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THE GENERAL ASSEMBLY OF PENNSYLVANIA

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SENATE BILL

No. 614 Session of  
2023

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INTRODUCED BY PENNYCUICK, LANGERHOLC, DUSH, STEFANO, ARGALL AND  
HAYWOOD, APRIL 25, 2023

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REFERRED TO HEALTH AND HUMAN SERVICES, APRIL 25, 2023

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AN ACT

1 Prohibiting the preparation, manufacture, sale or distribution  
2 of unsafe kratom products and the sale or distribution of  
3 kratom products to individuals younger than 21 years of age;  
4 providing for duties of Department of Health; and imposing  
5 penalties.

6 The General Assembly of the Commonwealth of Pennsylvania  
7 hereby enacts as follows:

8 Section 1. Short title.

9 This act shall be known and may be cited as the Kratom  
10 Consumer Protection Act.

11 Section 2. Definitions.

12 The following words and phrases when used in this act shall  
13 have the meanings given to them in this section unless the  
14 context clearly indicates otherwise:

15 "Department." The Department of Health of the Commonwealth.

16 "Food product." A food, food ingredient, dietary ingredient,  
17 dietary supplement or beverage for human consumption.

18 "Kratom extract." A food product that contains any part of a  
19 leaf from *mitragyna speciosa*, commonly known as kratom, which

1 has been extracted and concentrated to provide more standardized  
2 dosing.

3 "Kratom product." A food product that contains any part of a  
4 leaf from *Mitragyna speciosa*, commonly known as kratom, or a  
5 kratom extract, and is manufactured as a powder, capsule, pill,  
6 beverage or any other edible form.

7 "Processor." A person who prepares or manufactures a kratom  
8 product or who advertises, represents or holds oneself out as  
9 preparing or manufacturing a kratom product. The term does not  
10 include a retailer.

11 "Retailer." A person who sells or distributes a kratom  
12 product or who advertises, represents or holds oneself out as  
13 selling or distributing a kratom product. The term does not  
14 include a processor.

15 "The Controlled Substance, Drug, Device and Cosmetic Act."  
16 The act of April 14, 1972 (P.L.233, No.64), known as The  
17 Controlled Substance, Drug, Device and Cosmetic Act.

18 Section 3. Prohibition on preparation, manufacture, sale or  
19 distribution of unsafe kratom products.

20 A processor may not prepare or manufacture, and a retailer  
21 may not sell or distribute, a kratom product that meets any of  
22 the following criteria:

23 (1) The kratom product is mixed or packed with a  
24 nonkratom substance and the substance affects the quality or  
25 strength of the kratom product to such a degree as to render  
26 the kratom product injurious to a consumer of the kratom  
27 product.

28 (2) The kratom product contains a poisonous or otherwise  
29 deleterious nonkratom ingredient, including, but not limited  
30 to, any of the following:

1 (i) A controlled substance listed under section 4 of  
2 The Controlled Substance, Drug, Device and Cosmetic Act.

3 (ii) A controlled substance listed under 28 Pa. Code  
4 Ch. 25 Subch. A (relating to controlled substances,  
5 drugs, devices and cosmetics).

6 (iii) A substance that is temporarily scheduled as a  
7 controlled substance by the Secretary of Health under  
8 section 3(d) of The Controlled Substance, Drug, Device  
9 and Cosmetic Act.

10 (3) The kratom product contains a kratom extract with  
11 levels of residual solvents higher than the standards  
12 specified in the current edition of the United States  
13 Pharmacopeia/National Formulary (USP/NF) 467 on the effective  
14 date of this paragraph.

15 (4) The kratom product contains a level of 7-  
16 hydroxymitragynine in the alkaloid fraction that is greater  
17 than 2% of the overall alkaloid composition of the kratom  
18 product.

19 (5) The kratom product contains a synthetic alkaloid,  
20 including a synthetic mitragynine, a synthetic 7-  
21 hydroxymitragynine or any other synthetically derived  
22 compounds of the kratom plant.

23 (6) The kratom product does not include adequate  
24 labeling directions necessary for the safe and effective use  
25 by a consumer of the kratom product, including a recommended  
26 serving size.

27 Section 4. Prohibition on sale or distribution of kratom  
28 products to individuals younger than 21 years of age.

29 A retailer may not sell or distribute a kratom product to an  
30 individual younger than 21 years of age.

1 Section 5. Duties of department.

2 The department shall have the duty of enforcing the  
3 provisions of this act. The department may promulgate  
4 regulations as necessary to implement the provisions of this  
5 act.

6 Section 6. Penalties.

7 (a) Penalties.--In addition to any other penalty provided  
8 under The Controlled Substance, Drug, Device and Cosmetic Act,  
9 the department shall impose an administrative fine on a  
10 processor or retailer who violates section 3, section 4 or  
11 subsection (c) in accordance with the following:

12 (1) For a first offense, an administrative fine of not  
13 less than \$100 and not more than \$500.

14 (2) For a second offense, an administrative fine of not  
15 less than \$500 and not more than \$1,000.

16 (3) For a third offense, an administrative fine of not  
17 less than \$1,000 and not more than \$3,000.

18 (4) For a fourth or subsequent offense, an  
19 administrative fine of not less than \$3,000 and not more than  
20 \$5,000.

21 (b) Defense.--A retailer shall not be subject to an  
22 administrative fine under subsection (a) if, by a preponderance  
23 of the evidence, the retailer acted in good faith reliance upon  
24 a processor that the kratom product is not in violation of  
25 section 3.

26 (c) Plan of correction.--The department may order a  
27 processor or retailer to comply with a plan of correction which  
28 the department deems necessary to correct a violation of section  
29 3 or section 4. A processor or retailer who fails to comply with  
30 a plan of correction shall be subject to an administrative fine

1 under subsection (a) as a separate offense.

2 (d) Credit.--Money received from the administrative fines  
3 imposed under subsection (a) shall be paid into the State  
4 Treasury and shall be credited to the general government  
5 appropriations of the department for administering and enforcing  
6 the provisions of this act.

7 (e) Administrative Agency Law.--The provisions of this  
8 section shall be subject to 2 Pa.C.S. Chs. 5 Subch. A (relating  
9 to practice and procedure of Commonwealth agencies) and 7 Subch.  
10 A (relating to judicial review of Commonwealth agency action).  
11 Section 7. Effective date.

12 This act shall take effect in 60 days.