

## HOUSE BILL 563: Regulate Hemp-Derived Consumables & Kratom.

2023-2024 General Assembly

<b>Committee:</b>	House Finance. If favorable, re-refer to Rules,	Date:	August 15, 2023
	Calendar, and Operations of the House		
Introduced by:	Reps. McNeely, Sasser, Cotham, Fontenot	Prepared by:	Susan Sitze
Analysis of:	PCS to Second Edition		Staff Attorney
	H563-CSSAfa-34		

#### **OVERVIEW:** The Proposed Committee Substitute (PCS) for House Bill 563 would do the following:

- Regulate the sale and distribution of hemp-derived consumable products and kratom products.
- Require a license to sell, distribute, or manufacture hemp-derived consumable products and kratom products.
- Ban hemp-derived consumable products from school grounds.

#### CURRENT LAW AND BILL ANALYSIS:

# PART I. REGULATION OF HEMP-DERIVED CONSUMABLE PRODUCTS AND KRATOM PRODUCTS

Under current law, hemp and hemp products are excluded from the definition of marijuana and therefore are not controlled substances. The two terms are defined in G.S. 90-87 as follows:

- "Hemp" means the plant Cannabis sativa (L.) and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis.
- "Hemp products" means all products made from hemp, including, but not limited to, cloth, cordage, fiber, food, fuel, paint, paper, particleboard, plastics, seed, seed meal and seed oil for consumption, and verified propagules for cultivation if the seeds originate from hemp varieties.

Kratom is a tropical tree native to Southeast Asia whose leaves contain two psychoactive ingredients, mitragynine and 7-hydroxymytragynine. The crushed leaves are generally smoked, brewed with tea, or placed into gel capsules. Consumption produces both stimulant effects (in low doses) and sedative effects (in high doses). [Summarized from information provided by the Drug Enforcement Administration of the U.S. Department of Justice.] Kratom is currently not a controlled substance and is unregulated and legal in North Carolina.

#### Section 1.(a) – New Chapter 18D

The PCS would enact a new Chapter 18D to regulate both hemp-derived consumable products and kratom products in North Carolina.

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This bill analysis was prepared by the nonpartisan legislative staff for the use of legislators in their deliberations and does not constitute an official statement of legislative intent.

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Article 1 – Hemp-derived consumable products

Article 1 of Chapter 18D would provide requirements and regulations for hemp-derived consumable products.

G.S. 18D-100 would define terms applicable to hemp-derived consumable products.

"Hemp-derived consumable product" would be defined as follows:

"A hemp product intended for human ingestion or inhalation, that contains a concentration of not more than three-tenths of one percent (0.3%) on a dry weight basis total combined of delta-9 tetrahydrocannabinol, delta-7 tetrahydrocannabinol, delta-8 tetrahydrocannabinol, or delta-10 tetrahydrocannabinol, or any amount of another cannabinoid. This term does not include hemp products intended for topical application, or seeds or seed derived ingredients that are generally recognized as safe by the United States Food and Drug Administration (FDA)."

This definition includes consumable products commonly referred to as "CBD", "delta-7", "delta-8", and "delta-10", and others. It would not include topical products such as lotions or creams intended to be used externally, or items such as hemp milk that are derived from seed.

# For purposes of this summary, the term "THC" refers to all of the following unless otherwise specified: delta-9 tetrahydrocannabinol, delta-7 tetrahydrocannabinol, delta-8 tetrahydrocannabinol, and delta-10 tetrahydrocannabinol.

**G.S. 18D-101** would provide **sales restrictions** on hemp-derived consumable products and prohibit the following:

- Selling a hemp-derived consumable product to a person under 18.
- Distributing samples of a hemp-derived consumable product in or on a public street, sidewalk, or park.
- Engaging in the business of selling hemp-derived consumable products without a valid license.
- Selling a hemp-derived consumable product that has a concentration of more than 0.3% on a dry weight basis total combined of delta-9 tetrahydrocannabinol, delta-7 tetrahydrocannabinol, delta-8 tetrahydrocannabinol, or delta-10 tetrahydrocannabinol.

In general, there would be no criminal penalties for violation, but civil penalties could be imposed by the Department of Revenue (Department) as follows:

- > 1st violation up to \$500.
- > 2nd violation within 3 years up to \$750.
- > 3rd violation within 3 years of the 1st violation up to \$1,000 and 30 day suspension of license.
- 4th or subsequent violation within 3 years of the 1st violation up to \$2,000 and either (i) license suspension for up to 1 year or (ii) license revocation.

In any case where the Department is authorized to suspend or revoke a license, the Department may accept an offer in compromise of up to \$3,000. If the Department accepts the offer in compromise, it may suspend the license, but not revoke it.

Additionally, in any case in which the Department imposes a penalty for a violation of selling a product with more than 0.3% THC the seller shall also pay to the Department the actual costs paid by the Alcohol Law Enforcement (ALE) Division for testing the product samples resulting in the violation.

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This section does provide a Class A1 misdemeanor for any person who sells hemp-derived consumable products without a license if they have previously received a civil penalty from the Department for selling without a license.

G.S. 18D-102 would create criminal offenses for underage purchasing and use of fake IDs as follows:

- Giving a hemp-derived consumable product to a person under 18 without the consent of the underage person's parent or legal guardian.
- A person under 18 purchasing or attempting to purchase a hemp-derived consumable product.
- Using a fake, fraudulent, or borrowed ID to enter or attempt to enter a place where hemp-derived consumable products are sold or to purchase or attempt to purchase hemp-derived consumable products.
- Allowing an underage person to use the person's ID to purchase or attempt to purchase hempderived consumable products.

Violation of these provisions by a person under 18 would be a Class 2 misdemeanor. Violation by a person 18 or older would be a Class 1 misdemeanor. Aiding or abetting a violation would be punished the same as the commission of the offense.

**G.S. 18D-103** would create criminal offenses and civil penalties for the following **conduct when committed by a manufacturer or distributor**:

- Distributing samples of a hemp-derived consumable product in or on a public street, sidewalk, or park.
- Engaging in manufacturing or distributing a hemp-derived consumable product without a valid license.
- Manufacturing or distributing a hemp-derived consumable product with a concentration of more than 0.3% on a dry weight basis total combined of delta-9 tetrahydrocannabinol, delta-7 tetrahydrocannabinol, delta-8 tetrahydrocannabinol, or delta-10 tetrahydrocannabinol.

Violation of these provisions would be a Class A1 misdemeanor. In addition to the criminal penalties, the Department may also impose one or more of the following actions against a licensee:

- Suspend the license for up to 3 years.
- Revoke the license.
- > Impose conditions on the licensee's operating hours.
- Impose civil penalties as follows:
  - $\circ$  1st violation up to \$1,000.
  - $\circ$  2nd violation within 3 years up to \$5,000.
  - $\circ$  3rd violation within 3 years of the 1st violation up to \$7,500.

In any case where the Department is authorized to suspend or revoke a license, the Department may accept an offer in compromise of up to \$8,000. If the Department accepts the offer in compromise, it may suspend the license, but not revoke it.

Additionally, in any case in which the Department imposes a penalty for a violation of manufacturing or distributing a product with more than 0.3% THC the manufacturer or distributor shall also pay to the Department the actual costs paid by the Alcohol Law Enforcement (ALE) Division for testing the product samples resulting in the violation.

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The statute would authorize a defense for a violation of manufacturing or distributing a hemp-derived consumable product with more than 0.3% THC, if the manufacturer or distributor takes all of the following actions:

- Recalls all hemp-derived consumable products from the same batch on which the violation is based.
- Has samples of the batch tested by an independent testing laboratory in sample sizes of 5 times the amount required for pre-distribution testing.
- Provides certified results indicating the sample tested does not contain more than 0.3% THC.

**G.S. 18D-104** would require the manufacturer or distributor to conduct **testing prior to distribution**. Testing must be done by an independent testing laboratory using high-performance liquid chromatography for any separation and measurements to test for specified items and determine the amounts of those items present. Testing and must be done in sample quantities determined by the size of the product batch. The label of the product must include an expiration date conforming with federal law.

**G.S. 18D-105** would establish certain requirements for **packaging and serving sizes**, including limiting the amount of hemp-derived cannabinoid that may be present in a serving of an ingestible hemp-derived consumable product to (i) 200 mg, in the aggregate, of one or more hemp-derived cannabinoid, including THCs and (ii) 10 mg, in the aggregate of one or more of the THCs. This statute also places restrictions on **advertising** of hemp-derived consumable products.

**G.S. 18D-106** would clarify that the regulation of hemp-derived consumable products is not intended to allow the consumption of hemp-derived consumable products in various situations or limit an employer's ability to enforce a drug-free workplace.

#### Article 2 – Kratom Products

Article 2 of Chapter 18D would provide requirements and regulations for kratom products.

G.S. 18D-200 would define terms applicable to kratom products.

"Kratom product" would be defined as follows:

"Any consumer commodity containing any quantity of mitragynine or 7-hydroxymytragynine or both, extracted from the leaf of the plant mitragyna speciosa."

G.S. 18D-201 would provide sales restrictions on kratom products and prohibit the following:

- Selling a kratom product to a person under 18.
- Distributing samples of a kratom product in or on a public street, sidewalk, or park.
- Engaging in the business of selling kratom products without a valid license.
- Selling a kratom product that is adulterated or contaminated or otherwise violates the provisions of G.S. 18D-204.

In general, there would be no criminal penalties for violation, but civil penalties could be imposed by the Department of Revenue (Department) as follows:

- > 1st violation up to \$500.
- > 2nd violation within 3 years up to \$750.
- > 3rd violation within 3 years of the 1st violation up to 1,000 and 30 day suspension of license.

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4th or subsequent violation within 3 years of the 1st violation – up to \$2,000 and either (i) license suspension for up to 1 year or (ii) license revocation.

In any case where the Department is authorized to suspend or revoke a license, the Department may accept an offer in compromise of up to \$3,000. If the Department accepts the offer in compromise, it may suspend the license, but not revoke it.

Additionally, in any case in which the Department imposes a penalty for a violation of selling an adulterated or contaminated product, the seller shall also pay to the Department the actual costs paid by the Alcohol Law Enforcement (ALE) Division for testing the product samples resulting in the violation.

This section does provide a Class A1 misdemeanor for any person who sells kratom products without a license if they have previously received a civil penalty from the Department for selling without a license.

#### G.S. 18D-202 would create criminal offenses for underage purchasing and use of fake IDs as follows:

- Giving a kratom product to a person under 18 without the consent of the underage person's parent or legal guardian.
- A person under 18 purchasing or attempting to purchase a kratom product.
- Using a fake, fraudulent, or borrowed ID to enter or attempt to enter a place where kratom products are sold or to purchase or attempt to purchase kratom products.
- Allowing an underage person to use the person's ID to purchase or attempt to purchase kratom products.

Violation of these provisions by a person under 18 would be a Class 2 misdemeanor. Violation by a person 18 or older would be a Class 1 misdemeanor. Aiding or abetting a violation would be punished the same as the commission of the offense.

**G.S. 18D-203** would create criminal offenses and civil penalties for the following **conduct when committed by a manufacturer or distributor**:

- Distributing samples of a kratom product in or on a public street, sidewalk, or park.
- Engaging in manufacturing or distributing a kratom product without a valid license.
- Manufacturing or distributing a kratom product that is adulterated or contaminated or otherwise violates the provisions of G.S. 18D-204.

Violation of these provisions would be a Class A1 misdemeanor. In addition to the criminal penalties, the Department may also impose one or more of the following actions against a licensee:

- Suspend the license for up to 3 years.
- Revoke the license.
- > Impose conditions on the licensee's operating hours.
- Impose civil penalties as follows:
  - $\circ$  1st violation up to \$1,000.
  - $\circ$  2nd violation within 3 years up to \$5,000.
  - $\circ$  3rd violation within 3 years of the 1st violation up to \$7,500.

In any case where the Department is authorized to suspend or revoke a license, the Department may accept an offer in compromise of up to \$8,000. If the Department accepts the offer in compromise, it may suspend the license, but not revoke it.

Additionally, in any case in which the Department imposes a penalty for a violation of manufacturing or distributing an adulterated or contaminated product, the manufacturer or distributor shall also pay to the

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Department the actual costs paid by the Alcohol Law Enforcement (ALE) Division for testing the product samples resulting in the violation.

**G.S. 18D-204** would provide **product limitations** on the kratom products prepared, manufactured, distributed, or offered for sale. The following would be prohibited:

- A kratom product adulterated with a dangerous non-kratom substance.
- A kratom product contaminated with a dangerous non-kratom substance.
- A kratom extract containing levels of residual solvents higher than is allowed in the U.S. Pharmacopeia 467.
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 1% of the overall alkaloid composition of the product.
- A kratom product containing any synthetic alkaloids.
- A kratom product that does not provide adequate labeling directions necessary for safe use by consumers.

**G.S. 18D-205** would require manufacturers and distributors to **register all kratom products** offered for sale by the manufacturer or distributor in this State with the Department. Manufacturers and distributors would also be required to submit a copy of any **adverse event report** to the Department, as required by federal law. If an adverse event report is not submitted when required, the registration for that product would be revoked and the license for that manufacturer or distributor would be suspended or revoked.

**G.S. 18D-206** would clarify that the regulation of kratom products is not intended to allow the consumption of kratom products in various situations or limit an employer's ability to enforce a drug-free workplace.

#### Article 3 – Licensing for Hemp-derived consumable products and kratom products

Article 3 would require anyone in the business of manufacturing, distributing, or selling hemp-derived consumable products and kratom products in this State to obtain a license from the Department of Revenue.

G.S. 18D-300 incorporates the definitions from Articles 1 and 2 as appropriate.

**G.S. 18D-301** would require a **license to be obtained prior to commencement of business or by July 1, 2024,** whichever is later, and set out the minimum requirements for obtaining the license, including consent to reasonable inspections and taking of reasonable samples by the ALE Division. Only one license is required, but the application must include information on all types of business the person or entity engages in or intends to engage in pursuant to the license. A licensee engaged in more than one type of business would only pay a single fee, as provided in G.S. 18D-302. A license would be valid for one year, and could be renewed annually.

G.S. 18D-302 would set the initial application fees and renewal fees as follows:

- **Manufacturing license** \$5,000 initial, \$1,000 annual renewal. However, the application fee would be reduced to \$1,000 for an applicant submitting proof of a gross income of less than \$100,000 for the previous calendar year.
- **Distribution license** \$2,500 initial, \$750 annual renewal. However, the application fee would be reduced to \$750 for an applicant submitting proof of a gross income of less than \$100,000 for the previous calendar year.

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- **Retail sale license at physical location or online for delivery to a person within this State** \$100 for each retail location, both initially and renewal. However, a licensee with more than 25 retail locations, internet websites, or combination of the two, would pay \$2,500 and provide a list of all retail locations and internet websites.
- For an application for or renewal of a license to **engage in more than one business activity**, the fee would be the highest fee of those prescribed for the type of business indicated on the application or renewal, as applied to that applicant or licensee.

# **G.S. 18D-303** would **authorize the Department to revoke or refuse to issue a license** for any of the following:

- Failure to comply with or meet any qualification of G.S. 18D-301(b).
- Submission of false or misleading information in an application for licensure or renewal.
- Submission of false or misleading information in any report or information required to be submitted to the Department.
- Failure to comply with civil penalties authorized by the Chapter.

**G.S. 18D-304** would provide that **proceedings for civil penalties** would be governed by the Administrative Procedures Act, and also authorize the Department to institute a civil action to recover unpaid civil penalties.

**G.S. 18D-305** would require the Department to develop the license application and make it available online. Revenue from **fees collected would be remitted to the ALE Division** on a monthly basis to cover costs incurred in enforcing the Chapter.

#### Article 4 – Enforcement

Article 4 would grant enforcement authority to the ALE Division and provide a process for forfeiture of seized hemp-derived consumable products and kratom products.

**G.S. 18D-400** would authorize the **ALE Division to enforce** the provisions of the Chapter and would require the Division to report any violation for which civil penalties are authorized to the Department of Revenue, regardless of whether criminal charges have been filed. The Division would also be required to submit an annual report describing their enforcement efforts, and to also make that report available on their website.

**G.S. 18D-401** would authorize seizure and forfeiture of property for violation of the prohibition on more than 0.3% THC in a hemp-derived consumable product, or violation of the prohibition on adulterated or contaminated kratom products, and provide a process for the forfeiture and destruction of seized products.

<u>Section 1.(b)</u> would amend G.S. 18B-500 to give the **ALE Division subject matter authority** over criminal offenses occurring on the premises of or involving an entity with a license issued pursuant to Chapter 18D.

<u>Section 1.(c)</u> would amend G.S. 7A-304 to allow a **\$600 fee to be collected through court costs** to for a criminal conviction for violation of the prohibition on more than 0.3% THC in a hemp-derived consumable product, or violation of the prohibition on adulterated or contaminated kratom products if testing was conducted on products.

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<u>Section 1.(d) – Effective date</u> Section 1 would become effective July 1, 2024, and apply to all hempderived consumable products possessed, sold, distributed, or manufactured on or after that date, to all kratom products possessed, sold, distributed, or manufactured on or after that date, and to all offenses committed on or after that date.

#### PART II. TECHNICAL CHANGES

**Section 2** would repeal G.S. 90-94.1 which authorizes the use of hemp extract for intractable epilepsy. This statute was enacted as part of a temporary authorization and registration process before the federal approval of a medication that has now been approved and all other statutes were repealed effective July 1, 2021. This section would become effective December 1, 2023, and apply to offenses committed on or after that date.

#### PART III. APPROPRIATION

Section 3 would make the following appropriations:

- \$2,000,000 nonrecurring to the ALE Division to hire 20 full-time Special Agents to assist in implementing the provisions of this act.
- \$375,000 nonrecurring to be used for costs incurred by the Department of Revenue in implementing the provisions of this act.
- \$125,000 nonrecurring to be used for costs incurred by the ALE Division in implementing the provisions of this act.

Any nonrecurring funds that are not expended by the end of the 2023-2024 fiscal year would not revert. This section would become effective July 1, 2023.

# PART IV. PROHIBIT USE OF HEMP-DERIVED CONSUMABLE PRODUCTS AND KRATOM PRODUCTS FROM BEING USED ON SCHOOL GROUNDS

**Section 4** would require all governing bodies of public school units to adopt a policy prohibiting the use of hemp-derived consumable products and kratom products at all times on school property, including school sponsored events at another location when in the presence of students or school personnel.

This section would be effective when it becomes law and apply beginning with the 2024-2025 school year.

#### PART V. MISCELLANEOUS

**Section 5.(a)** would direct the Department of Revenue to establish guidance for the parties regulated by Chapters 18D and 18E, and to adopt rules to implement those Chapters prior to July 1, 2024. The Department shall accept applications and issue licenses prior to July 1, 2024, but no license shall take effect until July 1, 2024.

Section 5.(b) would direct the Department of Public Safety to adopt rules consistent with the provisions of this act.

Section 5.(c) and (d) would create a criminal savings clause and a severability clause respectively.

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**EFFECTIVE DATE:** Except as otherwise stated above, this act would be effective when it becomes law.

#### **BACKGROUND:**

Punishment for a Class A1 misdemeanor ranges from unsupervised probation to 150 days active, depending on prior record level.

Punishment for a Class 1 misdemeanor ranges from unsupervised probation to 120 days active, depending on prior record level.

Punishment for a Class 2 misdemeanor ranges from unsupervised probation to 60 days active, depending on prior record level.