

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control _____ Department or Agency Alabama Department of Forensic Sciences
Rule No. 370-4-1-01
Rule Title: Determination of Tetrahydrocannabinol (THC) Content in Cannabidiol (CBD) or any Other Preparation Thereof.
 New _____ Amend _____ Repeal _____ Adopt by Reference _____

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Reference Service.

Signature of certifying officer Michael J. Spaul
Date 2-3-17

(DATE FILED)
(STAMP)

(Agency Name)
(Agency Division, if applicable)

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Forensic Sciences

RULE NO. & TITLE: 370-4-1-.01 Determination of Tetrahydrocannabinol (THC) Content in Cannabidiol (CBD) or any Other Preparation Thereof.

INTENDED ACTION:
Adopt Rule

SUBSTANCE OF PROPOSED ACTION:

Adopt a rule to describing the method to determine THC content in CBD Products.

TIME, PLACE, MANNER OF PRESENTING VIEWS:

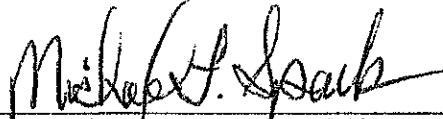
In writing to: Alabama Department of Forensic Sciences

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

April 3, 2017

CONTACT PERSON AT AGENCY:

Andrea Headrick, 2026 Valleydale Rd., Hoover, AL 35244



(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

RULES
OF
THE ALABAMA DEPARTMENT OF FORENSIC SCIENCES
CHAPTER 370-4-1

DETERMINATION OF TETRAHYDROCANNABINOL (THC) CONTENT IN
CANNABIDIOL (CBD) OR ANY OTHER PREPARATION THEREOF.

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370-4-1-.01 Determination of Tetrahydrocannabinol (THC) Content in Cannabidiol (CBD) or any Other Preparation Thereof.

(1) Purpose.

This rule describes the statutory elements required for the limited use of nonpsychoactive Cannabidiol (CBD) or any other preparation thereof as referred to by "Acts of Alabama, Act 2016-268". This rule contains the Methods (Procedures) for determining whether or not a submitted material is free from plant material and if the Tetrahydrocannabinol (THC) content, of samples submitted by law enforcement agencies pursuant to criminal investigations (§36-18-2 Code of Alabama, 1975), is greater than 3% relative to Cannabidiol. IN THE EVENT THAT ONE OF THESE REQUIREMENTS IS NOT FULFILLED, CHEMICAL ANALYSIS EVIDENCE MAY STILL BE OFFERED THROUGH TRADITIONAL EVIDENTIARY PREDICATE as described in *Powell v. State*, 515 So.2d 140 (Ala.Cr.App. 1986).

(2) Definitions and Abbreviations:

(a) *Analyte*. The substance being identified/amount determined by a chemical analysis.

- (b) *Batch*. A defined work list of cases (submitted materials) that has a beginning and an end. Qualitative/Quantitative batches must contain positive and negative controls at the beginning and end of the batch with the additional stipulation that 10% of the batch must contain quality control samples equally spaced within the batch and blanks between each case sample. In essence each batch has enough quality control samples contained within to be self validating batches.
- (c) *Botanical*. Derived from plants.
- (d) *Cannabis*. A genus of flowering plant known to contain Delta-9-Tetrahydrocannabinol (THC) and Cannabidiol (CBD) in varying amounts.
- (e) *Cannabidiol (CBD)*. [13956-29-1]. A (nonpsychoactive) cannabinoid found in the *Cannabis sativa* L. or any other preparation thereof that is free from plant material, and has a THC level (delta-9-tetrahydrocannabinol) of no more than 3% relative to CBD according to the rules adopted by the Alabama Department of Forensic Sciences. Also known as (synonyms): 2-[(1R,6R)-3-Methyl-6-(1-methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-1,3-benzenediol; trans-(-)-2-p-mentha-1,8-dien-3-yl-5-pentylresorcinol; (-)-Cannabidiol; (-)-trans-Cannabidiol; Cannabidiol (7CI); D1(2)-trans-Cannabidiol, *as described by* “Acts of Alabama, Act 2016-268”. For the purpose of this rule taxonomic and isomeric purity determinations are not a necessity.
- (f) *Confirmation*. A customary Forensic practice that tests a result or conclusion by reanalyzing the submitted material utilizing a different technique or process to ensure the result or conclusion can be replicated.
- (g) *DART-TOF/DART-Accu TOF*. Instrument capable of detecting a wide variety of controlled substances.
- (h) *Delta-9-Tetrahydrocannabinol (THC)*. [1972-08-3]. The principal psychoactive cannabinoid found in cannabis. Also known as (synonyms): Dronabinol, (-)-trans-delta-9-tetrahydrocannabinol, (-)-(6aR,10aR)-6,6,9-Trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromen-1-ol. For the purpose of this rule taxonomic and isomeric purity determinations are not a necessity.
- (i) *Derivatization*. An chemical technique that transforms a suspected target compound (THC) to a known compound; thereby, confirming the identity of the suspected target compound.
- (j) *Extract/Extraction*. A purification technique designed to separate target analytes from the matrix of the submitted material.
- (k) *Gas Chromatograph/Mass Spectrometer*. An instrument capable of separating components of a mixture, determining the identity of the component and determining the amount of the component.
- (l) *Internal Standard*. An internal standard is the “yardstick” by which analyte concentrations can be determined in quantitative analytical chemistry. For the purpose of this rule, the existing cannabidiol concentration, of the material

submitted, acts as the internal standard. Therefore, the relative concentration of the analyte (Tetrahydrocannabinol, THC) will be derived from the internal standard (Cannabidiol) concentration set to 100%.

- (m) *Liquid/Liquid Extraction.* An extraction technique utilizing two immiscible solvents (aqueous/organic) that is designed to preferentially partition the target analytes from the matrix of the submitted material into the solvent of choice.
- (n) *Method.* For the purpose of this rule, a method is an orderly and systematic approach to accomplishing a goal. The goal set forth in “Acts of Alabama, Act 2016-268” is the determination of whether or not a submitted material is free from plant material and the Tetrahydrocannabinol (THC) concentration, if any, exceeds 3% relative to Cannabidiol. Therefore, the method refers only to those tasks, manual or automated, that result in determining a submitted material is free from plant material and if the Tetrahydrocannabinol (THC) concentration exceeds 3% relative to Cannabidiol.
- (o) *Plant Material.* For the purpose of this rule, plant material is any material visible by the naked eye (without magnification) that upon magnification (usually required) reveals the presence of botanical features attributed to the cannabis plant.
- (p) *Qualitative Analysis.* A chemical analysis designed to determine the identity of chemical substances.
- (q) *Quantitative Analysis.* A chemical analysis designed to determine the amount of a chemical substance.
- (r) *Solid Phase Extraction.* An extraction technique utilizing a solid packing material designed to remove the target analytes from the matrix of the submitted material.
- (s) *Stereomicroscope.* A low magnification microscope providing visualization from two optical pathways.

(3) Method.

(a) Plant Material Inspection.

- (i) The submitted material shall be visually inspected for the presence of plant material. A stereomicroscope, camera or other device capable of visualizing botanical features shall be used to confirm of the presence of plant material.
- (ii) Documentation of the presence of plant material shall include but not limited to the image capture of one or more botanical features characteristic of cannabis, such as, Venation, Serrated Leaves,

Seeds, Fluted Stems, Flowering Tops, Cystolith Hairs, Bracts, Cover hairs, Glandular hairs, Styles and/or stigmas.

- (iii) Submitted materials determined to contain plant material are no longer subject to the provisions of this rule and any further analysis will be routed to the Drug Chemistry section to be conducted in the regular course of business. Submitted materials determined to be free of plant material will proceed to Delta-9-Tetrahydrocannabinol (THC) analysis as described in subsection 3b.

(b) Delta-9-Tetrahydrocannabinol (THC) Analysis.

- (i) Sample Preparation: A sample, aliquot or scraping of the material submitted shall be extracted by a liquid/liquid or solid phase extraction technique in batch. Batch extracts may be further concentrated or diluted if necessary.
- (ii) Analysis: The batch shall be analyzed Qualitatively and Quantitatively by Gas Chromatography/Mass Spectrometry (GC/MS).
- (iii) Confirmation: Submitted materials determined to be free of detectable amounts of CBD and THC shall be resampled and analyzed by DART-TOF/DART-Accu TOF to determine the presence of other controlled or dangerous substances. Submitted materials containing CBD and an amount of THC less than 3% will require no further testing. Submitted materials containing CBD and determined to contain THC levels greater than 3% relative to CBD shall be resampled, derivatized and qualitatively analyzed by GC/MS.
- (iv) Reporting: Expanded uncertainty of measurement will be determined utilizing a coverage factor of three. Only those submitted materials that are determined to be free of plant material and after analysis/confirmation are determined to possess in excess of the total amount of 3% Delta-9-Tetrahydrocannabinol (THC), plus the expanded uncertainty, relative to Cannabidiol (Internal Standard) shall be reported as positive for THC (in excess of permissible amount by statute).

Author: Dale A. Carpenter, Andrea Headrick, Tracy Segrest, Thao Hunter.

Statutory Authority: "Acts of Alabama, Act 2016-268"

History: Filed May 31, 2016, Permanent Rule Filed July 20, 2016.