

Legislative Analysis



KRATOM CONSUMER PROTECTION AND REGULATORY ACT

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House Bill 5477 (proposed substitute H-2)

Sponsor: Rep. Lori M. Stone

Committee: Regulatory Reform

Complete to 4-13-22

Analysis available at
<http://www.legislature.mi.gov>

SUMMARY:

House Bill 5477 would create the Kratom Consumer Protection and Regulatory Act to prohibit, beginning January 1, 2023, a person from distributing, selling, or manufacturing a **kratom product** in Michigan unless licensed to do so. Among other things, the bill also would do all of the following:

- Prohibit the sale of kratom products to individuals under 21 years of age.
- Require an applicant for licensure or license renewal to provide certain information to the Department of Licensing and Regulatory Affairs (LARA), along with an applicable application or renewal fee.
- Establish administrative sanctions and remedies for a licensee who violates the act.
- Require testing of raw materials used in the manufacture of kratom products to be sold or distributed in Michigan.
- Establish labeling requirements for kratom products, including certain health and safety warnings.
- Prohibit the sale or distribution of kratom products that contain certain substances or do not comply with certain labeling requirements.
- Allow LARA to seek declaratory relief or an injunction, or both, against a person who engages in conduct that violates the act.
- Require LARA to promulgate rules to implement the act.

Licensure

Under the bill, beginning January 1, 2023, a person could not distribute, sell, or manufacture a **kratom product** in Michigan unless licensed to do so.

Kratom product would mean a food that contains any part of the leaf of the plant *Mitragyna speciosa*.

A person would have to obtain a license for each location in which the person distributes, sells, or manufactures a kratom product in Michigan. A person also would have to obtain a license to distribute, sell, or offer to distribute or sell a kratom product online. The licensee would have to prominently display the certificate of licensure at each business or location where kratom products are distributed, sold, or manufactured or offered for distribution or sale. As described below, before applying for a license, a potential applicant would be required to have a sample of the raw materials used in the production of the products the applicant intends to manufacture, distribute, or sell tested by a laboratory.

An application would have to be on a form and in a manner prescribed by LARA and would have to include the following information:

- The applicant's full name, date of birth, telephone number, and address. If the applicant is not an individual, the EIN number of the applicant would have to be included.
- The address of each business or location where a kratom product would be distributed, sold, or manufactured or offered for distribution or sale.
- A list of the kratom products that would be distributed, sold, or manufactured or offered for distribution or sale.
- A copy of the certificate of analysis (described below).
- A statement that the information supplied is true to the best of the applicant's knowledge and that the application is signed under the penalty of perjury.

LARA would have to grant a license to an applicant that does all of the following:

- Submits a completed application.
- Submits an application fee of \$200.
- Meets the qualifications for a license under the bill.

(Note that the bill provides that each location where kratom products are manufactured, distributed, or sold must have a license, and that the license must be displayed at each location, but does not specify whether multiple licenses would be issued for a single fee or a separate fee would be required for each location.)

An application would have to be approved or denied no later than 30 business days after LARA receives a completed application. An incomplete application would have to be denied. If an application were denied, LARA would have to notify the applicant in writing not later than 30 business days after the application was received, state the deficiency in the application, and request additional information.

A license would be valid for three years and would not be transferable. To renew a license, a licensee would have to submit a completed application (as described above) and submit a renewal fee of \$125.

Product testing

Before applying for a license, a person that wishes to distribute, sell, manufacture, or offering to distribute or sell a kratom product would have to have a sample of the raw materials used to produce each kratom product tested by a **qualified laboratory** (a laboratory approved by LARA by rule) to certify that the product does not contain any of the prohibited substances described below (under "Prohibitions").

If the raw materials did not contain a prohibited substance, the qualified laboratory would have to provide the person with a certificate of analysis stating that the raw materials meet the bill's requirements. The person would have to provide a copy of the analysis to LARA with the license application and upon request. In addition, LARA could request a person have a sample of raw materials retested by a qualified laboratory and provide an updated certificate of analysis. The person would be responsible for the costs of the testing.

Labeling

A kratom product would have to be labeled with the following information:

- A statement, as specified in the bill, that *Mitragyna speciosa* is an unapproved dietary ingredient and that ingesting it may be dangerous, that a person should consult their physician as to its suitability, use, safety, and possible complications, among other things, and inform the physician of the product's alkaloid content as listed on the label.
- A statement, as specified in the bill, warning to keep the product out of reach of children and to avoid using it if pregnant, planning to become pregnant, or while breastfeeding, as well as a statement that the product is not for sale to minors.
- The product's alkaloid content.
- The amount of mitragynine and 7-hydroxymitragynine in the product.

Prohibitions

A licensee, whether in person or through an online website, could not distribute, sell, or offer for distribution or sale a kratom product to an individual under 21 years of age.

A person, whether in person or through an online website, could not sell, distribute, manufacture, or offer for distribution or sale any of the following:

- A kratom product adulterated with a dangerous non-kratom substance. (This would be a kratom product that is mixed or packed with a substance affecting the quality or strength of the kratom product to such a degree as to render it injurious to a consumer.)
- A kratom product contaminated with a dangerous non-kratom substance. (This would be a kratom product that contains a poisonous or otherwise deleterious non-kratom ingredient, including, but not limited to, any Schedule 1 substances.)
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the alkaloid composition of the product.
- A kratom product that contains a synthetic alkaloid, including, but not limited to, synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the plant *Mitragyna speciosa*.
- A kratom product that does not include on its package or label the amount of mitragynine and 7-hydroxymitragynine contained in the kratom product.

In addition, a person could not purchase a kratom product over the internet in Michigan if the product did not comply with the above.

Sanctions

After notice and an opportunity for an administrative hearing, a licensee violating section 7 (labeling requirements), section 9 (prohibited kratom products) or section 11 (distribution or sale of kratom product to minor or internet purchase of prohibited kratom products) could be subject to an administrative fine of up to \$500 for a first offense and up to \$1,000 for a second or subsequent offense. In addition to the administrative fine, or for any other violation of the act or a departmental rule, the licensee could be subject to license denial, limitation, suspension, or revocation.

(Note that the bill does not specify a penalty for a person who is not a licensee but who violates the prohibition against purchasing a product prohibited under section 9.)

In addition to any other action authorized by the bill, the director of LARA could bring an action to do either or both of the following:

- Obtain a declaratory judgment that a method, act, or practice is in violation of the bill.
- Obtain an injunction against a person who is engaging, or about to engage, in a method, act, or practice that violates the bill.

Rules

By January 1, 2023, LARA would have to promulgate rules to implement the act.

FISCAL IMPACT:

House Bill 5477 would have an indeterminate fiscal impact on LARA. The department would experience cost increases resulting from new responsibilities related to kratom licensure; these responsibilities would include intaking and processing licensure applications and enforcement activity. The magnitude of the costs would depend on the volume of licenses and the degree to which existing department personnel and infrastructure could accommodate the new regulatory activity. The bill would establish application and renewal fees. It is unclear whether this fee revenue would be sufficient to offset LARA's regulatory costs. The bill would establish administrative fines of up to \$500 for a first offense and up to \$1,000 for a second or subsequent offense, though the bill is silent as to where these revenues would be deposited or how they could be used (presumably any revenue would be deposited to the state's general fund).

In addition, under provisions of the bill that authorize the director to bring an action to either obtain a declaratory judgment or an injunction against a practice or person found to be in violation, there could be a fiscal impact on local court units. The fiscal impact would be directly related to how provisions of the bill affected court caseloads and related administrative costs.

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■ This analysis was prepared by nonpartisan House Fiscal Agency staff for use by House members in their deliberations and does not constitute an official statement of legislative intent.