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
has been extracted and concentrated to provide more standardized
dosing.

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

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

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

"The Controlled Substance, Drug, Device and Cosmetic Act."
The act of April 14, 1972 (P.L.233, No.64), known as The
Controlled Substance, Drug, Device and Cosmetic Act.
Section 3. Prohibition on preparation, manufacture, sale or
distribution of unsafe kratom products.

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

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

(2) The kratom product contains a poisonous or otherwise
deleterious nonkratom ingredient, including, but not limited
to, any of the following:
(i) A controlled substance listed under section 4 of The Controlled Substance, Drug, Device and Cosmetic Act.


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

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

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

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

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

Section 4. Prohibition on sale or distribution of kratom products to individuals younger than 21 years of age. A retailer may not sell or distribute a kratom product to an individual younger than 21 years of age.
Section 5. Duties of department.
The department shall have the duty of enforcing the provisions of this act. The department may promulgate regulations as necessary to implement the provisions of this act.

Section 6. Penalties.
(a) Penalties.—In addition to any other penalty provided under The Controlled Substance, Drug, Device and Cosmetic Act, the department shall impose an administrative fine on a processor or retailer who violates section 3, section 4 or subsection (c) in accordance with the following:

(1) For a first offense, an administrative fine of not less than $100 and not more than $500.
(2) For a second offense, an administrative fine of not less than $500 and not more than $1,000.
(3) For a third offense, an administrative fine of not less than $1,000 and not more than $3,000.
(4) For a fourth or subsequent offense, an administrative fine of not less $3,000 and not more than $5,000.

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

(c) Plan of correction.—The department may order a processor or retailer to comply with a plan of correction which the department deems necessary to correct a violation of section 3 or section 4. A processor or retailer who fails to comply with a plan of correction shall be subject to an administrative fine.
under subsection (a) as a separate offense.

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

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

Section 7. Effective date.

This act shall take effect in 60 days.