

1 AN ACT relating to the regulation of kratom.

2 *Be it enacted by the General Assembly of the Commonwealth of Kentucky:*

3 ➔SECTION 1. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO
4 READ AS FOLLOWS:

5 *As used in Sections 1 to 6 of this Act:*

- 6 *(1) "Certificate of analysis" means a document produced by a laboratory that has*
7 *been accredited pursuant to the standards of the International Organization for*
8 *Standardization attesting to the composition of a kratom product;*
- 9 *(2) "Consumer" means a person who uses kratom products;*
- 10 *(3) "Department" means the Department of Alcoholic Beverage Control;*
- 11 *(4) "Food" has the same meaning as in KRS 217.015 and includes any beverage,*
12 *dietary ingredient, dietary supplement, or food additive as defined in KRS*
13 *217.015 intended for human consumption;*
- 14 *(5) "Kratom extract" means a food containing any part of the leaf of the plant*
15 *Mitragyna speciosa that has been extracted and concentrated in order to provide*
16 *more standardized dosing;*
- 17 *(6) "Kratom processor" means a person or entity that prepares, manufactures,*
18 *distributes, or maintains kratom extracts or kratom products or advertises,*
19 *represents, or claims to sell, prepare, or maintain kratom extracts or kratom*
20 *products;*
- 21 *(7) "Kratom product" means a food, powder, capsule, pill, or any other product*
22 *intended for oral consumption that contains any part of the leaf of the plant*
23 *Mitragyna speciosa or any extract thereof;*
- 24 *(8) "Kratom retailer" means a person or entity that sells or advertises, represents, or*
25 *claims to sell kratom extracts or kratom products; and*
- 26 *(9) "OR code" has the same meaning as in KRS 217.039.*

27 ➔SECTION 2. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO

1 READ AS FOLLOWS:

2 (1) The department shall license kratom processors and kratom retailers and shall
3 enforce Sections 1 to 6 of this Act.

4 (2) (a) The licensing fee for a kratom processor shall be one thousand dollars
5 (\$1,000) per year.

6 (b) The licensing fee for a kratom retailer shall be five hundred dollars (\$500)
7 per year.

8 (3) The department shall promulgate administrative regulations in accordance with
9 KRS Chapter 13A to implement Sections 1 to 6 of this Act. Administrative
10 regulations promulgated pursuant to this subsection shall include:

11 (a) Standard qualifications for licensure;

12 (b) The licensure application and renewal process;

13 (c) The reasons the department may deny, suspend, or revoke a license;

14 (d) Licensing categories, privileges, and restrictions; and

15 (e) Prohibited conduct and enforcement procedures related to licensees.

16 ➔SECTION 3. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO

17 READ AS FOLLOWS:

18 A kratom processor or kratom retailer shall not:

19 (1) Prepare, manufacture, distribute, dispense, sell, or make available for sale any
20 kratom extract or kratom product without first obtaining a license to do so from
21 the department;

22 (2) Distribute, dispense, sell, or make available for sale any kratom extract or kratom
23 product to an individual who is under twenty-one (21) years of age;

24 (3) Prepare, manufacture, distribute, dispense, sell, or make available for sale a
25 kratom product that:

26 (a) Is adulterated with a dangerous nonkratom substance. A kratom product is
27 adulterated with a dangerous nonkratom substance if the kratom product is

1 mixed or packaged with a nonkratom substance and that substance affects
2 the quality or strength of the kratom product to such a degree as to render
3 the kratom product injurious to a consumer;

4 (b) Is contaminated with a dangerous nonkratom substance. A kratom product
5 is contaminated with a dangerous nonkratom substance if the kratom
6 product contains a poisonous or otherwise deleterious nonkratom
7 ingredient, including but not limited to a controlled substance as defined in
8 KRS Chapter 218A;

9 (c) Contains a level of 7-hydroxymitragynine in the alkaloid fraction that is
10 greater than two percent (2%) of the overall alkaloid composition of the
11 product;

12 (d) Contains any synthetic alkaloids, including synthetic mitragynine, synthetic
13 7-hydroxymitragynine, or any other synthetically derived compounds of the
14 plant *Mitragyna speciosa*; or

15 (e) Does not meet labeling requirements established pursuant to Section 4 of
16 this Act and any administrative regulations promulgated thereunder; or

17 (4) Prepare, manufacture, distribute, dispense, sell, or make available for sale a
18 kratom extract that:

19 (a) Contains levels of residual solvents higher than those permitted under the
20 United States Pharmacopeia Chapter 467; or

21 (b) Does not meet labeling requirements established pursuant to Section 4 of
22 this Act and any administrative regulations promulgated thereunder.

23 ➔SECTION 4. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO
24 READ AS FOLLOWS:

25 (1) All kratom extracts and kratom products sold or otherwise distributed in the
26 Commonwealth shall bear labeling to allow the consumer to access information
27 on the product, including a certificate of analysis for the product that meets the

1 requirements established in subsection (2) of this section, the number of servings
2 in the package, the location where the kratom extract or kratom product was
3 processed, and the address and phone number of the distributor using the
4 following:

5 (a) A scannable barcode including the batch number or serial number of the
6 product;

7 (b) A QR code; or

8 (c) A web address linked to a document or website.

9 (2) A certificate of analysis for kratom extracts and kratom products shall include
10 but not be limited to the amount of:

11 (a) 7-hydroxymitragynine;

12 (b) Any other kratom extract;

13 (c) Pesticide residues;

14 (d) Heavy metal traces;

15 (e) Mycotoxin contaminants;

16 (f) Residual solvents; and

17 (g) microbiological contaminants.

18 (3) No product labeling or advertising material for any kratom extract or kratom
19 product sold or otherwise distributed in the Commonwealth shall bear any claims
20 stating that the product can diagnose, treat, cure, or prevent any disease.

21 ➔SECTION 5. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO
22 READ AS FOLLOWS:

23 (1) A kratom processor or retailer who violates Sections 3 or 4 of this Act or any
24 administrative regulation promulgated thereunder shall be subject to the same
25 licensee penalties established in KRS 243.480(1)(c).

26 (2) A kratom processor or retailer who has been penalized as authorized by
27 subsection (1) of this section or by a license denial, suspension, or revocation

1 may, within thirty (30) days after receiving notice of the penalty from the
2 department, file a written request for an administrative hearing to appeal the
3 penalty. The hearing shall be conducted in compliance with the requirements of
4 KRS Chapter 13B.

5 (3) A kratom retailer does not violate Sections 3 or 4 of this Act if it can be shown
6 through a preponderance of evidence that the retailer relied in good faith upon
7 the representations of a manufacturer, processor, packer, or distributor of food
8 presented as a kratom product.

9 ➔SECTION 6. A NEW SECTION OF KRS CHAPTER 217 IS CREATED TO
10 READ AS FOLLOWS:

11 If at any time on or after the effective date of this Act, the federal government or any
12 department or agency thereof, including but not limited to the federal Drug
13 Enforcement Agency or Food and Drug Administration, regulates kratom, kratom
14 extracts, kratom products, any other derivative of the plant *Mitragyna speciosa*, kratom
15 processors, or kratom retailers, those regulations shall supersede and take precedence
16 over any provision of Sections 1, 2, 3, 4, and 5 of this Act and any administrative
17 regulations promulgated thereunder to the contrary.