

**R68. Agriculture and Food, Plant Industry.**

**R68-26. Cannabinoid Product Registration and Labeling.**

**R68-26-1. Authority and Purpose.**

1) Pursuant to Subsections 4-41-103(4) and 4-41-403(1), this rule establishes the requirements for labeling and registration of products made from and containing industrial hemp.

**R68-26-2. Definitions.**

- 1) "Cannabinoid product" means a product that:
  - a) contains or is represented to contain one or more naturally occurring cannabinoids; and
  - 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.
- 2) "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%.
- 3) "CBD" or "Cannabidiol" means the cannabinoid identified as CAS# 13956-29-1.
- 4) "Certificate of Analysis" (COA) means a document produced by a testing laboratory listing the quantities of the various analytes for which testing was performed.
- 5) "Conventional Food" means:
  - a) an article used for food or drink for human consumption or the components of the article; or
  - b) chewing gum or chewing gum components.
- 6) "Department" means the Utah Department of Agriculture and Food.
- 7) "Industrial Hemp" means any part of a cannabis plant, whether growing or not, with a concentration of less than 0.3% tetrahydrocannabinol by weight.
- 8) "Industrial hemp product class" means group of cannabinoid products:
  - a) that have all ingredients in common; and
  - b) are produced by and for the same company.
- 9) "Label" means the display of each written, printed, or graphic matter upon the immediate container or statement accompanying an industrial hemp product.
- 10) "Manufacturer" means a person who makes any industrial hemp products.
- 11) "Non-compliant material" means:
  - a) a hemp plant 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.
- 12) "Person" means an individual, partnership, association, firm, trust, limited liability company, or corporation or any employees of such.
- 13) "THC" or "Tetrahydrocannabinol" means delta-9-tetrahydrocannabinol, the cannabinoid identified as CAS # 1972-08-3.
- 14) a) "THC analog" means a substance that is structurally or pharmacologically substantially similar to, or is represented as being similar to, delta-9-THC.  
b) "THC analog" does not include the following substances or the naturally occurring acid forms of the following substances:
  - i) cannabichromene (CBC), the cannabinoid identified as CAS# 20675-51-8;
  - ii) cannabicyclol (CBL), the cannabinoid identified as CAS# 21366-63-2;
  - iii) cannabidiol (CBD), the cannabinoid identified as CAS# 13956-29-1;
  - iv) cannabidivaryl (CBDV), the cannabinoid identified as CAS# 24274-48-4; cannabidiol (CBD), the cannabinoid identified as CAS# 13956-29-1;
  - v) cannabielsoin (CBE), the cannabinoid identified as CAS# 52025-76-0;
  - vi) cannabigerol (CBG), the cannabinoid identified as CAS# 25654-31-3;
  - vii) cannabigerovarin (CBGV), the cannabinoid identified as CAS# 55824-11-8;
  - viii) cannabinol (CBN), the cannabinoid identified as CAS# 521-35-7;
  - ix) cannabivarin (CBV), the cannabinoid identified as CAS# 33745-21-0; or
  - x) delta-9-tetrahydrocannabivarin (THCV), the cannabinoid identified as CAS# 31262-37-0.
- 15) "Third-party laboratory" means a laboratory with no direct interest in a grower or processor of industrial hemp or industrial hemp products that is capable of performing mandated testing utilizing validated methods.

**R68-26-3. Product Registration.**

1) Each cannabinoid product or industrial hemp product class distributed or available for distribution in Utah shall be officially registered annually with the department.

2) Application for registration shall be made to the department on a form provided by the department including the following information:

- a) the name and address of the applicant and the name and address of the person whose name will appear on the label, if other than the applicants;
  - b) the name of the product;
  - c) the type and use of the product;
  - d) a complete copy of the label as it will appear on the product in a legible format; and
  - e) if the product has been assigned a National Drug Code in accordance with 21 CFR 207.33, the applicant shall provide the National Drug Code number.
- 3) The application shall include a certificate of analysis from a third-party laboratory for the product in compliance with Section R68-26-4. The certificate of analysis shall show the cannabinoid profile of the product by percentage of mass.
- 4) A registration fee per product, as set forth in the fee schedule approved by the legislature, shall be paid to the department with the submission of the application.
- 5) The department may deny registration for an incomplete application.
- 6) A new registration is required for any of the following:
- a) any change in the cannabinoid product ingredients;
  - b) any change to the directions for use; and
  - c) any change of name for the product.
- 7) Other changes shall not require a new registration but the registrant shall submit copies of each label change to the department as soon as they are effective.
- 8) The person registering the cannabinoid product is responsible for the accuracy and completeness of information submitted.
- 9) A registration is good for one calendar year from the date of registration and shall be renewed through payment of an annual renewal fee before expiration.
- 10) A cannabinoid product that has been discontinued shall continue to be registered in the state until the product is no longer available for distribution.
- 11) A late fee shall be assessed for a renewal of an industrial hemp product registration submitted after June 30th and shall be paid before the registration renewal is issued.
- 12) The department shall not register a cannabinoid product if the product:
- a) uses the cannabinoid as a food additive; or
  - b) is represented for use as a conventional food, with the exception of:
    - i) a gummy if the gummy is shaped as a gelatinous cube or gelatinous rectangular cuboid or in another basic geometric shape and not in a shape that could be considered appealing to children such as a star shape, fruit, or animal shape; or
    - ii) a liquid suspension under two ounces.

**R68-26-4. Certificate of Analysis.**

- 1) A certificate of analysis for any industrial hemp product containing a cannabinoid shall be available through a QR code or website listed on the label.
- 2) Testing shall be conducted on the product in its final form for:
  - a) the cannabinoid profile by percentage of mass;
  - b) solvents;
  - c) pesticides;
  - d) microbials;
  - e) heavy metals; and
  - f) mycotoxins.
- 3) The test results required in Subsection R68-26-4(1) shall be reported in accordance with the requirements for a cannabinoid product in Rule R68-29 including the specified units of measure.
- 4) The certificate of analysis shall include the following information:
  - a) the batch identification number;
  - b) the date received;
  - c) the date of completion;
  - d) the method of analysis for each test conducted; and
  - e) proof that the certificate of analysis is connected to the product.

**R68-26-5. Label Requirements.**

- 1) Cannabinoid products produced for oral human consumption shall be labeled in accordance with:
  - a) 21 CFR 101.1, Principal display panel of package form food;
  - b) 21 CFR 101.2, Information panel of package form food;
  - c) 21 CFR 101.3, Identity labeling of food in packaged form;
  - d) 21 CFR 101.4, Food; designation of ingredients;
  - e) 21 CFR 101.5, Food; name and place of business of manufacturer, packer, or distributor;
  - f) 21 CFR 101.7, Declaration of net quantity of contents;
  - g) 21 CFR 101.9(j)(13) and (17), Nutrition labeling of food;
  - h) 21 CFR 101.15, Food; prominence of required statements; and

- i) 21 CFR 101.36, Nutrition labeling of dietary supplements;
- i) a label may contain the term "product facts" in place of "supplement facts" provided the information required in 21 CFR 101.36 is on the label; and
- ii) the label shall include the following text, prominently displayed: "This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- 2) A cannabinoid product intended to be vaporized for inhalation shall:
  - a) be labeled in accordance with Subsection R68-26-5(1); or
  - b) be labeled in accordance with 21 CFR 101.1, 21 CFR 101.2, 21 CFR 101.3, 21 CFR 101.4, 21 CFR 101.5, 21 CFR 101.7, 21 CFR 101.15, and contain the following text, prominently displayed: "This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."
- 3) Industrial hemp products containing a cannabinoid produced for absorption by humans shall be labeled in accordance with 21 CFR 701, Cosmetic Labeling.
- 4) Industrial hemp products containing cannabinoids other than CBD shall contain the following text, prominently displayed: "Warning - The safety of this product has not been determined."
- 5) Notwithstanding Subsection R68-26-5(1) or R68-25-5(3), an industrial hemp product containing a cannabinoid produced for human use that has a National Drug Code issued shall be labeled in accordance with 21 CFR 201.66.
- 6) In addition to the requirements of Subsections R68-26-5(1) through R68-26-5(3) an industrial hemp product containing a cannabinoid shall have on the label a scannable barcode, QR code, or web address linked to a document containing the following information:
  - a) the total quantity produced; and
  - b) a downloadable link for a certificate of analysis for the batch identified.
- 7) Cannabinoid products shall not contain medical claims on the label unless the product has been registered with the FDA and is labeled in accordance with Subsection R68-26-5(4).
- 8) Cannabinoid product labeling shall clearly show that the product contains material derived from industrial hemp and not cannabis or medical cannabis.
- 9) Cannabinoid product labeling shall not:
  - a) have any likeness bearing resemblance to a cartoon character or fictional character; or
  - b) appear to imitate a food or other product that is typically marketed toward or appealing to children.

**R68-26-6. Inspection and Testing.**

- 1) The department shall conduct randomized inspection of cannabinoid products distributed or available for distribution in the state for compliance with this rule.
- 2) The department shall periodically sample, analyze, and test industrial hemp products distributed within the state for compliance with registration and labeling requirements and the certificate of analysis.
- 3) The department may conduct inspection of cannabinoid products distributed or available for distribution for any reason the department deems necessary.
- 4) The sample taken by the department shall be the official sample.

**R68-26-7. Violation.**

- 1) Each improperly labeled cannabinoid product shall be a separate violation of this rule.
- 2) Cannabinoid products not meeting the labeling requirements shall be considered misbranded.
- 3) Cannabinoid products shall be considered falsely advertised if they do not meet the labeling requirements of this rule.
- 4) It is a violation to distribute or market a cannabinoid product that is not registered with the department.
- 5) It is a violation to distribute or market industrial hemp flower as a final product.
- 6) It is a violation to distribute or market a cannabinoid product that contains greater than 0.3% THC.
- 7) It is a violation to distribute or market a cannabinoid product that has not been tested as required by Rule R68-29.
- 8) It is a violation to distribute or market a cannabinoid product as a conventional food product, unless the product is exempted under Subsection R68-26-3(12)(b).
- 9) It is a violation to distribute or market a cannabinoid product as a food additive.
- 10) It is a violation to distribute or market a cannabinoid product that is marketed toward or is appealing to children.
- 11) It is a violation to market a cannabinoid product as cannabis or medical cannabis.
- 12) It is a violation to submit a fraudulent COA to the department.

**R68-26-8. Violation Categories.**

- 1) Public Safety Violations: Each person shall be fined \$3,000-\$5,000 per violation. This category is for violations that present a direct threat to public health or safety including:
  - a) industrial hemp sold to an unlicensed source;
  - b) industrial hemp purchased from an unlicensed source;
  - c) refusal to allow inspection;
  - d) failure to comply with labeling requirements;
  - e) failure to comply with testing requirements;

- f) possessing, manufacturing, or distributing a cannabinoid product that a person knows or should know appeals to children; or
  - g) engaging in or permitting a violation of the Title 4, Chapter 41, Hemp and Cannabinoid Act that amounts to a public safety violation as described in this subsection.
- 2) Regulatory Violations: Each person shall be fined \$1,000-\$5,000 per violation. This category is for violations involving this rule and other applicable state rules under Title R68 including:
- a) failure to register an industrial hemp product;
  - b) failure to provide a certificate of analysis as required by Section R68-26-4;
  - c) failure to keep and maintain records;
  - d) engaging in or permitting a violation of Title 4, Chapter 41a, Hemp and Cannabinoid Act or this rule that amounts to a regulatory violation as described in this subsection.
- 3) Licensing Violations: Each person shall be fined \$500-\$5,000 per violation. This category is for violations involving licensing requirements including:
- a) engaging in or permitting a violation of this rule, other applicable rules under Title R68, or Title 4, Chapter 41, Hemp and Cannabinoid Act, that amounts to a licensing violation; or
  - b) failure to respond to violations.
- 4) The department shall calculate penalties based on the level of violation and the adverse effect or potential adverse effect at the time of the incidents giving rise to the violation.
- 5) The department may enhance or reduce the penalty based on the seriousness of the violation.

**KEY: CBD labeling, CBD products, cannabinoid product registration**

**Date of Last Change: August 23, 2022**

**Authorizing, and Implemented or Interpreted Law: 4-41-403(1); 4-41-402(2); 4-41-103(4)**