 2) The applicant is not eligible to receive a license if they have been convicted of a drug-related felony or its equivalent.
- 3) An applicant seeking an industrial hemp processing license shall submit the following to the department:
 - a) a complete application form provided by the department;
 - b) a physical description of the processing facility;
 - c) a plan review of the building, facilities, and equipment;
 - d) a street address for each building or site where industrial hemp or cannabinoid products will be processed, handled, or stored;
 - e) the planned source of industrial hemp material; and
 - f) a statement of the intended end use or disposal for each part of the industrial hemp plant and hemp material.
- 4) Each applicant and key participant shall submit to a background check pursuant to the requirements of Subsection 4-41-103.2(6) and shall provide the department with an authorization form allowing the department to access their background information.
- 5) The applicant shall submit a fee as approved by the legislature in the fee schedule.
- 6) The department shall deny any applicant who does not submit the required information.
- 7) Each applicant for a Tier one, Tier Two, or Tier Three license shall be required to register as a food establishment under Section 4-5-301 pursuant to the requirements of Section R68-25-7.

R68-25-5. Processing Facility Restrictions.

- 1) A licensee shall not process or store leaf or floral material from industrial hemp in any structure that is used for residential purposes.
- 2) A licensee shall not process or store industrial hemp within 1,000 feet of a community location.
- 3) A licensee shall not process or handle industrial hemp or hemp material from any person who is not licensed by the department or the United States Department of Agriculture (USDA) or from a person outside the state who is not authorized by the laws of that state.
- 4) A licensee shall not permit a person under the age of 18 to access industrial hemp or cannabinoid products.
- 5) A licensee shall ensure that each key participant has submitted to a background check as required in Subsection 4-41-103.2(6) and authorized the department to access their background information within the first month of employment.
- 6) The licensee shall notify the department if a key participant separates from the licensee within two weeks following the separation.

R68-25-6. Extraction Methods.

- 1) In addition to the requirements of Section R68-25-4, an applicant seeking to engage in the extraction of cannabinoid concentrate from industrial hemp shall submit to the department a detailed description of the proposed extraction method.
- 2) The applicant shall describe the proposed process for the removal of any solvents added during the extraction process, if applicable.
- 3) The applicant shall describe the safety measures proposed to protect the public and employees from dangers associated with extraction methods.
- 4) The department may deny a license for methods that pose a significant risk to public health and safety.
- 5) Each licensee shall adhere to the following extraction guidelines:
 - a) ensure hydrocarbons n-butane, isobutane, propane, or heptane are of at least 99% purity;
 - b) use a professional grade closed loop extraction system designed to recover the solvents, work in an environment with proper ventilation, and control each source of ignition where a flammable atmosphere is or may be present;
 - c) ensure that any carbon dioxide (CO₂) gas extraction system uses a professional grade closed loop CO₂ gas extraction system where each vessel is rated to a minimum of six hundred pounds per square inch and CO₂ shall be at least 99% purity;
 - d) ensure that closed loop hydrocarbon, alcohol, or CO₂ extraction systems are commercially manufactured and bear a permanently affixed and visible serial number;
 - e) upon request, provide the department with documentation showing that the system is:
 - i) safe for its intended use; and

- ii) commercially manufactured.
- 6) The applicant shall indicate whether they will be using derivative or synthetic cannabinoids and how they will produce or procure them.

R68-25-7. Processing Practices.

1) The department incorporates by reference 21 CFR 111, Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements for a licensee engaged in processing a cannabinoid product intended for human consumption.

2) The department incorporates by reference 21 CFR 507, Current Good Manufacturing Practice, Hazard analysis, and Risk-Based Preventive Controls for Food for Animals for a licensee engaged in processing cannabinoid products for animal consumption.

3) Each licensee shall comply with the federal Food Drug and Cosmetic Act, 21 U.S.C. Chapter 9, and any other applicable state laws and regulations relating to product development, product manufacturing, consumer safety, and public health.

4) A licensee that manufactures cannabinoid products for human consumption or use as cosmetics shall be registered with the Division of Regulatory Services within the department.

5) A licensee shall use a standardized scale that is registered with the department when industrial hemp or cannabinoid products are:

- a) packaged for sale by weight; or
- b) bought and sold by weight.

6) A licensee that also is a holder of a medical cannabis processing license shall adhere to the separation requirements of Section R68-28-5 to ensure physical separation of medical cannabis and industrial hemp in their facility.

R68-25-8. Required Reports.

- 1) A licensee shall submit a completed Production Report on a form provided by the department by December 31st.
- 2) The failure to submit a timely completed form may result in the denial of a renewal license.

R68-25-9. Additional Records.

1) The licensee shall keep records of receipt for any industrial hemp material obtained including:

- a) the date of receipt;
- b) quantity received;
- c) an identifying lot number created by the licensee; and
- d) the seller's information including:
 - i) the seller's department license number;
 - ii) seller's contact information; and
 - iii) the address of the facility or growing area from which the industrial hemp material was shipped.

2) The licensee shall keep records that include the following information for each batch of industrial hemp material processed;

- a) the date of processing;
- b) the lot number of the material;
- c) the amount processed;
- d) the type of processing; and
- e) any lab test conducted on the industrial hemp material or product during the processing.

3) The licensee shall keep records of any derivative or synthetic cannabinoids procured or produced and the products they are used for.

4) The licensee shall keep records of any tests conducted with the identifying lot number.

5) A licensee processing a cannabinoid product for human consumption shall keep records required by 21 CFR 111 including:

- a) written procedures for preventing microbial contamination;
- b) documentation of training of employees;
- c) cleaning logs of equipment;
- d) procedures for cleaning the physical facility;
- e) documentation of your qualification of supplier; and
- f) documentation of calibration of machinery.

6) A licensee processing a cannabinoid product for animals shall keep records as required by 21 CFR 507 including:

- a) written procedures for preventing microbial contamination;
- b) documentation of training of employees;
- c) cleaning logs of equipment;
- d) procedures for cleaning the physical facility; and
- e) documentation of calibration of machinery.

7) The licensee shall keep records of any products they have manufactured and the disposition of any cannabinoid material that leaves the facility.

- 8) Records shall be maintained for a minimum of three years.
- 9) Records are subject to review by department officials at the time of inspection or upon request.

R68-25-10. Testing.

- 1) For cannabinoid products that will be used for human consumption or absorption the product shall be tested for the following before being made available for retail sale:
 - a) cannabinoid profile;
 - b) solvents;
 - c) pesticides;
 - d) microbials;
 - e) heavy metals; and
 - f) foreign matter.
- 2) The testing shall be completed by a third-party laboratory.
- 3) The department shall conduct random testing of cannabinoid products and materials.
- 4) The sample taken by the department shall be the official sample.

R68-25-11. Inspections and Sampling.

- 1) The department shall have complete and unrestricted access to industrial hemp plants, seeds, and materials and any land, buildings, and other structures used to process industrial hemp.
- 2) Samples of industrial hemp or cannabinoid product may be randomly taken from the facility by department officials.
- 3) The department may review records kept in accordance with rule requirements.
- 4) The department shall notify a licensee of test results greater than 0.3% THC.
- 5) Any laboratory test with a result greater than 0.3% THC may be considered a violation of the terms of the license and may result in an immediate license revocation.
- 6) Any laboratory test of a final product with a result of 1% THC or greater shall be turned over to the appropriate law enforcement agency and revocation of the processor license shall be immediate.
- 7) The department shall notify the licensee of any solvents, metals, microbials, pesticides, or foreign matter found during testing.
- 8) The presence of deleterious or harmful substances may be considered a violation of the terms of the license and may result in a license revocation.

R68-25-12. Storage of Industrial Hemp and Cannabinoid Products.

- 1) A licensee may store hemp and cannabinoid products at their licensed facility provided:
 - a) the licensee informs the department of the type and amount of the product being stored in the storage facility;
 - b) the storage facility is outside of the public view; and
 - c) the storage facility is secured with physical containment such as walls, fences, locks, and with an alarm system to provide maximum reasonable security.
- 2) A licensee may store a cannabinoid concentrate that exceeds 0.3% THC provided:
 - a) the concentrate is kept in a secure room;
 - b) the concentrate is kept separate from other hemp products;
 - c) access to the concentrate is limited; and
 - d) a record is kept of the amount of concentrate being stored and when it is being moved.
- 3) Storage facilities shall be maintained in accordance with the practice adopted in Section R68-25-7.
- 4) Storage facilities and records are subject to random inspection by department officials.

R68-25-13. Transportation of Industrial Hemp Material.

- 1) Each movement of industrial hemp material shall include a transport manifest that includes the following information:
 - a) a copy of the COA for each batch included in the shipment;
 - b) the location of the sending and receiving parties;
 - c) proof of registration or licensure for the sending and receiving parties; and
 - d) a bill of lading for the transported material.

R68-25-14. Restriction on the Sale and Transfer of Industrial Hemp Material.

- 1) A licensee shall not sell or transfer living plants, viable plants, viable seed, leaf material, or floral material to any person not licensed by the department or the USDA.
- 2) A licensee shall not sell or transfer living plants, viable seed, leaf material, or floral material to any person outside the state who is not authorized by the laws of that state or the USDA.
- 3) A licensee may sell stripped stalks, fiber, and nonviable seed to the general public provided the material's THC level is less than 0.3%.

R68-25-15. Renewal.

- 1) A licensee shall resubmit the documents required in Section R68-25-4, with updated information, before December 31st of the current year.
- 2) The department may deny a renewal for an incomplete application.
- 3) The department may deny renewal for any licensee who has violated any portion of this rule or state law.

R68-25-16. Violation.

- 1) It is a violation to process industrial hemp or industrial hemp material on a site not approved by the department.
- 2) It is a violation to process industrial hemp or industrial hemp material on a site within 1,000 feet of a community location.
- 3) It is a violation to process industrial hemp or industrial hemp material from a source that is not approved by the department.
- 4) A licensee shall not allow unsupervised public access to hemp processing facilities.
- 5) It is a violation to employ a person under the age of 18 in the processing or handling of industrial hemp or cannabinoid products.
- 6) It is a violation to sell a cannabinoid product to the general public or another licensee in violation of this section or state laws governing the final product.
- 7) It is a violation to add cannabinoids to a food product.
- 8) It is a violation to process raw concentrate without the appropriate industrial hemp processor license.
- 9) It is a violation to fail to keep records required by this rule or to fail to adhere to the notification requirements of this rule.
- 10) It is a violation to use derivative or synthetic cannabinoids in cannabinoid products without notifying the department.
- 11) It is a violation for a licensee to allow an employee that has been convicted of a drug-related felony or its equivalent access to hemp material or cannabinoid product that contains over 0.3% THC or has the potential to contain over 0.3% THC.
- 12) It is a violation to possess cannabinoid concentrate without an industrial hemp processing license.
- 13) It is a violation to store cannabinoid concentrate with greater than 0.3% THC concentration without following the requirements of Subsection R68-25-12(2).
- 14) It is a violation to store industrial hemp material without a processor license from the department or a cultivator license from the USDA.
- 15) It is a violation to possess non-compliant material.
- 16) It is a violation for a licensee to engage in practices outside of the scope of their license.
- 17) It is a violation to use an extraction method that is not authorized by Section R68-25-6.
- 18) It is a violation to employ a key participant without a background check for longer than 30 days.
- 19) It is a violation to operate a facility that does not meet current Good Manufacturing Practice requirements.
- 20) For holders of industrial hemp and medical cannabis processing licenses, it is a violation to operate a facility that does not adhere to the separation requirements of Section R68-28-5.
- 21) It is a violation to sell a cannabinoid product that has not been tested as required by Section R68-25-10.
- 22) It is a violation to deny the department the ability to take a sample of a cannabinoid product during an inspection or as part of an investigation.
- 23) It is a violation to deny the department access to an industrial hemp processing facility or industrial hemp processing facility records during regular business hours.

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