GENERAL ASSEMBLY OF NORTH CAROLINA SESSION 2023

H.B. 563 Apr 4, 2023 HOUSE PRINCIPAL CLERK

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HOUSE BILL DRH10279-MLfa-121B

Short Title:	Regulate Cannabinoid Products & Kratom. (P	ublic)
Sponsors:	Representative McNeely.	
Referred to:		
	A BILL TO BE ENTITLED	
AN ACT TO REGULATE THE SALE AND DISTRIBUTION OF PRODUCTS CONTAINING		
A HEMP-DERIVED CANNABINOID AND TO ESTABLISH A REGULATORY		
FRAME	WORK FOR THE COMMERCIALIZATION OF KRATOM.	
The General	Assembly of North Carolina enacts:	
PART I. RE	GULATION OF HEMP-DERIVED CANNABINOID PRODUCTS	
S	ECTION 1.(a) The General Statutes are amended by adding a new Chapter to	read:
	" <u>Chapter 18D.</u>	
	"Regulation of Hemp-Derived Cannabinoid Products.	
" <u>§ 18D-100.</u>	Definitions.	
Unless th	e context requires otherwise, the following definitions apply in this Chapter:	
<u>(1</u>	ALE Division. – As defined in G.S. 18B-101.	
<u>(2</u>	<u>Batch. – A single stock keeping unit with common cannabinoid input</u>	t or a
	hemp flower of the same varietal and harvested on the same	
	manufactured during a defined cycle in such a way that it could be exp	ected
	to be of a uniform character and should be designated as such.	
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<u>(4</u>	· · · · · · · · · · · · · · · · · · ·	
	that plant, including the seeds thereof and all derivatives, ext	
	cannabinoids, isomers, acids, salts, and salts of isomers, whether growing	
	not, with a delta-9 tetrahydrocannabinol concentration of not more	than
	three-tenths of one percent (0.3%) on a dry weight basis.	
<u>(5</u>		
	prepare products containing a hemp-derived cannabinoid, including	
	processes of extraction, infusion, packaging, repackaging, labeling	<u>, and</u>
	relabeling of products containing a hemp-derived cannabinoid.	_
<u>(6</u>		
	identification card that contains a photograph of the person and confirm	ns the
	person's age as 21 years of age or older.	
<u>(7</u>		<u>nably</u>
	suitable for a single person's daily use.	
"§ 18D-101. Offenses involving the manufacture, distribution, and sale of hemp-derived		
	annabinoid products.	
<u>(a)</u> O	ffenses. – It is unlawful for a person to do any of the following:	



1 (1) Knowingly sell or distribute a product containing a hemp-derived cannabinoid 2 to a person who is under 21 years of age. 3 Knowingly purchase a product containing a hemp-derived cannabinoid on **(2)** 4 behalf of a person who is under 21 years of age. 5 Knowingly persuade, entice, send, or assist a person who is under 21 years of (3) 6 age to purchase, acquire, receive, or attempt to purchase a product containing 7 a hemp-derived cannabinoid. 8 Knowingly distribute samples of products containing a hemp-derived <u>(4)</u> 9 cannabinoid in or on a public street, sidewalk, or park. 10 Knowingly sell or distribute a product containing a hemp-derived cannabinoid <u>(5)</u> without having first obtained proof of age from the purchaser or recipient. 11 12 (6) Engage in the business of manufacturing, distributing, or selling a product 13 containing a hemp-derived cannabinoid without a valid license issued in 14 accordance with G.S. 18D-104. Knowingly manufacture, distribute, or sell a product containing a 15 (7) hemp-derived cannabinoid that has a delta-9 tetrahydrocannabinol 16 17 concentration of more than three tenths of one percent (0.3%) on a dry weight 18 basis. 19 Exception. – Nothing in this section precludes law enforcement efforts involving 20 either of the following: 21 The use of a minor if the minor's parent or legal guardian has consented to this (1) 22 action. 23 (2) The use of a person under 21 years of age who is not a minor if the individual 24 has consented to this action. 25 Penalty. – A violation of subsection (a) of this section is a Class A1 misdemeanor. 26 Additionally, punishment imposed for a violation of subdivision (7) of subsection (a) of this 27 section shall include the following: 28 For a first offense, the Commission shall impose a civil penalty on the (1) 29 distributor in the amount of five thousand dollars (\$5,000). 30 For a second offense within a three-year period, the Commission shall (2) suspend, for a period of 30 days, the licenses issued under G.S. 18D-104 to 31 32 the manufacturer and distributor of the product that exceeded the limitation 33 set forth in subdivision (7) of subsection (a) of this section and impose a civil 34 penalty on each in the amount of ten thousand dollars (\$10,000). 35 For a third offense within a three-year period, the Commission shall suspend, <u>(3)</u> 36 for a period of one year, the licenses issued under G.S. 18D-104 to the 37 manufacturer and distributor of the product that exceeded the limitation set forth in subdivision (7) of subsection (a) of this section and impose a civil 38 39 penalty on each in the amount of fifteen thousand dollars (\$15.000). 40 Proceeds of Civil Penalty. – The clear proceeds of any civil penalty imposed under this section shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with 41 42 G.S. 115C-457.2. 43 Forfeiture. - Any product manufactured, distributed, or sold in violation of subdivision (6) or (7) of subsection (a) of this section shall be subject to forfeiture pursuant to 44 45 the procedures set forth in G.S. 18B-504. "§ 18D-102. Offenses involving the purchase, possession, or receipt of hemp-derived 46 cannabinoid product by a person under 21 years of age. 47 48 Offenses. – It is unlawful for a person under 21 years of age to do either of the (a)

hemp-derived cannabinoid.

Knowingly purchase, possess, or accept receipt of a product containing a

following:

(1)

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- (2) Knowingly present purported proof of age that is false, fraudulent, or not actually that person's for the purpose of purchasing or receiving a product containing a hemp-derived cannabinoid.
- (b) Exception. Nothing in this section precludes law enforcement efforts involving either of the following:
 - (1) The use of a minor if the minor's parent or legal guardian has consented to this action.
 - (2) The use of a person under 21 years of age who is not a minor if the individual has consented to this action.
 - (c) Penalty. A violation of subsection (a) of this section is a Class A1 misdemeanor.

"§ 18D-103. Enforcement.

- (a) Authority. The ALE Division shall enforce the provisions of this Chapter in a manner that may reasonably be expected to reduce the extent to which products containing a hemp-derived cannabinoid are sold or distributed to persons under 21 years of age and shall conduct random, unannounced inspections at locations where products containing a hemp-derived cannabinoid are sold or distributed to ensure compliance with the provisions of this Chapter.
- (b) Report. Beginning January 1, 2025, the ALE Division shall submit an annual report to the General Assembly describing in detail the ALE Division's enforcement efforts under this Chapter. The ALE Division shall also make the report required under this subsection on the ALE Division's website.

"§ 18D-104. Licensing for manufacturing, distribution, and selling of hemp-derived cannabinoid products.

- (a) Requirement. A person or entity that is in the business of manufacturing, distributing, or selling products containing a hemp-derived cannabinoid in this State shall obtain a license from the Commission authorizing the person or entity to engage in that business prior to the commencement of business or by January 1, 2024, whichever is later.
- (b) Qualifications. In order to obtain and maintain a license under subsection (a) of this section, a person shall meet all of the following criteria:
 - (1) Submit to the Commission any information determined by the Commission to be necessary for the efficient enforcement of this Chapter.
 - (2) Pay to the Commission a fee as follows:
 - a. For a manufacturing license, a fee of five thousand dollars (\$5,000).
 - <u>b.</u> For a distribution license, a fee of two thousand five hundred dollars (\$2,500).
 - <u>c.</u> For a sales license, a fee of one hundred dollars (\$100.00) per location.
 - (3) Consent to reasonable inspection and sampling by the ALE Division of the person's inventory of products containing a hemp-derived cannabinoid.
- (c) <u>Ineligibility. A person is not eligible to obtain or maintain a license under subsection</u>
 (a) of this section while serving a sentence for, or for 10 years following completion of a sentence for, a drug-related felony offense in any state or federal jurisdiction.
- (d) <u>Duration and Renewal. A license issued pursuant to this section is valid for a period of one year and may be renewed annually. The Commission shall charge an annual renewal fee as follows:</u>
 - (1) For a manufacturing license, a renewal fee of one thousand dollars (\$1,000).
 - (2) For a distribution license, a renewal fee of five hundred dollars (\$500.00).
 - (3) For a sales license, a renewal fee equal to the initial licensing fee established under subsection (b) of this section.
- (e) <u>Rules. The Commission shall have authority to adopt, amend, and repeal rules to carry out the provisions of this Chapter. Those rules shall become effective when adopted and filed pursuant to the provisions of Chapter 150B of the General Statutes.</u>

DRH10279-MLfa-121B

 (f) <u>Distribution of Revenue. – The revenue collected from fees established under this section shall be remitted to the Department of Revenue on a monthly basis. The Department of Revenue shall then remit that revenue to the ALE Division to be used to cover costs incurred by the ALE Division from enforcing the provisions of this Chapter. To the extent the funds described in this subsection are deemed unappropriated, the funds are hereby appropriated for the purpose set forth in this subsection.</u>

"§ 18D-105. Testing.

- (a) Requirement. A product containing a hemp-derived cannabinoid shall be tested after being manufactured to determine the presence and amounts of any of the following:
 - (1) Cannabinoids.
 - (2) Heavy metals.
 - (3) Microbials.
 - (4) Mycotoxins.
 - (5) <u>Pesticides.</u>
 - (6) Residual solvents.
- (b) <u>Laboratory Qualifications. A manufacturer or distributor shall contract with a third-party laboratory to provide the testing required under subsection (a) of this section. A third-party laboratory performing such testing shall be ISO 17025 accredited and be registered with the United States Drug Enforcement Administration.</u>
- (c) <u>Testing Method. A laboratory providing testing required under subsection (a) of this section shall use high-performance liquid chromatography for any separation and measurement required in the testing.</u>
- (d) <u>Batch Testing.</u> <u>Each batch manufactured shall undergo testing and obtain a</u> certificate of analysis by a third-party laboratory qualified under subsection (b) of this section.
- (e) Expiration Date. An expiration date on the label of a product containing a hemp-derived cannabinoid shall be in conformance with applicable federal law.
 - (f) Commission Duties. The Commission shall do all of the following:
 - (1) Adopt rules specifying pass or fail action levels for safety and toxicity with respect to the testing required under subsection (a) of this section.
 - (2) Maintain and post on its website a registry of testing laboratories that are qualified to test intermediate manufactured material and finished products containing a hemp-derived cannabinoid.
 - (3) Develop an application and process by which qualifying laboratories are listed on its website. The application submitted by a potentially qualifying laboratory shall include a sample certificate of analysis issued by the applying laboratory.

"§ 18D-106. Additional requirements and restrictions for hemp-derived cannabinoid products.

- (a) Packaging Requirements. A product containing a hemp-derived cannabinoid that is sold in this State shall meet both of the following requirements:
 - (1) The product shall satisfy the child-resistant effectiveness standards under 16 C.F.R. § 1700.15(b)(1) when tested in accordance with the requirements of 16 C.F.R. § 1700.20.
 - (2) The product shall be labelled with all of the following:
 - <u>a.</u> <u>A list of ingredients and possible allergens and a nutritional fact panel.</u>
 - b. The words "CANNABIS USE WHILE PREGNANT OR BREASTFEEDING MAY BE HARMFUL. CONSUMPTION OF CERTAIN CANNABINOIDS IMPAIRS YOUR ABILITY TO DRIVE AND OPERATE HEAVY MACHINERY. PLEASE USE EXTREME CAUTION."

Page 4

1 A statement that the product is not approved for any medical use by <u>c.</u> 2 the United States Food and Drug Administration. 3 The words "KEEP OUT OF REACH OF CHILDREN. CONSULT <u>d.</u> 4 YOUR PHYSICIAN BEFORE USE IF YOU ARE PREGNANT, 5 BREASTFEEDING, OR TAKING ANY MEDICATIONS." 6 <u>e.</u> If the product is ingestible, the amount of cannabinoid in each serving 7 of the product, measured in milligrams. 8 The total amount of hemp-derived cannabinoid in the entire package, <u>f.</u> 9 measured in milligrams. 10 The net weight of the product. g. 11 A code that can be scanned to access a website providing the product's h. 12 batch number, date received, date of completion, and method of analysis for the testing required under G.S. 18D-105. 13 14 An expiration date in accordance with applicable federal law. 15 (b) Advertising Restrictions. – A manufacturer or distributor of a product containing a hemp-derived cannabinoid shall not advertise, market, or offer for sale the product by using, in 16 17 the labelling or design of the product or product packaging or in advertising or marketing 18 materials for the product trade dress, trademarks, branding, or other related imagery or scenery 19 that depicts or signifies characters or symbols known to appeal primarily to persons under 21 20 years of age, including, but not limited to, superheroes, comic book characters, video game 21 characters, television show characters, movie characters, mythical creatures, and unicorns. 22 Ingestible Product Restrictions. – An ingestible product containing a hemp-derived 23 cannabinoid shall not do either of the following: 24 (1) Be sold in a serving that contains more than 75 milligrams, in the aggregate, 25 of one or more hemp-derived cannabinoids. 26 Be formed not the shape of an animal or cartoon character. (2) 27 "§ 18D-107. Construction of Chapter. 28 Nothing in this Chapter shall be construed as doing any of the following: 29 Permit a person to undertake any task under the influence of a hemp-derived **(1)** 30 cannabinoid when doing so would constitute negligence or professional 31 malpractice. 32 **(2)** Permit a person to operate, navigate, or be in actual physical control of a motor 33 vehicle, aircraft, motorized watercraft, or any other vehicle while under the 34 influence of a hemp-derived cannabinoid. 35 Require an employer to accommodate the use of a hemp-derived cannabinoid <u>(3)</u> in a workplace or an employee working while under the influence of a 36 37 hemp-derived cannabinoid. Require an individual or establishment in lawful possession of property to 38 (4) 39 admit a guest, client, customer, or other visitor who is impaired as a result of 40 the person's use of a hemp-derived cannabinoid. 41 Exempt a person from prosecution for a criminal offense related to impairment (5) 42 or intoxication resulting from the use of a hemp-derived cannabinoid or 43 relieve a person from any requirement under law to submit to a breath, blood, 44 urine, or other test to detect the presence of a controlled substance. 45 Limit the ability of an employer to establish, continue, or enforce a drug-free (6) 46 workplace program or policy. 47 Create a cause of action against an employer for wrongful discharge or <u>(7)</u> 48 discrimination. 49 Allow the possession, sale, manufacture, or distribution of any substance that <u>(8)</u>

DRH10279-MLfa-121B Page 5

is otherwise prohibited by Article 5 of Chapter 90 of the General Statutes.

Page 6

Prohibit the use or possession of hemp extract in accordance with 1 (9) 2 G.S. 90-94.1." 3 **SECTION 1.(b)** This section becomes effective October 1, 2023, and applies to 4 offenses committed on or after that date. 5 6 PART II. CONFORMING CHANGES 7 **SECTION 2.(a)** G.S. 18B-500(b)(1) reads as rewritten: 8 Occurring, encountered, or otherwise discovered on the premises of, or 9 elsewhere when the conduct relates to, a location under application for or holding a permit or license issued by the North Carolina Alcoholic Beverage 10 11 Control Commission or the North Carolina Education Lottery Commission." **SECTION 2.(b)** G.S. 90-87(13a) is repealed. 12 **SECTION 2.(c)** G.S. 90-94.1 reads as rewritten: 13 14 "§ 90-94.1. Exemption for use or possession of hemp extract. 15 16 (b) Notwithstanding any other provision of this Chapter, Chapter or Chapter 18D of the General Statutes, an individual may possess or use hemp extract, and is not subject to the 17 18 penalties described in this Chapter, if the individual satisfies all of the following criteria: 19 Possesses or uses the hemp extract only to treat intractable epilepsy, as defined (1) 20 in G.S. 90-113.101. 21 (2) Possesses, in close proximity to the hemp extract, a certificate of analysis that 22 indicates the hemp extract's ingredients, including its percentages of tetrahydrocannabinol and cannabidiol by weight. 23 24 (3) Is a caregiver, as defined in G.S. 90-113.101. 25 (c) Notwithstanding any other provision of this Chapter, Chapter or Chapter 18D of the 26 General Statutes, an individual who possesses hemp extract lawfully under this section may 27 administer hemp extract to another person under the individual's care and is not subject to the 28 penalties described in this Chapter for administering the hemp extract to the person if the 29 individual is the person's caregiver, as defined in G.S. 90-113.101. 30" 31 **SECTION 2.(d)** This section becomes effective October 1, 2023. 32 33 PART III. APPROPRIATION 34 **SECTION 3.(a)** The following sums are appropriated from the General Fund to the 35 Department of Public Safety in nonrecurring funds for the 2023-2024 fiscal year: 36 Two million dollars (\$2,000,000) to be used to hire 20 full-time equivalent (1) positions in the Alcohol Law Enforcement Division of the Department of 37 Public Safety (ALE Division) to serve as Special Agents and assist in 38 39 implementing the provisions of this act. 40 Five hundred thousand dollars (\$500,000) to be used for any other costs (2) incurred by the Alcoholic Beverage Control Commission (ABC Commission) 41 42 and the ALE Division from implementing the provisions of this act. 43 **SECTION 3.(b)** This section becomes effective July 1, 2023. 44 45 PART IV. REGULATION OF KRATOM 46 **SECTION 4.(a)** G.S. 106-121 reads as rewritten: "§ 106-121. Definitions and general consideration. 47 For the purpose of this Article: 48 49 50 The term "kratom processor" means a person that sells, prepares, (9a) manufactures, distributes, or maintains kratom products to consumers in the 51

DRH10279-MLfa-121B

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State, or advertises, represents, or holds itself out as selling, preparing, or 1 2 maintaining kratom products to consumers in the State. 3 The term "kratom product" means a consumer commodity containing any part (9b)4 or extract of the leaf of the plant mitragyna speciosa. 5 6 **SECTION 4.(b)** G.S. 106-139 is amended by adding two new subsections to read: 7 The Board shall adopt rules for regulating kratom processors (processors) to ensure "(f) 8 the quality and safety of kratom products (products) sold in the State. The Board shall include, 9 at a minimum, the following requirements in adopting rules under this subsection: 10 Registration. - The Board shall require all processors (i) to register as a (1) 11 processor with the Department and (ii) to register all products offered for sale 12 by the processor, in the State, with the Department. The registration shall include any information that the Board deems necessary to ensure compliance 13 14 with the provisions of this Article. Noncompliance provisions. – The Board shall require a processor, upon 15 <u>(2)</u> receipt of a violation report of noncompliance with the provisions of this 16 17 Article, to take such corrective action as the Board deems necessary to become compliant with this Article within a time line set out by the Board. If the 18 19 processor is not compliant within the time allotted, the registration for that 20 product shall be revoked and the registration for that processor shall be 21 suspended or revoked, at the discretion of the Board. Adverse event reports. – The Board shall require a processor, upon receipt of 22 <u>(3)</u> any adverse event (AE) report related to a product sold by that processor, to 23 24 submit a copy of the AE report, as required under section 761 of the federal 25 Food Drug and Cosmetic Act, to the Department within 30 days. If the 26 processor does not submit a copy of the AE report within the time allotted, the 27 registration for that product shall be revoked and the registration for that 28 processor shall be suspended or revoked, at the discretion of the Board. 29 The manufacture, sale, delivery, holding, or offering for sale of any kratom products 30 that are falsely certified as compliant with the certification rules adopted by the Board under subsection (f) of this section shall be prohibited under this Article and shall also be subject to 31 32 G.S. 106-123 and G.S. 106-125." 33 34 PART V. MISCELLANEOUS 35 **SECTION 5.(a)** The Board of Agriculture, the Department of Public Safety, and the 36 37 38 to amend any rules as required under this section. 39

ABC Commission shall adopt rules, or amend their rules, consistent with the provisions of this act. The Board, Department, and Commission may use the procedure set forth in G.S. 150B-21.1

SECTION 5.(b) Prosecutions for offenses committed before the effective date of this act are not abated or affected by this act, and the statutes that would be applicable but for this act remain applicable to those prosecutions.

SECTION 5.(c) If any provision of this act or its application is held invalid, the invalidity does not affect other provisions or applications of this act that can be given effect without the invalid provisions or application and, to this end, the provisions of this act are severable.

SECTION 5.(d) Except as otherwise provided, this act becomes effective July 1, 2023.

DRH10279-MLfa-121B Page 7