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Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Fraizer and Lipps

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SUMMARY

- Requires the Director of Agriculture to create a program to monitor and regulate kratom processing (converting kratom into a kratom product) and the sale of kratom products.
- Requires the Director to adopt rules, in consultation with the Governor and the Attorney General, establishing standards and procedures for the regulation of kratom processing under the kratom processing program.
- Requires a person who intends to process kratom into a kratom product to obtain a kratom processing license from the Director.
- Establishes prohibitions, procedures (including corrective action plan requirements), and criminal penalties to enforce the program.
- Authorizes the Director, at reasonable times, to enter into any public or private property where kratom is being processed, distributed, or sold to determine program compliance.
- Authorizes the Director, when the Director determines that certain emergency conditions exist, to issue an order requiring those conditions to be mitigated.
- Establishes the Kratom Program Fund in the state treasury for the Department of Agriculture to use to administer and enforce the program.
- Prohibits the State Board of Pharmacy from adopting any rules to include kratom or a kratom product in a schedule as a controlled substance.
- Specifies that kratom and kratom products are not drugs for purposes of the laws governing regulated pharmaceuticals and criminal drug offenses.

DETAILED ANALYSIS

Kratom

Kratom is a plant that grows naturally in Thailand, Malaysia, Indonesia, and Papua New Guinea. According to the National Institutes of Health:

Traditionally, in Southeast Asia, people have chewed its leaves or made them into a tea that's used to fight fatigue and improve work productivity. Kratom has also traditionally been used during religious ceremonies and to treat medical conditions such as pain and diarrhea, sometimes as a substitute for opium.

Two compounds in kratom leaves, mitragynine and 7-hydroxymitragynine, interact with opioid receptors in the brain, producing sedation, pleasure, and decreased pain when taken in high doses. Lower doses cause alertness instead of sedation.

Some people in Western countries use kratom to try to treat pain or manage opioid withdrawal symptoms.¹

Kratom is not currently regulated at the federal level under the Controlled Substances Act and the federal Food and Drug Administration has not approved kratom for any medical use. The federal Drug Enforcement Agency (DEA) has listed kratom as a Drug and Chemical of Concern, meaning DEA finds that kratom may pose certain health risks to individuals who abuse it.²

Regulation of kratom

The bill requires the Department of Agriculture to create a program to monitor and regulate kratom processing (converting kratom into a kratom product) and the sale of kratom products.³ At the same time, it prohibits the State of Ohio Board of Pharmacy from regulating kratom as a controlled substance and specifies that kratom and kratom products are not drugs for purposes of the pharmaceuticals law and criminal drug offenses.⁴ The regulatory scheme established by the bill is very similar to the hemp cultivation and processing program established under S.B. 57 of the 133rd General Assembly.⁵

¹ Kratom, National Institutes of Health: National Center for Complementary and Integrative Health (November 2018), last visited March 29, 2021, *available at*: <https://www.nccih.nih.gov/health/kratom>.

² Kratom Drug Fact Sheet, Drug Enforcement Agency (April 2020) *available at*: https://www.dea.gov/sites/default/files/2020-06/Kratom-2020_0.pdf.

³ R.C. 930.02(A).

⁴ R.C. 4729.01(E) and 3719.41(D). See also R.C. 2925.01, not in the bill.

⁵ See R.C. Chapter 928, not in the bill.

Under the bill, kratom is the plant *mitragyna speciosa* and any part of that plant, including the seeds thereof and all derivatives and extracts. A kratom product is a product made with kratom and may include dietary supplements or food intended for human consumption.⁶

Licensing

For purposes of the program, the Director of Agriculture must issue kratom processing licenses to eligible applicants. A person seeking to process kratom into a kratom product must apply for and obtain a kratom processing license. However, no license is required to possess, buy, or sell kratom or kratom products, provided the kratom or kratom products do not violate certain prohibitions (see below). Once issued, a kratom processing license is valid for three years, unless the Director suspends or revokes it.⁷

Rules

The bill requires the Director to adopt rules, in consultation with the Governor and the Attorney General, establishing standards and procedures for the regulation of kratom processing. The Director must include in those rules all of the following:

- The form of an application for a kratom processing license and the information required to be included in each license application;
- The initial application fee an applicant must submit and the amount of an annual fee that a licensee must submit, provided:
 - The Director must establish the fees at a rate that does not exceed an amount sufficient to cover costs the Department incurs to administer and enforce the program; and
 - The rate for the application fee and annual license fee must be uniform for all applicants for a kratom processing license.
- Requirements and procedures regarding standards of financial responsibility for each applicant for a kratom processing license;
- Procedures and requirements for license issuance, renewal, denial, suspension, and revocation, including providing for an administrative hearing with regard to a license denial, suspension, or revocation;
- Grounds for the denial, suspension, and revocation of a license;
- A requirement that any person who materially falsifies information in an application for a kratom processing license is ineligible to receive the license;

⁶ R.C. 930.01.

⁷ R.C. 930.02.

- A procedure for testing kratom products for purposes of determining compliance with the program;
- Requirements and procedures for the issuance, administration, and enforcement of corrective action plans (see “**Negligence: corrective action plan,**” below);
- A procedure for conducting annual inspections of, at a minimum, a random sample of kratom processing license holders to verify that kratom plants are not being processed in violation of program requirements;
- A procedure for effective disposal of all products derived from kratom plants processed in violation of program requirements;
- Annual reporting requirements and procedures for kratom processing license holders;
- Recordkeeping and documentation maintenance requirements and procedures for license holders;
- Fees for the laboratory testing of plants and products;
- Standards for the labeling of kratom products that require a label to include, at a minimum, specific directions necessary for the safe and effective use of a kratom product by consumers and a recommended serving size;
- Procedures and requirements for the transportation and distribution of kratom products; and
- Any other requirements or procedures the Director determines necessary to administer and enforce the program.⁸

Enforcement

Generally, violations of requirements of the kratom processing program that involve criminal negligence must be addressed through a corrective action plan, and violations that involve a culpable mental state of recklessness (or greater) must be referred for criminal prosecution. Under Ohio law, a culpable mental state is the degree of culpability necessary to commit a criminal offense. In descending order, the various degrees of culpability are:

- Purposely (specific intent to cause a certain result);
- Knowingly (with knowledge that a certain result probably will occur);
- Recklessly (heedless indifference to consequences that a known risk may cause a certain result); and
- Negligently (a substantial lapse in due care that an act may cause a certain result).

⁸ R.C. 930.03.

Each mental state includes the levels of mental states listed after it. For example, if a criminal offense requires a person to have acted recklessly, then a person acting knowingly or purposely would be guilty of that offense.⁹

Prohibitions

The bill prohibits all of the following activities:

- Processing kratom without a kratom processing license;
- Holding a license and violating any provision of the kratom processing program or rules;
- Transporting kratom in violation of the program or rules;
- Failing to comply with a corrective action plan issued by the Director.¹⁰

The bill further prohibits distributing, selling, or exposing for sale any of the following:

- A kratom product that is adulterated with a dangerous nonkratom substance. A kratom product is adulterated if it is mixed or packed with a nonkratom substance and that substance makes the kratom product injurious to a consumer;
- A kratom product that is contaminated with a dangerous nonkratom substance. A kratom product is contaminated with a dangerous nonkratom substance if it contains a poisonous or otherwise deleterious nonkratom ingredient, like a drug or a controlled substance (this could include an illegal drug, such as cocaine, or a prescription or over-the-counter drug);
- A kratom product containing a level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2% of the overall alkaloid composition of the kratom product;
- A kratom product containing any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant;
- A kratom product that is not labeled in accordance with the requirements of the program; and
- A kratom product with a label containing claims that the kratom product is intended to diagnose, treat, cure, or prevent any medical condition or disease.¹¹

Negligence: corrective action plan

The bill requires the Director to issue a corrective action plan to any person whom the Director determines has negligently violated the bill's prohibitions. The corrective action plan must include both:

⁹ R.C. 2901.22, not in the bill.

¹⁰ R.C. 930.04(B) to (E).

¹¹ R.C. 930.04(F).

- A reasonable date by which the person must correct the violation; and
- A requirement that the person report to the Director regarding the person's compliance with the program, rules, and the corrective action plan for two calendar years immediately following the date of the violation.

If the Director determines that a person negligently violated any of the prohibitions three or more times in any five-year period, the Director must revoke the person's kratom processing license (if any). And, the Director may not issue a license to that person for a five-year period beginning on the date that the Director determines that the person committed the most recent violation.¹²

Recklessness: criminal penalties and prosecution

The bill requires the Director to report a person whom the Director determines has violated the prohibitions – with a culpable mental state of recklessness (or greater) – to the Attorney General and applicable county prosecutor (either of which may prosecute the offense).

The following criminal penalties apply to a violation of any of the prohibitions:

- For a first offense, a minor misdemeanor;
- For each subsequent offense, a fourth degree misdemeanor.

The bill requires the sentencing court to issue an order that prohibits a repeat offender (a person who has been convicted of or who has pleaded guilty to a third or subsequent offense) from obtaining a kratom processing license. The court must provide notice of that order to the Director. The Director must then revoke any license the person holds and refuse to issue the person a license beginning on the date of the court order.¹³

Additional enforcement mechanisms for compliance

The bill authorizes the Director, at reasonable times, to enter into any public or private property where kratom is being processed, distributed, or sold to determine program compliance. The Director may apply for, and any appropriate judge may issue, a search warrant if needed.

The bill also authorizes the Director to issue an emergency order requiring specific actions be taken to mitigate an emergency condition requiring immediate action to protect public health, safety, or the environment. The emergency order may be issued without prior notice or a hearing. Any person to whom the order is issued must immediately comply, but the person may apply to the Director for an adjudication hearing. The Director must hold the hearing as soon as practicable and no later than 30 days after the application is received. On the basis of the hearing, the Director must continue, revoke, or modify the order. Under the bill, the

¹² R.C. 930.05(A) and (B).

¹³ R.C. 930.05(C) and 930.99.

Director, the Attorney General, and a county prosecutor may apply to the court of common pleas in the county where a violation (including a violation of an emergency order) is happening for an injunction to restrain the person from continuing that violation.¹⁴

Kratom Program Fund

The bill establishes the Kratom Program Fund in the state treasury consisting of all fees collected under the program, money appropriated to the fund, and any other money received from gifts or federal grants. The fund's investment earnings must be credited to the fund. The bill requires the Director to use the fund to administer and enforce the program and rules.¹⁵

HISTORY

Action	Date
Introduced	03-25-21

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¹⁴ R.C. 930.07.

¹⁵ R.C. 930.06.