

THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE BILL

No. 2357 Session of 2022

INTRODUCED BY PENNYCUICK, SAPPEY, HELM, O'MARA, HENNESSEY, SCHLOSSBERG, HEFFLEY, QUINN AND T. DAVIS, MARCH 8, 2022

AS REPORTED FROM COMMITTEE ON HEALTH, HOUSE OF REPRESENTATIVES, AS AMENDED, JUNE 13, 2022

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 18 years of <--
4 age; providing for duties of Department of Health; and
5 imposing 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 section.~~

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 3. Prohibition on sale or distribution of kratom <--
28 products to individuals younger than 21 18 years of <--
29 age.

30 A retailer may not sell or distribute a kratom product to an

1 individual younger than ~~21~~ 18 years of age. <--

2 Section ~~5~~ 4. Duties of department. <--

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

7 Section ~~6~~ 5. Penalties. <--

8 (a) Penalties.--~~In addition to any other penalty provided~~ <--

9 ~~under The Controlled Substance, Drug, Device and Cosmetic Act,~~

10 NOTWITHSTANDING ANY OTHER PROVISION OF LAW, the department shall <--

11 impose an administrative fine on a ~~processor or~~ retailer who <--

12 violates section 3, ~~section 4~~ or subsection ~~(e)~~ (B) in <--

13 accordance with the following:

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

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

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

20 (4) For a fourth or subsequent offense, an
21 administrative fine of not less \$3,000 and not more than
22 \$5,000.

23 ~~(b) Defense. A retailer shall not be subject to an~~ <--

24 ~~administrative fine under subsection (a) if, by a preponderance~~

25 ~~of the evidence, the retailer acted in good faith reliance upon~~

26 ~~a processor that the kratom product is not in violation of~~

27 ~~section 3.~~

28 ~~(e)~~ (B) Plan of correction.--The department may order a <--

29 ~~processor or~~ retailer to comply with a plan of correction which <--

30 the department deems necessary to correct a violation of section

1 3 ~~or section 4. A processor or.~~ A retailer who fails to comply <--
2 with a plan of correction shall be subject to an administrative
3 fine under subsection (a) as a separate offense.

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

9 ~~(e)~~ (D) Administrative Agency Law.--The provisions of this <--
10 section shall be subject to 2 Pa.C.S. Ch. 5 Subch. A (relating
11 to practice and procedure of Commonwealth agencies) and Ch. 7
12 Subch. A (relating to judicial review of Commonwealth agency
13 action).

14 Section 7 6. Effective date. <--

15 This act shall take effect in 60 days.