

H-8168

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 service establishment*" means any establishment
20 providing or serving food directly to consumers that is
21 regulated by the department and local public health agencies.

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

24 6. "*Kratom food service establishment*" means any food
25 service establishment that sells finished kratom products.

26 7. "*Kratom product*" means a food product, food ingredient,
27 dietary ingredient, dietary supplement, or beverage intended
28 for human consumption that contains any part of the leaf of the
29 kratom plant and is manufactured as a powder, capsule, pill, or
30 other consumable form.

31 8. "*Processor*" means an entity that does any of the
32 following:

33 a. Refines kratom into input ingredients for the purpose of
34 manufacturing a finished kratom product.

35 b. Manufactures finished kratom products.

1 *c.* Packages finished kratom products for resale.

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

3 Finished kratom products sold to consumers at a retail
4 establishment, a convenience store, or a kava or kratom bar in
5 this state:

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

7 *a.* Dried leaf.

8 *b.* Powder.

9 *c.* Pill.

10 *d.* Liquid.

11 *e.* Capsule.

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

14 3. Shall be registered with the department.

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

18 *a.* A maximum dosage of one hundred milligrams of kratom
19 alkaloids per serving.

20 *b.* The number of servings per package.

21 *c.* The amount in milligrams of 7-hydroxymitragynine and
22 mitragynine per serving.

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

25 *e.* A warning prohibiting use by individuals who are under
26 twenty-one years of age.

27 *f.* A warning advising against use by individuals who are
28 pregnant or breast-feeding.

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

32 *h.* The following warning statement:

33 "These statements have not been evaluated by the United
34 States Food and Drug Administration. This product is not
35 intended to diagnose, treat, cure, or prevent any disease."

- 1 *i.* The expiration date.
- 2 *j.* The name and place of business of the registrant.
- 3 5. Shall comply with the packaging and labeling
4 requirements set forth in this chapter and the rules adopted
5 thereunder.
- 6 6. Shall not be attractive to children.
- 7 7. Shall be in a container that meets all of the following
8 conditions:
- 9 *a.* Is suitable to contain products for human consumption.
- 10 *b.* Is compliant with the federal Poison Prevention Packaging
11 Act of 1970, 15 U.S.C. §1471 et seq.
- 12 *c.* Contains a graduated measuring device, if applicable.
- 13 8. Shall not be adulterated including but not limited to by
14 containing metals, pesticides, or pathogens in excess of the
15 limits set by this chapter or department rule.
- 16 9. Shall be sold only in establishments that restrict entry
17 to persons who are twenty-one years of age or older and require
18 age verification.
- 19 10. Shall not be served in a form that combines or mixes
20 finished kratom products with psychoactive substances that
21 impact the central nervous system including but not limited to
22 alcohol, caffeine, kava, cannabinoids, and nicotine.
- 23 Sec. 3. NEW SECTION. **124F.3 Manufacturing and distribution.**
- 24 1. Kratom products shall be manufactured or distributed
25 in this state only by a processor who is subject to and in
26 compliance with all state laws and regulations applicable to
27 food processors. Kratom products shall not be manufactured or
28 distributed by a cottage food producer under section 137F.20.
- 29 2. A processor that manufactures, processes, packs, or
30 offers for sale kratom, kratom products, or finished kratom
31 products shall be properly registered with the United States
32 food and drug administration.
- 33 3. A processor shall comply with current good manufacturing
34 practices contained in 21 C.F.R. pt. 210.
- 35 4. A processor shall maintain product liability insurance

1 with a minimum occurrence limit of three million dollars.

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

16 a. Alkaloid and alkaloid metabolites.

17 b. Residual solvents.

18 c. Heavy metals including but not limited to cadmium,
19 arsenic, mercury, and lead.

20 d. Pesticides and any other substance limited by rule of the
21 department.

22 6. A finished kratom product served by a kratom food service
23 establishment shall be registered with the department and
24 comply with the requirements of this chapter. A person shall
25 not serve kratom beverages combined with alcohol, drugs, or
26 other kratom products.

27 7. This chapter shall not apply to finished kratom products
28 processed or manufactured in this state and subsequently
29 shipped or transported out of this state for sale or use
30 outside of this state.

31 8. Finished kratom products produced in this state and
32 subsequently shipped or transported out of this state for sale
33 or use outside of this state:

34 a. Shall not be sold, shipped, or transported to a consumer
35 in this state, to a retail establishment in this state, or to a

1 person who sells or intends to sell such products to a consumer
2 in this state.

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

5 NOT FOR USE OR RETAIL SALE IN IOWA

6 *c.* Shall be physically separated from finished kratom
7 products that are, or are intended to be, sold or used in this
8 state.

9 **Sec. 4. NEW SECTION. 124F.4 Adverse health events.**

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

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

24 **Sec. 5. NEW SECTION. 124F.5 Penalties.**

25 1. A processor that manufactures, delivers, offers for
26 sale, distributes, or sells a finished kratom product that
27 violates section 124F.2 or 124F.3 shall be guilty of a serious
28 misdemeanor.

29 2. Kratom products possessed, manufactured, delivered,
30 offered for sale, distributed, or sold in violation of this
31 chapter by an entity regulated under this chapter may be
32 detained or embargoed and the entity in violation is subject to
33 all penalties and remedies that apply for a violation of this
34 chapter. The department shall not grant permission to remove
35 or use, except for disposal, detained or embargoed finished

1 kratom products that are attractive to children until the
2 finished kratom products comply with this chapter.

3 3. If a processor fails to provide the department with a
4 certificate of analysis within seven days after receiving a
5 request from the department or fails to immediately report an
6 adverse health event to the department as required by section
7 124F.4, the department may revoke the processor's finished
8 kratom product registration.

9 4. A processor that manufactures, delivers, offers for
10 sale, distributes, or sells a kratom product that contains
11 any controlled substance or adulterants commits a serious
12 misdemeanor and may be subject to criminal penalties under
13 chapter 124.

14 5. A laboratory that fails to ensure the accuracy of its
15 certificates of analysis issued under this chapter is subject
16 to an administrative fine in an amount determined by the
17 department by rule.

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

19 The department shall adopt rules pursuant to chapter 17A
20 necessary to administer this chapter.

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

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

24 2. Title page, by striking lines 1 and 2 and inserting <An
25 Act establishing the Iowa kratom consumer protection Act, and
26 providing penalties.>

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