

**2023 -- H 5330 SUBSTITUTE A**

LC001244/SUB A/3

**STATE OF RHODE ISLAND**

**IN GENERAL ASSEMBLY**

**JANUARY SESSION, A.D. 2023**

**A N A C T**

**RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT**

Introduced By: Representatives Edwards, and Kennedy

Date Introduced: February 03, 2023

Referred To: House Corporations

It is enacted by the General Assembly as follows:

1 SECTION 1. Title 21 of the General Laws entitled "FOOD AND DRUGS" is hereby  
2 amended by adding thereto the following chapter:

3 CHAPTER 28.12

4 KRATOM CONSUMER PROTECTION ACT

5 **21-28.12-1. Short title.**

6 This chapter shall be known and may be cited as the "Kratom Consumer Protection Act  
7 (KCPA)."

8 **21-28.12-2. Definitions.**

9 As used in this chapter:

10 (1) "Director" means the director of the department of health.

11 (2) "Food" means a dietary ingredient, dietary supplement, botanical supplement, or  
12 beverage for human consumption.

13 (3) "Kratom extract" means a dietary ingredient, dietary supplement, botanical supplement  
14 or containing any part of the leaf of the plant *Mitragyna speciosa* that has been extracted and  
15 concentrated in order to provide more standardized dosing

16 (4) "Kratom product" means a dietary ingredient, dietary supplement, botanical  
17 supplement, or containing any part of the leaf of the plant *Mitragyna speciosa* or an extract of it; is  
18 manufactured as a powder, capsule, pill, beverage, or other edible form; and all kratom products  
19 are dietary ingredients, dietary supplements, or botanical supplements.

1 (5) "Processor" means a person that sells, prepares, manufactures, distributes, or maintains  
2 kratom products.

3 (6) "Retailer" means any person that sells, distributes, advertises, represents, or holds itself  
4 out as selling or maintaining kratom products.

5 **21-28.12-3. Kratom product limitations.**

6 A processor shall not prepare, distribute, sell, or expose for sale any of the following:

7 (1) A kratom product that is adulterated with a dangerous non-kratom substance. A kratom  
8 product is adulterated with a dangerous non-kratom substance if the kratom product is mixed or  
9 packed with a non-kratom substance and that substance affects the quality or strength of the kratom  
10 product to such a degree as to render the kratom product injurious to a consumer.

11 (2) A kratom product that is contaminated with a dangerous non-kratom substance. A  
12 kratom product is contaminated with a dangerous non-kratom substance if the kratom product  
13 contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to,  
14 the substances listed in § 21-28-2.08.

15 (3) A kratom extract that contains levels of residual solvents higher than is allowed in the  
16 U.S. Pharmacopeia 467.

17 (4) A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction  
18 that is greater than one percent (1%) of the overall alkaloid composition of the product.

19 (5) A kratom product containing any synthetic alkaloids including synthetic mitragynine,  
20 synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.

21 (6) A kratom product that does not provide adequate labeling directions necessary for safe  
22 and effective use by consumers, including a recommended serving size.

23 **21-28.12-4. Age limits.**

24 A processor shall not distribute, sell, or expose for sale a kratom product to an individual  
25 under twenty-one (21) years of age.

26 **21-28.12-5. Kratom product registration.**

27 (a) A processor shall register annually any kratom product intended to be offered for sale  
28 to an end consumer in Rhode Island that is in an approved kratom delivery form and pay a fee,  
29 adjusted annually, to cover all administrative costs for processing and administering such  
30 registrations. The registration shall include a certificate of analysis from a certified independent  
31 third-party laboratory showing compliance with the KCPA requirements for safe kratom products.

32 (b) A retailer shall register annually to sell any kratom product sold in their establishment  
33 and pay a fee (adjusted annually) to cover all administration costs for processing and administering  
34 such registrations. A retailer shall not sell any kratom product that is not registered for sale as

1 provided in subsection (a) of this section.

2 (c) Product non-compliance reports. Upon receipt of a violation report on any kratom  
3 product offered for sale, the department shall require the processor to produce an updated and  
4 current certificate of analysis in a reasonable time frame from a certified independent third-party  
5 laboratory showing compliance with the KCPA requirements for safe kratom products. If the  
6 processor does not provide the certificate of analysis in the specified time frame, the registration  
7 for that product shall be revoked.

8 (d) Adverse event reports. Upon receipt of any adverse event related to a registered kratom  
9 product, the processor shall be required to submit a copy via certified mail to the department of  
10 their adverse event report that is required to be submitted to the U.S. Food and Drug Administration  
11 (FDA) under Section 761 of the Federal Food Drug & Cosmetic Act. Any documented failure to  
12 report an adverse event to the department shall authorize the department to revoke the product's  
13 registration.

14 (e) Third-party verification: If the department has a reasonable basis to require an  
15 independent third-party test of a registered kratom product by a laboratory of the department's  
16 choice, the processor shall be required to submit payment for the test within a reasonable time  
17 frame. If the processor does not tender payment to the department within thirty (30) days of receipt  
18 of the invoice for the testing, the department shall revoke the registration for that product.

19 **21-28.12-6. Violations.**

20 (a) A processor or retailer that violates the provisions of § 21-28.12-3 shall be subject to  
21 an administrative fine of not more than five hundred dollars (\$500) for the first offense and not  
22 more than one thousand dollars (\$1,000) for a second or subsequent offense. Upon the request of a  
23 person to whom an administrative fine is issued, the director shall conduct a hearing in accordance  
24 with the procedures as set forth in chapter 35 of title 42 ("administrative procedures").

25 (b) Upon receipt of a third violation pursuant to subsection (a) of this section, the  
26 registration of the retailer shall be revoked and the retailer shall be prohibited from selling any  
27 kratom product.

28 (c) A retailer does not violate § 21-28.12-3 if it is shown by a preponderance of the evidence  
29 that the retailer relied in good faith upon the representations of a manufacturer, processor, packer,  
30 or distributor of food represented to be a kratom product.

31 **21-28.12-7. Taxation of kratom products.**

32 A "kratom product" as defined in 21-28.12-2., is subject to sales and use tax, at the rates as  
33 provided in §§ 44-18-18 and 44-18-20.

34 **21-28.12-8. Removal of mitragynine and 7-hydroxymitragynine from notice of**

1 **designation of controlled substances for mitragynine and hydroxymitragynine under**  
2 **schedule I section 2.08 (g).**

3 [Upon enactment, mitragynine and 7-hydroxymitragynine shall be removed from § 21-28-](#)  
4 [2.08\(g\) of the Rhode Island Uniform Controlled Substances Act.](#)

5 SECTION 2. This act shall take effect on January 1, 2024.

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EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF  
A N A C T  
RELATING TO FOOD AND DRUGS -- KRATOM CONSUMER PROTECTION ACT

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1           This act would regulate the distribution of the product known as "kratom" and would ban  
2 the adulteration of kratom with a dangerous non-kratom substance as to render the product injurious  
3 to a consumer. This act would require that any kratom product shall contain adequate labeling  
4 directions necessary for safe and effective use by consumers. Violations of this chapter would be  
5 subject to administrative fines from five hundred dollars (\$500) to one thousand dollars (\$1,000).

6           This act would take effect on January 1, 2024.

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