

R68-25-15. Violation.

- 1) It is a violation to process industrial hemp or industrial hemp material on a site not approved by the department as listed on the license or within 1,000 feet of a school or public recreational area.
- 2) It is a violation to process industrial hemp or industrial hemp material from a source that is not approved by the department.
- 3) A licensee shall not allow unsupervised public access to hemp processing facilities.
- 4) It is a violation to employ a person under the age of eighteen (18) in the processing or handling of industrial hemp or its products.
- 5) It is a violation to sell a product to the general public in violation of this section or state laws governing the final product.
- 6) It is a violation to add CBD to a food product.
- 7) It is a violation to fail to keep records required by this section.
- 8) It is a violation for a licensee to allow an employee that has been convicted of a felony or its equivalent access to hemp material or product which contains over 0.3% THC or has the potential to contain over 0.3% THC.
- 9) It is a violation for a licensee to allow an employee that has been convicted of a drug-related misdemeanor within the last ten (10) years access to hemp material or product which contains over 0.3% THC or has the potential to contain over 0.3% THC.

KEY: cannabidiol, hemp products, hemp extraction, hemp oil
Date of Enactment or Last Substantive Amendment: 2018
Authorizing, and Implemented or Interpreted Law: 4-41-103(4)

Agriculture and Food, Plant Industry
R68-26
 Industrial Hemp Product Registration
 and Labeling

NOTICE OF PROPOSED RULE
 (New Rule)

DAR FILE NO.: 43147
 FILED: 08/10/2018

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: This proposed rule sets forth registration and labeling requirements for individuals seeking to sell industrial hemp in the state of Utah in accordance with Subsections 4-41-103(4) and 4-41-403(1).

SUMMARY OF THE RULE OR CHANGE: This proposed rule requires all industrial hemp products distributed in the state to be registered with the Department of Agriculture and Food (Department). It establishes the labeling requirements for the various products being distributed. It sets up quality assurance procedures the Department will follow to test the products for label accuracy and to ensure that products

intended for ingestion or absorption by humans or animals are free of contaminants.

STATUTORY OR CONSTITUTIONAL AUTHORIZATION FOR THIS RULE: Subsection 4-41-103(4) and Subsection 4-41-402(2) and Subsection 4-41-403(1)

MATERIALS INCORPORATED BY REFERENCE:

- ◆ Adds 21 CFR 740, Cosmetic Product Warnings Statements, published by Government Printing Office, 04/01/2017
- ◆ Adds 21 CFR 701, Cosmetic Labeling, published by Government Printing Office, 04/01/2018
- ◆ Adds 21 CFR 101, Food Labeling, published by Government Printing Office, 04/01/2017

ANTICIPATED COST OR SAVINGS TO:

◆ **THE STATE BUDGET:** As this is a new program, the state will have the additional cost of starting up the program and purchasing the needed equipment to effectively run the Industrial Hemp Program. The Department will need to hire two new employees, an office specialist to oversee the registration process, as well as conduct the initial label review, and an inspector to inspect the store for product and to ensure that products being distributed are registered and take random samples to the lab for label verification. It is estimated that the new employees will cost \$136,000. These employees will need to receive training which the Department anticipates will cost \$10,000. Testing equipment and standards will be necessary to test the products for THC compliance. Additional tests will need to be done to ensure that the products are free of harmful contaminants. Standards and laboratory equipment will run around \$5,000. Sampling equipment and supplies are estimated to cost \$3,000. The total cost of the first year of the program is then estimated to be \$154,000. The second year the Department anticipates that the cost will stay much the same with some slight decreases in inspection supplies, as well as the cost for training, but the Department does anticipate the need to have at least one additional employee. It is likely, depending on the number of growers, that another inspector will be needed to cover both the northern and southern ends of the state. Therefore, the cost of employees would be \$216,000. The training cost would be \$5,000. The cost of laboratory testing standards and maintenance of the laboratory equipment will remain the same at \$5,000. The Department will need to purchase another vehicle and sampling supplies for the new inspector which is estimated to be \$31,500. For a total cost of the second year being \$257,500. It may be necessary to hire more inspectors as the program grows in the third year, but the Department anticipates that the cost for the program will remain similar to the second year in the third year. The cost may decrease if no new inspectors are needed as training will not be necessary nor will new vehicles or supplies. The cost of employees will remain the same at \$216,000 and laboratory cost remain at \$5,000. Sampling cost of training will be \$0 and there will be minimal sampling equipment which the Department estimates at \$700. The total cost then for year three would be \$221,700. The

Department has a grower license fee of \$500. Each product will have to have a registration fee attached to the registration. The amount of the fee is determined by the type of product being registered. A product containing hemp oil, extract, or CBD will pay a \$200 registration fee. A seed product or product containing seed will pay a \$100 registration fee. The fee must be paid before the product is considered registered in the state. The Department is unable to estimate the amount this registration fee will generate for the Department as this is a new and developing industry and it is not known how many products containing hemp will be brought into the state. However, the Department will be generating some revenue from the licensing fees.

♦ LOCAL GOVERNMENTS: There are no anticipated costs or benefits to local governments as this rule neither requires action from nor provides benefits to local governments.

♦ SMALL BUSINESSES: This rule allows for the legal sale of hemp products in the state. Previously, some of these hemp products were not legally available for purchase because of state laws. While the purchase of hemp clothing and some seed material was allowed federally, aside for the registration fee of \$100 to \$200, there are no additional requirements placed on these businesses by this rule that previously were not required by either state or federal law. Due to the nature of the products being distributed, the Department is unable to estimate how many participants there will be in program.

♦ PERSONS OTHER THAN SMALL BUSINESSES, BUSINESSES, OR LOCAL GOVERNMENTAL ENTITIES: This proposed rule allows for the legal distribution of hemp products in the state. This rule will allow for those who wish to consume CBD oil to purchase products in the state with the added benefits of knowing what the product contains and that it is free of contaminants. However, due to the nature of the industry, it is impossible for the Department to estimate the cost or benefits to the consumer.

COMPLIANCE COSTS FOR AFFECTED PERSONS: There will be \$100 to \$200 registration fee depending on the type of product being registered. A product containing hemp oil, extract, or CBD will pay a \$200 registration fee. A seed product or product containing seed will pay a \$100 registration fee. The fee must be paid before the product is considered registered in the state. Fiber products must register, but there is no fee attached to that registration.

COMMENTS BY THE DEPARTMENT HEAD ON THE FISCAL IMPACT THE RULE MAY HAVE ON BUSINESSES: This proposed rule will open new markets to our agricultural producers and manufacturers previously closed to them. This proposed rule will allow for producers to diversify the products they produce and attempt to enter into a new and emerging market. This rule will allow for the legal sale of hemp products in the state. Previously, some of these hemp products were not legally available for purchase because of state laws. While the purchase of hemp clothing and some seed material was allowed federally, aside for the registration fee of \$100 to \$200, there are no additional requirements placed on these businesses by this rule that previously were not required by either state or federal law.

THE FULL TEXT OF THIS RULE MAY BE INSPECTED, DURING REGULAR BUSINESS HOURS, AT:

AGRICULTURE AND FOOD
PLANT INDUSTRY
350 N REDWOOD RD
SALT LAKE CITY, UT 84116-3034
or at the Office of Administrative Rules.

DIRECT QUESTIONS REGARDING THIS RULE TO:

- ♦ Bracken Davis by phone at 801-538-7188, or by Internet E-mail at brackendavis@utah.gov
- ♦ Melissa Ure by phone at 801-538-4976, or by Internet E-mail at mure@utah.gov
- ♦ Robert Hougaard by phone at 801-538-7187, by FAX at 801-538-7189, or by Internet E-mail at rhougaard@utah.gov
- ♦ Scott Ericson by phone at 801-538-7102, by FAX at 801-538-7126, or by Internet E-mail at sericson@utah.gov

INTERESTED PERSONS MAY PRESENT THEIR VIEWS ON THIS RULE BY SUBMITTING WRITTEN COMMENTS NO LATER THAN AT 5:00 PM ON 10/01/2018

THIS RULE MAY BECOME EFFECTIVE ON: 10/08/2018

AUTHORIZED BY: LuAnn Adams, Commissioner

Appendix 1: Regulatory Impact Summary Table*

Fiscal Costs	FY 2019	FY 2020	FY 2021
State Government	\$154,000	\$257,700	\$221,700
Local Government	\$0	\$0	\$0
Small Businesses	\$200	\$200	\$200
Non-Small Businesses	\$200	\$200	\$200
Other Person	\$0	\$0	\$0
Total Fiscal Costs:	\$154,400	\$258,100	\$222,100
Fiscal Benefits			
State Government	\$400	\$400	\$400
Local Government	\$0	\$0	\$0
Small Businesses	\$0	\$0	\$0
Non-Small Businesses	\$0	\$0	\$0
Other Persons	\$0	\$0	\$0
Total Fiscal Benefits:	\$400	\$400	\$400
Net Fiscal Benefits:	-\$154,000	-\$257,700	-\$221,700

*This table only includes fiscal impacts that could be measured. If there are inestimable fiscal impacts, they

will not be included in this table. Inestimable impacts for State Government, Local Government, Small Businesses and Other Persons are described above. Inestimable impacts for Non-Small Businesses are described below.

Appendix 2: Regulatory Impact to Non-Small Businesses
This rule allows for the legal sale of hemp products in the state. Previously, some of these hemp products were not legally available for purchase because of state laws. While the purchase of hemp clothing and some seed material as allowed federally, aside for the registration fee of \$100 to \$200, there are no additional requirements placed on these businesses by this rule that previously were not required by either state or federal law. Due to the nature of the products being distributed, the Department is unable to estimate how many products will be registered nor the number of business that will be affected by the rule.

The Commissioner of the Department of Agriculture and Food, LuAnn Adams, has reviewed and approved this fiscal analysis.

R68. Agriculture and Food, Plant Industry.

R68-26. Industrial Hemp Product Registration and Labeling.

R68-26-1. Authority and Purpose.

1) Pursuant to Section 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) "CBD" means cannabidiol.
- 2) "Certificate of Analysis" means a certificate from a third-party laboratory describing the results of the laboratory's testing of a sample.
- 3) "Department" means the Utah Department of Agriculture and Food
- 4) "Industrial Hemp" means any part of a cannabis plant, whether growing or not, with a concentration of less than 0.3% tetrahydrocannabinol by weight.
- 5) "Industrial hemp product" means products derived from, or made by processing industrial hemp plants or plant parts.
- 6) "Label" means the display of all written, printed, or graphic matter upon the immediate container or statement accompanying an industrial hemp product.
- 7) "Manufacturer" means a person who makes any industrial hemp products.
- 8) "Person" means an individual, partnership, association, firm, trust, limited liability company, or corporation or any employees of such.
- 9) "THC" means total composite tetrahydrocannabinol, including delta -9- tetrahydrocannabinol and tetrahydrocannabinolic acid.
- 10) "Third-party laboratory" means a laboratory which has 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) All industrial hemp products 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 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; and
- d) a complete copy of the label which will appear on the product.

3) If the industrial hemp product being registered contains CBD, the application shall include a certificate of analysis from a third-party laboratory for the product in compliance with R68-26-4.

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 incomplete applications.

6) The department may exempt an industrial hemp product that is determined to be adequately regulated by a federal agency.

7) A new registration is required for any of the following:

- a) changes in the industrial hemp product ingredients;
- b) changes to the directions for use; and
- c) a change of name for the product.

8) Other changes shall not require a new registration but the registrant shall submit copies of all label changes to the department as soon as they are effective.

9) The person registering the industrial hemp product is responsible for the accuracy and completeness of all information submitted.

10) A registration is renewable for up to a one year period with an annual renewal fee per product which shall be paid on or before June 30th of each year.

11) An industrial hemp product that has been discontinued shall continue to be registered in the state until the product is no longer available for distribution.

12) 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.

R68-26-4. Certificate of Analysis.

1) The certificate of analysis for industrial hemp products containing CBD shall include the following test results:

- a) the cannabinoid profile by percentage of dry weight;
- b) solvents;
- c) pesticides;
- d) microbials; and
- e) heavy metals.

2) The certificate of analysis shall include the following information:

- a) the batch identification number;
- b) the date received;
- c) the date of completion; and
- d) the method of analysis for each test conducted.

R68-26-5. Label Requirements.

1) Industrial hemp products containing CBD produced for human consumption shall 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 101.9(j)(13), 21 CFR 101.9(j)(17), 21 CFR 101.15, and 21 CFR 101.36.

2) Industrial hemp products produced for absorption by humans shall be labeled in accordance with 21 CFR 701, Cosmetic Labeling and 21 CFR 740, Cosmetic Product Warning Statements.

3) In addition to the requirements of R68-26-5(1) and (2), an industrial hemp product containing CBD shall have on the label a scannable bar code, QR code, or web address linked to a document containing the following information:

- a) the batch identification number;
- b) the product name;
- c) the batch date;
- d) an expiration date;
- e) the batch size;
- f) the total quantity produced; and
- g) a downloadable link for a certificate of analysis for the batch identified.

4) Industrial hemp products shall not contain medical claims on the label.

5) Industrial hemp products which do not contain CBD intended for human consumption shall be labeled in accordance with 21 CFR 101, Food Labeling.

6) Industrial hemp products which do not contain CBD intended for human absorption shall be labeled in accordance with 21 CFR 701, Cosmetic Labeling and 21 CFR 740, Cosmetic Product Warnings Statements.

7) Industrial hemp products meant for animal consumption shall be labeled and comply with all applicable federal laws and regulations and all other applicable state laws and regulations.

8) Industrial hemp seed products intended for cultivation shall be labeled in accordance with Utah Seed Act.

9) All industrial hemp products shall comply with the federal Food Drug and Cosmetic Act, 21 U.S.C. Chapter 9 and other applicable federal laws and regulations and all applicable state laws and regulations relating to the labeling of food, cosmetics, and fiber.

R68-26-6. Inspection and Testing.

1) The department shall conduct randomized inspection of industrial hemp 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, if applicable.

3) The department may conduct inspection of industrial hemp 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. Retailer Responsibilities.

- 1) A retailer shall:
 - a) ensure that any industrial hemp product is labeled correctly; and

b) ensure that all industrial hemp products sold are properly registered with the department.

2) Retailers shall provide the identity of the manufacturer of industrial hemp products sold upon request of the department.

3) A retailer may register the product in lieu of the manufacturer if the product is not registered.

R68-26-8. Violation.

1) Each improperly labeled industrial hemp product shall be a separate violation of this rule.

2) Industrial hemp products not meeting the label requirements shall be deemed to be misbranded.

3) Industrial hemp products shall be considered falsely advertised if it does not meet the labeling requirements of this rule.

4) It is a violation to distribute or market and Industrial hemp products that is not registered with the department.

5) It is a violation to distribute or market an industrial hemp product that contains greater than 0.3% THC.

6) It is a violation to distribute or market an industrial hemp product containing CBD which is not in a medical dosage form.

KEY: CBD labeling, CBD products, hemp product registration

Date of Enactment or Last Substantive Amendment: 2018

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

Commerce, Administration
R151-4
 Department of Commerce
 Administrative Procedures Act Rule

NOTICE OF PROPOSED RULE

(Amendment)

DAR FILE NO.: 43148

FILED: 08/13/2018

RULE ANALYSIS

PURPOSE OF THE RULE OR REASON FOR THE CHANGE: This change simplifies procedures for the filing and service of pleadings, updates the disclosure required for an expert witness' written report consistent with the Utah Rules of Civil Procedure (URCP) Rule 26(a)(4)(B), updates the requirement for electronic testimony in formal hearings consistent with the URCP, clarifies that the 30-day deadline for filing a request for agency review is a jurisdictional deadline that may be extended only for good cause, and updates references to certain provisions relating to decisions from the Division of Corporations and Commercial Code.

SUMMARY OF THE RULE OR CHANGE: Section R151-4-109 is amended to clearly state that the elements in Subsection R151-4-109(1) do not apply to a request for agency review. Changes are made to Section R151-4-401 to