

House File 612 - Introduced

HOUSE FILE 612
BY GOLDING and BARKER

A BILL FOR

- 1 An Act relating to the regulation of kratom, and making penalties
- 2 applicable.
- 3 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

unofficial

1 Section 1. NEW SECTION. **124F.1 Definitions.**

2 As used in this chapter:

3 1. "*Attractive to children*" means a kratom product that
4 is manufactured in the shape of cartoons or animals or is
5 manufactured or packaged in a form that bears any reasonable
6 resemblance to an existing candy product that is familiar to the
7 public as a widely distributed, branded food product, such that a
8 product could be mistaken for the branded product, especially by
9 children.

10 2. "*Department*" means the department of health and human
11 services.

12 3. "*Independent testing laboratory*" means a laboratory that
13 is accredited to standard ISO/IEC 17025 by an international
14 organization for standards-approved accrediting body.

15 4. "*Kratom*" means the plant *Mitragyna speciosa* or any part of
16 the plant, including all alkaloids present in the plant.

17 5. "*Kratom extract*" means a substance or compound obtained
18 by extraction of the *Mitragyna speciosa* leaf, intended for
19 ingestion, containing more than trace amounts of *Mitragyna*
20 *speciosa* and containing other alkaloids of the kratom plant, but
21 does not contain any controlled substances or levels of residual
22 solvents higher than is allowed in the United States pharmacopeia
23 467.

24 6. "*Kratom food service establishment*" means a person who
25 sells kratom as a beverage prepared on site, or sells prepackaged
26 kratom beverages or finished kratom products, at a food
27 establishment as defined in section 137F.1.

28 7. "*Kratom processor*" means a person who manufactures,
29 distributes, maintains, or sells a kratom product or a person who
30 advertises, represents, or claims to sell, prepare, or maintain a
31 kratom product.

32 8. "*Kratom product*" means a finished article containing any
33 part of a leaf of the plant *Mitragyna speciosa* in fresh,
34 dehydrated, or dried form, or a kratom extract.

35 9. "*Registrant*" means a person or kratom processor that

1 sells, prepares, manufactures, distributes, or maintains kratom
2 products, or advertises, represents, or holds itself out as
3 selling, preparing, or maintaining kratom products.

4 10. "Retailer" means a person that sells, distributes,
5 advertises, represents, or holds itself out as selling kratom
6 products.

7 11. "Synthesized material" means an alkaloid or alkaloid
8 derivative that has been created by chemical synthesis
9 or biosynthetic means, including fermentation, recombinant
10 techniques, yeast-derived techniques, and enzymatic techniques,
11 rather than traditional food preparation techniques, such as
12 heating or extracting, that synthetically alters the composition
13 of any kratom alkaloid or constituent.

14 Sec. 2. NEW SECTION. **124F.2 Kratom product —**
15 **registration.**

16 1. A person responsible for placing a kratom product into
17 commerce in the state shall register annually to offer the
18 kratom product for sale or distribution. The application for
19 registration shall include all of the following:

20 a. A certification from a qualified independent auditor
21 that the applicant meets or exceeds guidelines published by
22 the federal food and drug administration for current good
23 manufacturing practices for any facility that manufactures,
24 processes, packs, or holds a kratom product.

25 b. A current federal food and drug administration food
26 facility registration certificate for any kratom processor
27 facility that manufactures, processes, packs, or holds a kratom
28 product.

29 c. A statement that the applicant has a reasonable basis
30 that the product is safe for consumption under the conditions
31 of use set forth on the label and that the applicant assumes
32 responsibility and liability for any kratom product offered for
33 sale by the applicant.

34 d. A certificate of analysis from an independent testing
35 laboratory showing compliance with the requirements of this

1 chapter for residual solvents, 7-hydroxymitragynine content, and
2 heavy metal contaminants.

3 e. An application fee as determined by the board by rule.

4 2. An application for registration may include multiple
5 kratom products if the kratom products contain the same
6 ingredients sold in the same form but in a different container,
7 package, or volume.

8 3. The department shall create and maintain on the
9 department's internet site a database of all kratom products that
10 are registered for sale in this state.

11 Sec. 3. NEW SECTION. **124F.3 Kratom product —**
12 **limitations.**

13 1. A registrant shall not prepare, distribute, sell, or
14 expose for sale a kratom product containing a level of
15 7-hydroxymitragynine in the alkaloid fraction that is greater
16 than two percent of the alkaloid composition of the kratom
17 product. A product that contains a level of 7-hydroxymitragynine
18 greater than two percent shall not be marketed as, labeled as,
19 or contain any reference on the product's packaging, that it is
20 a kratom product or state that the product is derived from the
21 alkaloid mitragynine.

22 2. A kratom processor, registrant, or retailer shall not
23 offer for sale a kratom product that contains any of the
24 following:

25 a. A poisonous or otherwise deleterious non-kratom
26 ingredient, including a controlled substance.

27 b. A dangerous psychoactive compound, including synthetic
28 cannabinoids, synthetic cathinones, or any other compound that
29 significantly alters the safety profile of the kratom product.

30 3. A kratom processor, registrant, or retailer shall not
31 offer for sale any of the following:

32 a. A kratom product that is combustible, intended to be used
33 for vaporization, or injectable.

34 b. A kratom product that is attractive to children.

35 c. A product containing kratom that is not a kratom product.

1 Sec. 4. NEW SECTION. **124F.4 Kratom product — labeling.**

2 A kratom product produced, manufactured, distributed, offered,
3 sold, or offered for sale shall include a label that clearly and
4 conspicuously provides all of the following information on each
5 retail package:

6 1. A statement against the use by individuals who are
7 under twenty-one years of age, who are pregnant, or who are
8 breastfeeding.

9 2. A recommendation to consult a health care professional
10 prior to use.

11 3. A statement that kratom may be habit forming.

12 4. The following statement: "These statements have not been
13 evaluated by the United States food and drug administration.
14 This product is not intended to diagnose, treat, cure, or prevent
15 any disease."

16 5. The name and address for the place of business of the
17 registrant.

18 6. Directions for use that include all of the following:

19 a. A recommended amount of the kratom product per serving.

20 (1) For kratom products sold as capsules, gummies, or
21 prepackaged single-serving units, the recommended amount shall be
22 clearly described on the label.

23 (2) For kratom products sold as beverages, liquids, or loose
24 powders, a clear instruction or a mark on the package or
25 container that clearly informs the consumer of the recommended
26 serving size.

27 b. The number of servings that can be safely consumed in a
28 twenty-four-hour period.

29 c. A listing of the servings per container.

30 d. A listing of kratom alkaloids and other ingredients in the
31 product, including a quantitative not-to-exceed declaration of
32 the amount per serving of each of the following:

33 (1) Mitragynine.

34 (2) 7-hydroxymitragynine.

35 e. A kratom food service establishment that sells kratom as

1 a beverage prepared on site shall provide an equivalent label
2 in card form, or prominently display the required language in a
3 location next to the point-of-sale device to the customer, at the
4 time the beverage is purchased by the consumer.

5 *f.* A kratom product that contains psychoactive compounds
6 otherwise permitted by law must be clearly labeled with a full
7 disclosure of all active ingredients, the exact concentration
8 of each compound, and adequate warning statements about the
9 potential interactions and risks associated with the combined use
10 of these substances.

11 Sec. 5. NEW SECTION. **124F.5 Enforcement.**

12 1. A person shall not sell or distribute a kratom product
13 that is not currently registered for sale in this state. The
14 department shall seize and destroy an unregistered kratom product
15 and the costs shall be assessed to the person responsible for
16 the availability of the kratom product in this state. A kratom
17 processor that sells or distributes a kratom product that is not
18 currently registered for sale in this state is subject to the
19 following penalties:

20 *a.* For the first sale or distribution of an unregistered
21 kratom product, ten thousand dollars, to be collected by the
22 department and deposited in the general fund of the state.

23 *b.* For the second sale or distribution of an unregistered
24 kratom product for which a fine was imposed pursuant to paragraph
25 "a", fifteen thousand dollars, to be collected by the department
26 and deposited in the general fund of the state.

27 *c.* Upon the third sale or distribution of an unregistered
28 kratom product for which a fine was imposed pursuant to paragraph
29 "a", the kratom processor shall be prohibited from selling or
30 distributing any kratom product in this state for a period of
31 two years following the third sale of the unregistered kratom
32 product.

33 2. A person shall not knowingly or willfully sell or
34 distribute a kratom product to a person under twenty-one years
35 of age. A person who violates this subsection shall be subject

1 to the following:

2 a. For a first offense, a simple misdemeanor.

3 b. For a second or subsequent offense within one year of the
4 date of the first offense, a serious misdemeanor.

5 3. A person shall not knowingly or willfully manufacture,
6 deliver, hold, offer for sale, distribute, or sell a kratom
7 product that contains any controlled substance. A person who
8 violates this subsection is guilty of a class "D" felony.

9 4. A person shall not knowingly or willfully manufacture,
10 deliver, hold, offer for sale, distribute, or sell a
11 kratom product that contains synthetic mitragynine, synthetic
12 7-hydroxymitragynine, or any other synthetically derived compound
13 of the plant *Mitragyna speciosa*. A person who violates this
14 subsection is guilty of a serious misdemeanor.

15 5. a. If the department has reason to believe that a
16 registered kratom product in this state violates the requirements
17 for registration under this chapter, the department shall require
18 the registrant to produce a current certificate of analysis
19 from an independent testing laboratory showing compliance with
20 the requirements for registration under this chapter. If the
21 registrant does not produce a current certificate of analysis
22 showing compliance with the requirements for registration under
23 this chapter within a reasonable time period, the department
24 shall revoke the registration for the kratom product and
25 immediately order the stoppage of all sales of the kratom
26 product.

27 b. If the department has reason to believe that the
28 independent testing laboratory used by a registrant has not
29 provided accurate results, the department shall submit the kratom
30 product for testing to an independent testing laboratory of the
31 department's choice and the costs of the test shall be assessed
32 to the registrant. If the registrant fails to tender payment
33 within thirty calendar days of receipt of a request for payment
34 from the department, the department shall revoke the registration
35 for the kratom product and immediately order the stoppage of all

1 sales of the kratom product.

2 6. A registrant does not violate this section by
3 manufacturing, delivering, holding, offering for sale,
4 distributing, or selling a kratom product that contains
5 psychoactive compounds that has been reviewed and approved by the
6 department for safe consumption under clearly defined conditions
7 of use.

8 7. A retailer does not violate this section if the retailer
9 shows by a preponderance of the evidence that the retailer relied
10 in good faith upon the representations of a manufacturer, packer,
11 or kratom processor regarding a product represented to be a
12 kratom product.

13 Sec. 6. NEW SECTION. **124F.6 Rules.**

14 The department shall adopt rules pursuant to chapter 17A for
15 the administration of this chapter. The rules shall include all
16 of the following:

17 1. The process for the registration of a kratom product by a
18 kratom processor or retailer.

19 2. The requirements for the enforcement of the prohibition of
20 the sale of a kratom product to a person under twenty-one years
21 of age.

22 3. Testing requirements for independent testing laboratories
23 that issue certificates of analysis for kratom products.

24 4. Other rules as necessary for the implementation of this
25 chapter.

26 Sec. 7. NEW SECTION. **124F.7 Legislative intent.**

27 It is the intent of the general assembly that this chapter be
28 liberally construed to ensure the safety of kratom products and
29 prevent the distribution of kratom products to minors.

30 EXPLANATION

31 The inclusion of this explanation does not constitute agreement with
32 the explanation's substance by the members of the general assembly.

33 This bill relates to the regulation of kratom. The bill
34 requires a person responsible for placing a kratom product,
35 defined in the bill, into commerce in the state to annually

1 register that product for sale with the department of health and
2 human services (department). The bill requires an application
3 for registration to include a certification that the product is
4 manufactured, processed, and held in a facility that complies
5 with federal laws for good manufacturing practices, a current
6 federal food and drug administration food facility registration
7 certificate, a statement that the applicant has a reasonable
8 basis to believe that the kratom product is safe, a certificate
9 from an independent testing laboratory showing compliance with
10 the requirements of the bill, and an application fee. The bill
11 allows an application for registration to include multiple kratom
12 products if the kratom products contain the same ingredients
13 sold in the same form but in a different container, package, or
14 volume. The bill requires the department to create and maintain
15 a database of all kratom products that are registered for sale in
16 this state.

17 The bill prohibits a kratom product from containing certain
18 adulterants. The bill prohibits a kratom processor, registrant,
19 or retailer from selling a kratom product that is combustible,
20 vaporizable, attractive to children, as defined in the bill, or a
21 product containing kratom that is not a kratom product.

22 The bill requires a kratom product produced, manufactured,
23 distributed, offered, sold, or offered for sale in this state
24 to include a label that advises against use by individuals
25 who are under 21 years of age, who are pregnant, or who
26 are breastfeeding, recommends consultation with a health care
27 professional, states that kratom may be habit forming, states
28 that the efficacy of the product has not been evaluated by the
29 United States food and drug administration, includes the name and
30 address for the place of business of the registrant, and includes
31 directions for use.

32 The bill prohibits a person from selling or distributing a
33 kratom product that is not currently registered for sale in this
34 state. The bill requires the department to seize and destroy
35 an unregistered kratom product and to assess the costs to the

1 person responsible for the availability of the kratom product in
2 this state. The bill requires the department to impose a fee
3 for the first and second sale or distribution of a particular
4 unregistered kratom product and to prohibit a person from selling
5 or distributing kratom products for two years following the third
6 sale or distribution of an unregistered kratom product. The
7 bill prohibits a person from knowingly or willfully selling or
8 distributing a kratom product to a person under 21 years of age.
9 A person who violates this provision of the bill for the first
10 time is guilty of a simple misdemeanor. A simple misdemeanor
11 is punishable by confinement for no more than 30 days and a
12 fine of at least \$105 but not more than \$855. A person who
13 violates this provision of the bill a second or subsequent time
14 within one year of the first offense is guilty of a serious
15 misdemeanor. A serious misdemeanor is punishable by confinement
16 for no more than one year and a fine of at least \$430 but not
17 more than \$2,560. The bill prohibits a person from knowingly
18 or willfully manufacturing, delivering, holding, offering for
19 sale, distributing, or selling a kratom product that contains a
20 controlled substance. A person who violates this provision of
21 the bill is guilty of a class "D" felony. A class "D" felony
22 is punishable by confinement for no more than five years and a
23 fine of at least \$1,025 but not more than \$10,245. The bill
24 prohibits a person from knowingly or willfully manufacturing,
25 delivering, holding, offering for sale, distributing, or selling
26 a kratom product that contains synthetically derived compounds
27 of the plant *Mitragyna speciosa*. A person who violates this
28 provision of the bill is guilty of a serious misdemeanor.

29 If the department has reason to believe that a registered
30 kratom product violates the requirements for registration, the
31 bill requires the department to require the registrant to
32 produce a current certificate of analysis from an independent
33 testing laboratory showing compliance with the requirements for
34 registration under the bill. If the registrant does not timely
35 produce a certificate showing compliance, the bill requires the

1 department to revoke the registration of the kratom product
2 and immediately order the stoppage of all sales of the kratom
3 product. If the department has reason to believe that the
4 independent testing laboratory used by a registrant has not
5 provided accurate results, the bill requires the department to
6 submit the kratom product for testing to an independent testing
7 laboratory of the department's choice, with costs assessed to
8 the registrant. If the registrant fails to tender payment
9 within 30 calendar days of receipt of a request for payment
10 from the department, the bill requires the department to revoke
11 the registration of the kratom product and immediately order
12 the stoppage of all sales of the kratom product. The bill
13 exempts a retailer from punishment for a violation of the bill
14 if the retailer shows by a preponderance of the evidence that
15 the retailer relied in good faith upon the representations of
16 a manufacturer, packer, or kratom processor regarding a product
17 represented to be a kratom product.

18 The bill requires the department to adopt rules for the
19 implementation of the bill, including for the process of
20 registration of a kratom product, the requirements for enforcing
21 the prohibition on sale of kratom products to persons under 21
22 years of age, the testing requirements for independent testing
23 laboratories, and other rules as necessary for implementation of
24 the bill.

25 The bill includes legislative intent language.