

KRATOM CONSUMER PROTECTION AND REGULATORY ACT

Phone: (517) 373-8080
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House Bill 5477 (H-2) as reported from committee
Sponsor: Rep. Lori M. Stone
1st Committee: Regulatory Reform
2nd Committee: Rules and Competiveness
Complete to 5-18-22

BRIEF 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. The bill would also 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.

FISCAL IMPACT: The bill could have an indeterminate fiscal impact on LARA and the judiciary. (See **Fiscal Information**, below, for a detailed discussion.)

THE APPARENT PROBLEM:

According to committee testimony, kratom, derived from the leaves of an evergreen grown in tropical Southeast Asia, has been used safely for centuries. Use of kratom in the United States has grown into a billion-dollar industry with an estimated consumer base of 12 to 15 million people. At low doses, kratom acts as stimulant, with some comparing the energy boost to that of coffee. It also is promoted as relieving pain and anxiety. At higher doses, many believe it can help break an opioid addiction with less severe withdrawal symptoms.

In recent years, kratom has become a substance of concern nationally and globally, primarily due to deaths associated with salmonella contamination and health risks associated with products being adulterated with opioids such as fentanyl, morphine, and heroin or contaminated by heavy metals, bacteria, fungus, or mold. Higher doses can also

result in negative health impacts such as seizures, liver and kidney damage, aggression, and delusions, among others. Currently, kratom is not regulated by the Food and Drug Administration (FDA) or the Drug Enforcement Administration (DEA), although it remains a drug of concern for both and the FDA is actively monitoring available information on the substance to see if evidence meets criteria to schedule it as a controlled substance. A handful of states prohibit sales of kratom, and several others have adopted some form of regulation. Globally, kratom is banned in several European countries, Japan, and Russia. In December 2021, the World Health Organization (WHO) concluded there is insufficient evidence to recommend a critical review of kratom, but still lists kratom as a substance under surveillance.

It has been suggested that Michigan adopt certain regulations to improve the safety of kratom products for Michigan consumers who feel they are receiving a benefit from its properties, until such time as evidence does support regulation by the FDA or international regulation by WHO.

THE CONTENT OF THE BILL:

House Bill 5477 would create the Kratom Consumer Protection and Regulatory Act. 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*.

Licensure

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 requires 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 it does not indicate 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 that violates 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.

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.

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

Rules

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

FISCAL INFORMATION:

House Bill 5477 would have an indeterminate net fiscal impact on LARA, though the bill would necessitate additional expenditures and authorize new revenues. The department would experience cost increases resulting from new responsibilities related to kratom licensure; these responsibilities would include intaking and processing licensure applications, enforcement activities, and rules promulgation. 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 a license application fee of \$200 and a triennial renewal fee of \$125. 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 this revenue and licensure revenue would be deposited or how it 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.

ARGUMENTS:

For:

Kratom is marketed by the health and wellness industry as an herbal substance that can promote energy, reduce anxiety, and provide other health benefits. For those in the throes of a substance use addiction, kratom is promoted as a holistic aid in the recovery of an opiate addiction. Used responsibly, many report positive benefits, especially with reducing chronic pain and anxiety, as well as enabling some to break the cycle of opiate addiction. However, used improperly, kratom can have negative health impacts. For instance, if taken during pregnancy, the baby may need treatment for withdrawal symptoms. There also have been deaths associated with kratom use, primarily due to some products being contaminated with salmonella, but others because the kratom product had been adulterated with opiates such as fentanyl.

Because kratom currently falls in the category of an herbal supplement, there is no federal regulation or quality control measures for its production. In addition, many kratom products fail to include the most basic guidelines as to use such as appropriate dosage, how

much kratom and which type (different types can have different effects) is contained in a capsule or a teaspoon of a powder, contraindications as to drug interactions, or warnings that the product should not be used by children or during pregnancy or when breastfeeding. In addition, there is a lot of misinformation about kratom on the internet, leading some to believe that since it is natural, it is totally safe for all users of any age.

Although the FDA and DEA are continuing to monitor kratom, currently, neither agency has been able to scientifically support a ban on kratom or making kratom a scheduled drug under the federal Controlled Substance Act. However, in light of potential adverse effects if used improperly or if products are adulterated with opiates or other dangerous substances, many feel that it is important for states to enact standards to protect consumers.

Under House Bill 5477, sales to minors would be prohibited; certain warnings would be required to be listed on the package; and products manufactured, sold, or distributed in the state would have to undergo testing to ensure that no contaminated or adulterated products were on store shelves. Businesses that do not comply with the bill's requirements could be subject to administrative fines and license sanctions, including license revocation. Supporters argue that the bill should help screen out bad actors who market potentially hazardous products or market products irresponsibly.

Against:

According to committee testimony, the legislation is intended to create accountability for production and distribution of products containing kratom, limit tainted products from being sold to consumers, establish labeling requirements, and restrict use of kratom products to adults. However, as the bill is currently written, it may be difficult to implement, and its goals may be difficult to achieve, for reasons described below.

Analysis of raw materials prior to licensure

Under the bill, an initial (and presumably renewal) application would have to list all the products to be distributed, sold, or manufactured at each of an applicant's business locations in the state and include a certificate of analysis of the raw materials used to produce each of those products prepared by a qualified laboratory. However, it is not clear how a distributor or a retail business would access the raw materials of each product, as they would have only the finished product already packaged for distribution and sale. Further, only manufacturers located in Michigan, who would have access to the raw materials, would be licensed and subject to the required testing.

The testing of each product would be required only prior to initial and renewal licensing, which would mean once every three years. There is no requirement for a licensee to provide testing of a new product chosen for manufacture, distribution, or sale until the next renewal cycle. In addition, a different batch manufactured in a different month or year, or stored improperly by a distributor or retailer, could contain harmful or prohibited adulterants or contaminants.

Labeling requirements

Although committee testimony discussed the lack of dosage recommendations, and such contraindications as potential interactions with other medicinal or herbal products, the bill would not require such information to be included on the label.

Penalties for violations

The bill's administrative fines (\$500 for a first violation, \$1,000 for each subsequent violation) would apply only to licensees. An unlicensed business, even if it violated multiple provisions, would appear to be subject only to an injunction. It is unclear, then, whether the bill offers sufficient incentive to comply with its provisions.

Online purchases

The bill would prohibit a person from buying a kratom product online if it is adulterated or contaminated or contains specifically prohibited ingredients. However, it is unclear how a consumer would know that the product contained a harmful or prohibited ingredient. It is also unclear how state regulators would know that a resident had bought a prohibited product. In addition, other than receiving a cease and desist order, there is no penalty in the bill for a person who violates this prohibition.

POSITIONS:

A representative of the American Kratom Association testified in support of the bill.
(4-13-22)

Representatives of the following entities indicated support for the bill:

- Michigan Nurses Association (4-13-22)
- Wild Bill's Tobacco (2-22-22)
- MyCare Health Center (4-13-22)
- The Prevention Network (4-13-22)

Legislative Analyst: Susan Stutzky
Fiscal Analysts: Marcus Coffin
Robin Risko

■ 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.