

HOUSE BILL NO. 4061

February 01, 2023, Introduced by Reps. Stone, Aiyash, Haadsma, Rheingans, MacDonell, Hood, Brabec, Tyrone Carter, Rogers, Weiss, Glanville, Tsernoglou, Dievendorf, Young, Byrnes, Conlin, Breen, McKinney and Andrews and referred to the Committee on Regulatory Reform.

A bill to regulate the distribution, sale, and manufacturing of kratom products; to require licensing for certain conduct related to kratom and kratom products; to prohibit the distribution, sale, and manufacturing of certain kratom products; to provide for the powers and duties of certain state governmental officers and entities; to prescribe fines and sanctions; to provide remedies; and to require the promulgation of rules.

THE PEOPLE OF THE STATE OF MICHIGAN ENACT:

1 Sec. 1. This act may be cited as the "kratom consumer

1 protection and regulatory act".

2 Sec. 3. As used in this act:

3 (a) "Certificate of licensure" means a document issued as
4 evidence of authorization to distribute, sell, or manufacture a
5 kratom product.

6 (b) "Department" means the department of licensing and
7 regulatory affairs.

8 (c) "Director" means the director of the department or his or
9 her designee.

10 (d) "Food" means that term as defined in section 1107 of the
11 food law, 2000 PA 92, MCL 289.1107.

12 (e) "Kratom product" means a food that contains any part of
13 the leaf of the plant *Mitragyna speciosa*.

14 (f) "License" means an authorization granted by the department
15 under this act to distribute, sell, or manufacture a kratom
16 product.

17 (g) "Licensee" means a person that holds a license.

18 (h) "Rule" means a rule promulgated under the administrative
19 procedures act of 1969, 1969 PA 306, MCL 24.201 to 24.328.

20 Sec. 5. (1) Beginning January 1, 2024, a person shall not do
21 any of the following unless the person holds a license:

22 (a) Distribute a kratom product in this state.

23 (b) Sell a kratom product in this state.

24 (c) Manufacture a kratom product in this state.

25 (2) A person shall obtain a license for each location in which
26 the person distributes, sells, or manufacturers a kratom product in
27 this state. A person shall obtain a license if the person
28 distributes, sells, or offers to distribute or sell a kratom
29 product through an online website to a person in this state.

1 (3) A person applying for a license under this section shall
2 do so on a form and in a manner prescribed by the department. An
3 application must include all of the following information:

4 (a) The applicant's full name, date of birth, telephone
5 number, and address. If the applicant is not an individual, the
6 application must include the EIN number of the applicant.

7 (b) The address of each business or location where a kratom
8 product will be distributed, sold, or manufactured or offered for
9 distribution or sale.

10 (c) A list of the kratom products that will be distributed,
11 sold, or manufactured or offered for distribution or sale at each
12 business or location described under subdivision (b).

13 (d) A copy of the certificate of analysis received under
14 section 13.

15 (e) A statement that the information supplied by the applicant
16 is, to the best of the applicant's knowledge, true and is signed
17 under penalty of perjury.

18 (4) The department shall grant an applicant a license under
19 this section if the applicant does all of the following:

20 (a) Submits a completed application under subsection (3).

21 (b) Submits an application fee of \$200.00.

22 (c) Meets the qualifications for a license specified under
23 this act.

24 (5) The department shall approve or deny an application for a
25 license not later than 30 business days after a completed
26 application is received. The department shall deny an application
27 for a license if the application is incomplete.

28 (6) If the department denies an application for a license
29 because it is incomplete, the department shall notify the applicant

1 in writing of the denial not later than 30 business days after the
2 application is received, state the deficiency, and request
3 additional information.

4 (7) A license is not transferable and is valid for 3 years.

5 (8) To renew a license, an applicant must do both of the
6 following:

7 (a) Submit a completed application under subsection (3).

8 (b) Submit a renewal fee of \$125.00.

9 (9) A licensee shall prominently display the certificate of
10 licensure at each business or location where kratom products are
11 distributed, sold, or manufactured or offered for distribution or
12 sale.

13 Sec. 7. A kratom product must be labeled, and the product
14 label must contain the following information:

15 (a) Both of the following statements:

16 (i) "*Mitragyna speciosa* is an unapproved dietary ingredient.
17 Ingesting *Mitragyna speciosa* may be dangerous. Consult your
18 physician about whether this product is for you, how to use this
19 product safely, potential interactions, precautionary measures
20 before considering this product, and potential dependency,
21 seizures, and other possible complications. Inform your physician
22 of the alkaloid content labeled on this package.".

23 (ii) "Keep out of reach of children. DO NOT USE IF YOU ARE
24 PREGNANT, PLAN TO BECOME PREGNANT, OR WHILE BREASTFEEDING. NOT FOR
25 SALE TO MINORS.".

26 (b) The alkaloid content in the kratom product.

27 (c) The amount of mitragynine and 7-hydroxymitragynine
28 contained in the kratom product.

29 Sec. 9. A person shall not in person or through an online

1 website distribute, sell, manufacture or offer for distribution or
2 sale any of the following:

3 (a) A kratom product that is adulterated with a dangerous
4 nonkratom substance. A kratom product is adulterated with a
5 dangerous nonkratom substance if the kratom product is mixed or
6 packed with a nonkratom substance and that substance affects the
7 quality or strength of the kratom product to such a degree as to
8 render the kratom product injurious to a consumer.

9 (b) A kratom product that is contaminated with a dangerous
10 nonkratom substance. A kratom product is contaminated with a
11 dangerous nonkratom substance if the kratom product contains a
12 poisonous or otherwise deleterious nonkratom ingredient, including,
13 but not limited to, any of the substances listed in section 7212 of
14 the public health code, 1978 PA 368, MCL 333.7212.

15 (c) A kratom product that contains a level of 7-
16 hydroxymitragynine in the alkaloid fraction that is greater than 2%
17 of the alkaloid composition of the product.

18 (d) A kratom product that contains a synthetic alkaloid,
19 including, but not limited to, any of the following:

20 (i) Synthetic mitragynine.

21 (ii) Synthetic 7-hydroxymitragynine.

22 (iii) Any other synthetically derived compound of the plant
23 *Mitragyna speciosa*.

24 (e) A kratom product that does not include on its package or
25 label the amount of mitragynine and 7-hydroxymitragynine contained
26 in the kratom product.

27 Sec. 11. (1) A licensee shall not in person or through an
28 online website distribute, sell, or offer for distribution or sale
29 a kratom product to an individual in this state who is under 21

1 years of age.

2 (2) A person shall not purchase a kratom product over the
3 internet in this state if the kratom product does not comply with
4 section 9.

5 Sec. 13. (1) Before applying for a license under section 5, a
6 person that wishes to distribute, sell, or manufacture or offer for
7 distribution or sale a kratom product shall have a sample of the
8 raw materials used to produce each kratom product tested by a
9 qualified laboratory to certify that the kratom product does not
10 contain any substance in violation of section 9.

11 (2) If raw materials tested under subsection (1) do not
12 contain a substance in violation of section 9, the qualified
13 laboratory shall provide the person with a certificate of analysis
14 that states that the raw materials meet the requirements prescribed
15 under this act.

16 (3) A person shall provide a copy of the certificate of
17 analysis described under subsection (2) to the department with an
18 application for a license under section 5 or upon request. The
19 department may request that a person have a sample of raw materials
20 retested by a qualified laboratory under subsection (1) and provide
21 an updated certificate of analysis. If the department requests that
22 a person have a sample of raw materials retested under this
23 subsection, the person is responsible for the costs of the testing.

24 (4) As used in this section, "qualified laboratory" means a
25 laboratory approved by the department by rule.

26 Sec. 15. (1) After notice and an opportunity for a hearing
27 under the administrative procedures act of 1969, 1969 PA 306, MCL
28 24.201 to 24.328, a licensee may be subject to the following:

29 (a) For a violation of section 7, 9, or 11, an administrative

1 fine of not more than \$500.00 for the first offense and not more
2 than \$1,000.00 for a second or subsequent offense.

3 (b) In addition to an administrative fine under subsection (a)
4 or for any other violation of this act or a rule promulgated under
5 this act, a denial, limitation, suspension, or revocation of a
6 license.

7 (2) A person that violates section 5(1) may be ordered to pay
8 a civil fine of not more than \$500.00 for the first offense and not
9 more than \$1,000.00 for a second or subsequent offense.

10 (3) In addition to any other action authorized by this act,
11 the director may bring an action to do 1 or more of the following:

12 (a) Obtain a declaratory judgment that a method, act, or
13 practice is in violation of this act.

14 (b) Obtain an injunction against a person that is engaging, or
15 about to engage, in a method, act, or practice that violates this
16 act.

17 Sec. 17. By January 1, 2024, the department shall promulgate
18 rules pursuant to the administrative procedures act of 1969, 1969
19 PA 306, MCL 24.201 to 24.328, to implement this act.