CLIENT ALERTS & INSIGHTS

Ohio House of Representatives Passes Bill Regulating the Processing and Sale of Kratom Products

MARCH 14, 2022

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House Bill 236, which has passed the Ohio House of Representatives, would regulate the processing of kratom and the sale of kratom products in Ohio. With House Bill 236's enactment, Ohio would become the sixth state to regulate the processing and sale of kratom.

Backround

Kratom is a tropical tree in the coffee family native to Southeast Asia. In those areas where kratom is grown, people traditionally chew or smoke its leaves, or make them into a tea. It may also be ingested in the form of a tablet, capsule, or extract. Kratom has also been used to treat pain and diarrhea, or as a substitute for opium, and more recently as treatment for opioid withdrawal symptoms.

According to the United States Drug Enforcement Administration, the consumption of kratom leaves in low doses produces stimulant effects, while consumption in higher doses produces sedative effects that can lead to psychotic symptoms (including hallucinations, delusion and confusion) and psychological and physiological dependence. Kratom advocates argue that its addictive effects are generally far milder than opioid dependence and claim that kratom is a valuable treatment in combatting the opioid epidemic.

Current Regulation

In 2016, the DEA announced its intent to list kratom as a Schedule I substance under the federal Controlled Substance Act, which would have effectively banned kratom in the United States. The DEA's notice of intent was quickly withdrawn, however, due to the large number of public comments the agency received touting the beneficial uses of kratom. Although kratom remains uncontrolled under the Controlled Substances Act, the United States Food and Drug Administration has not approved kratom for any medical use, and the DEA does consider it as a "drug and chemical of concern."

Six states-Alabama, Arkansas, Indiana, Rhode Island, Vermont and Wisconsin-currently ban kratom. Three others--Illinois, New Hampshire and Tennessee-ban its sale and/or use by minors, but otherwise leave the substance largely unregulated. Arizona, Georgia, Nevada, Oklahoma and Utah currently regulate kratom in a manner similar to that set forth in House Bill 236. The remaining states, like Ohio currently, leave kratom unregulated.

House 236 Summary

House Bill 236 would require the Ohio Department of Agriculture to create a program to monitor and regulate kratom processing-defined as "converting kratom into a kratom product," including dietary supplements or food intended for human consumption. The bill would also prohibit the Ohio Board of Pharmacy from regulating kratom as a controlled substance under state law, and expressly provides that it is not a drug for purposes of state pharmaceutical or criminal drug laws.

Under the bill, the program adopted by the Department of Agriculture would require the Department to issue licenses for kratom processing, and to promulgate rules establishing standards for the issuance of such licenses and procedures for the regulation of kratom processing. The Department's rules must establish, among other things:

- a procedure for testing kratom products for compliance with state statutes and regulations;
- a procedure for conducting annual inspections of kratom processing license holders to ensure that kratom plants are not being processed in violation of state statutes and regulations;
- recordkeeping and annual reporting requirements for kratom processing license holders;
- standards for the labeling of kratom products, including specific directions for their safe and effective use and recommended serving size; and
- procedures and requirements for the transportation and distribution of kratom products.

The bill would not require a license for the possession, purchase or sale of kratom products.

Violation of program requirements involving criminal negligence would be addressed by the issuance of a corrective action plan by the Director of Agriculture, while violations committed recklessly, knowingly, or purposely, would be referred for criminal prosecution. House Bill 236 would expressly prohibit:

- the processing of kratom without a kratom processing license;
- a licensee from violating any provision of the program or rules;
- transporting kratom in violation of the program or rules;
- failing to comply with a corrective action plan issued by the Director; and

- distributing or selling, or exposing for sale any kratom product:
  - adulterated with a dangerous nonkratom substance that makes the kratom product injurious to a consumer;
  - contaminated with a dangerous nonkratom substance such a drug or controlled substance;
  - containing any synthetic alkaloid or more than 2% of 7-hydroxymitragynine in its alkaloid composition;
  - not labeled in accordance with program requirements; or
  - with a label indicating that it is intended to diagnose, treat, cure, or prevent any medical condition or disease.

Current Statuts

House Bill 236 passed the Ohio House of Representatives on February 9, 2022, by an 83-10 vote. It has been referred to the Senate Health Committee where it remains pending. Benesch will monitor the legislation as it progresses. Please reach out to a member of the firm's Government Relations Practice Group or Regulated Industries Group with any questions.

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