

H-8202

1 Amend House File 2133 as follows:

2 1. By striking everything after the enacting clause and
3 inserting:

4 <Section 1. NEW SECTION. 124F.1 Definitions.

5 As used in this chapter, unless the context otherwise
6 requires:

7 1. "*Attractive to children*" means a quality of a product
8 manufactured that is either:

9 a. In a shape that resembles a human, a cartoon character,
10 or an animal.

11 b. In a form that resembles an existing candy product that
12 is a widely distributed, branded food item.

13 2. "*Department*" means the department of health and human
14 services.

15 3. "*Finished kratom product*" means a kratom product that is
16 ready for sale to the end user. For purposes of registration,
17 a finished kratom product is differentiated by its ingredients,
18 not by its weight, volume, or size.

19 4. "*Food establishment*" means any establishment providing
20 or serving food directly to consumers that is regulated by the
21 department of inspection, appeals, and licensing and local
22 public health agencies.

23 5. "*Kratom*" means the plant, or any part of the plant,
24 *Mitragyna speciosa*.

25 6. "*Kratom alkaloids*" means the sum of all alkaloids
26 naturally occurring in the kratom plant and any semi-synthetic
27 derivatives of those alkaloids present in a kratom product
28 including but not limited to mitragynine, speciogynine,
29 speciociliatine, payantheine, and 7-hydroxymitragynine, as
30 determined through validated analytical testing.

31 7. "*Kratom food establishment*" means any food establishment
32 that sells finished kratom products.

33 8. "*Kratom product*" means a food product, food ingredient,
34 dietary ingredient, dietary supplement, or beverage intended
35 for human consumption that contains any part of the leaf of the

1 kratom plant and is manufactured as a powder, capsule, pill, or
2 other consumable form.

3 9. "Processor" means an entity that does any of the
4 following:

5 a. Refines kratom into input ingredients for the purpose of
6 manufacturing a finished kratom product.

7 b. Manufactures finished kratom products.

8 c. Packages finished kratom products for resale.

9 d. Serves as a warehouse or distributor of kratom products.

10 Sec. 2. NEW SECTION. 124F.2 Product requirements.

11 Finished kratom products sold to consumers at a retail
12 establishment, a convenience store, or a kava or kratom bar in
13 this state:

14 1. Shall be in one of the following delivery forms:

15 a. Dried leaf.

16 b. Powder.

17 c. Pill.

18 d. Liquid.

19 e. Capsule.

20 2. Shall possess a certificate of analysis that has been
21 submitted to the department as required under this chapter.

22 3. Shall be registered with the department.

23 4. Shall include directions for consumption of the kratom
24 product on the product's label, including but not limited to
25 the following information:

26 a. A maximum dosage of one hundred milligrams of kratom
27 alkaloids per serving.

28 b. The number of servings per package.

29 c. The amount in milligrams of 7-hydroxymitragynine and
30 mitragynine per serving.

31 d. A warning advising consumers of the number of servings
32 that may be safely consumed in a twenty-four-hour period.

33 e. A warning prohibiting use by individuals who are under
34 twenty-one years of age.

35 f. A warning advising against use by individuals who are

1 pregnant or breast-feeding.

2 *g.* A warning advising the consumer to consult a health care
3 professional before use, that the product may be habit-forming,
4 and that the product may cause adverse health effects.

5 *h.* The following warning statement:

6 "These statements have not been evaluated by the Food and
7 Drug Administration. This product is not intended to diagnose,
8 treat, cure, or prevent any disease."

9 *i.* The expiration date, best if used by date, or date of
10 manufacture.

11 *j.* The name and place of business of the registrant.

12 5. Shall comply with the packaging and labeling
13 requirements set forth in this chapter and the rules adopted
14 thereunder.

15 6. Shall not be attractive to children.

16 7. Shall be in a container that meets all of the following
17 conditions:

18 *a.* Is suitable to contain products for human consumption.

19 *b.* Is compliant with the federal child-resistant packaging
20 standards contained in 16 C.F.R. §1700.15 and 1700.20.

21 *c.* Contains a graduated measuring device, if applicable.

22 8. Shall be sold only to persons who are twenty-one years of
23 age or older and with proper age verification.

24 9. Shall not be served in a form that combines or mixes
25 finished kratom products with kava.

26 10. A person shall not manufacture, distribute,
27 sell, or offer for sale a kratom product that contains
28 7-hydroxymitragynine in a concentration that exceeds
29 twenty-five milligrams per serving. For the purposes of this
30 section, the concentration of 7-hydroxymitragynine shall be
31 determined by validated laboratory analysis.

32 **Sec. 3. NEW SECTION. 124F.3 Manufacturing and distribution.**

33 1. Kratom products shall be manufactured or distributed
34 in this state only by a processor who is subject to and in
35 compliance with all state laws and regulations applicable to

1 food processors. Kratom products shall not be manufactured or
2 distributed by a cottage food producer under section 137F.20.

3 2. A processor shall comply with current practices
4 contained in 21 C.F.R. pts. 111 and 117.

5 3. A processor shall maintain product liability insurance
6 with a minimum occurrence limit of three million dollars.

7 4. For each batch of a registered finished kratom product,
8 the processor shall retain and submit, upon request, a
9 certificate of analysis to the department from a laboratory
10 accredited pursuant to international organization for
11 standardization/international electrotechnical commission
12 standard 17025 or other comparable accreditation standard
13 required by the department. The processor shall not have
14 any direct or indirect financial or economic interest in the
15 laboratory or accrediting body. The processor shall maintain
16 the certificates of analysis for a minimum of one year after
17 the finished kratom product's expiration date. The certificate
18 of analysis shall demonstrate that the finished kratom product
19 is in compliance with the concentration limits established by
20 statute or rule for the following:

21 a. Kratom alkaloids and kratom alkaloid metabolites.

22 b. Residual solvents.

23 c. Heavy metals including but not limited to cadmium,
24 arsenic, mercury, and lead.

25 d. Pesticides and any other substance limited by rule of the
26 department.

27 5. A finished kratom product served by a kratom food
28 establishment shall be registered with the department and
29 comply with the requirements of this chapter. A person shall
30 not serve kratom beverages combined with alcohol, drugs, or
31 other kratom products.

32 6. This chapter shall not apply to finished kratom products
33 processed or manufactured in this state and subsequently
34 shipped or transported out of this state for sale or use
35 outside of this state.

1 7. Finished kratom products produced in this state and
2 subsequently shipped or transported out of this state for sale
3 or use outside of this state:

4 a. Shall not be sold, shipped, or transported to a consumer
5 in this state, to a retail establishment in this state, or to a
6 person who sells or intends to sell such products to a consumer
7 in this state.

8 b. Shall be in a package with the following marking in a
9 bold font size of at least thirty-six points:

10 NOT FOR USE OR RETAIL SALE IN IOWA

11 c. Shall be physically separated from finished kratom
12 products that are, or are intended to be, sold or used in this
13 state.

14 Sec. 4. NEW SECTION. 124F.4 Adverse health events.

15 1. If a processor or the department receives notice of any
16 adverse health event suspected to be related to the processor's
17 kratom product, the processor or the department shall submit an
18 adverse event report, as set out in the Federal Food, Drug, and
19 Cosmetic Act, 21 U.S.C. §379aa-1(b)(1), to the United States
20 food and drug administration.

21 2. If probable cause exists that a kratom product may
22 be adulterated, the department may require an independent
23 third-party test of the kratom product by a laboratory of the
24 department's choice, and the processor shall pay the cost of
25 the test. If the processor does not make such payment to the
26 department within thirty days after receiving the invoice for
27 the testing fee, the department shall revoke the registration
28 for that product.

29 Sec. 5. NEW SECTION. 124F.5 Penalties.

30 1. A processor that manufactures, delivers, offers for
31 sale, distributes, or sells a finished kratom product that
32 violates section 124F.2 or 124F.3 shall be guilty of a serious
33 misdemeanor.

34 2. Kratom products possessed, manufactured, delivered,
35 offered for sale, distributed, or sold in violation of this

1 chapter by an entity regulated under this chapter may be
2 detained or embargoed and the entity in violation is subject to
3 all penalties and remedies that apply for a violation of this
4 chapter. The department shall not grant permission to remove
5 or use, except for disposal, detained or embargoed finished
6 kratom products that are attractive to children until the
7 finished kratom products comply with this chapter.

8 3. If a processor fails to provide the department with a
9 certificate of analysis within seven days after receiving a
10 request from the department or fails to immediately report an
11 adverse health event to the department as required by section
12 124F.4, the department may revoke the processor's finished
13 kratom product registration.

14 4. A processor that manufactures, delivers, offers for
15 sale, distributes, or sells a kratom product that contains
16 any controlled substance or adulterants commits a serious
17 misdemeanor and may be subject to criminal penalties under
18 chapter 124.

19 5. A laboratory that fails to ensure the accuracy of its
20 certificates of analysis issued under this chapter is subject
21 to an administrative fine in an amount determined by the
22 department by rule.

23 Sec. 6. NEW SECTION. 124F.6 Rules.

24 The department shall adopt rules pursuant to chapter 17A
25 necessary to administer this chapter.

26 Sec. 7. NEW SECTION. 124F.7 Citation.

27 This chapter shall be known as and may be cited as the "*Iowa*
28 *Kratom Consumer Protection Act*".>

29 2. Title page, by striking lines 1 and 2 and inserting <An
30 Act establishing the Iowa kratom consumer protection Act, and
31 providing penalties.>