

SESSION OF 2021

SUPPLEMENTAL NOTE ON HOUSE BILL NO. 2056

As Recommended by House Committee on
Federal and State Affairs

Brief*

HB 2056 would amend the Kansas Food, Drug and Cosmetic Act (Act) by adding provisions concerning the regulation of kratom.

Definitions

The bill would define “kratom dealer” (dealer) to mean a person that manufactures, sells, prepares, produces, distributes, or maintains kratom products, or advertises or represents that such person manufactures, sells, prepares, produces, distributes, or maintains kratom products, including, but not limited to a manufacturer, wholesaler, retail store, restaurant, hotel, catering facility, camp, bakery, delicatessen, grocery store, convenience store, or nursing home.

The bill would also define “kratom product” (product) to mean a food containing any part of the plant *mitragyna speciosa*.

*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

Adulterated Products

In addition to the definition of “adulteration” already contained in the Act, the bill would specify that products would be considered adulterated if such products contain:

- A level of 7-hydroxymitragynine in the alkaloid fraction that is greater than 2.0 percent of the alkaloid composition of such product; or
- Any synthetic alkaloids including synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compounds of the kratom plant.

Annual Dealer Licenses

The bill would require applications for dealer licenses to be made in such form and manner as required by the Secretary of Agriculture (Secretary) and be accompanied by the required application and license fees.

License applications for dealer licenses involving the retail or wholesale distribution of products, but not including the production, manufacture, packaging, or labeling of products, would be required to be approved upon:

- Submission of a complete application; and
- Timely payment of applicable fees.

The bill would require license applications for dealers involved in the production, manufacture, packaging, or labeling of products to be approved by the Secretary upon:

- Submission of a complete application;
- Timely payment of applicable fees; and

- Completion of a successful inspection of the premises listed in the application.

Dealer licenses issued under the Act would:

- Be in addition to any other license, permit, or registration required by the Act, or other state or federal law;
- Apply only to the premises described in the application and in the license issued on such application, which could describe only one location;
- Be required to be displayed conspicuously in the licensed premises for which it was issued;
- Not be transferable to any other person or location; and
- Expire on March 31 following the date of issuance unless otherwise provided for in law.

License Renewal

The bill would state a dealer license could be renewed by applying to the Secretary before the license expiration date. The bill would require applications for license renewal to be made in a form and manner prescribed by the Secretary and accompanied by the required application and fees.

Denial of License Issuance or Renewal

If the Secretary denied the issuance or renewal of any license, the Secretary would be required to provide written notice of such denial to the applicant or licensee. The bill would require the written notice to specify the changes needed for complete compliance with the provisions of the Act and all rules and regulations adopted under the Act and state that, if compliance is achieved within the time frame

designated in the notice, the license would be issued or renewed. If such compliance were not achieved within the prescribed time frame, the Secretary, after notice and an opportunity for a hearing under the Kansas Administrative Procedure Act (KAPA), would be required to deny the application or renewal application.

License Fees

The Secretary would be required to adopt rules and regulations establishing fees for issuing annual dealer licenses and other necessary expenses to defray the cost of implementing and enforcing the Act.

If a dealer license were lost, destroyed, or mutilated, a duplicate license would be issued to a qualified licensee upon application and payment of a \$5 fee.

The bill would require all money received as fees under the provisions of the bill to be remitted to the State Treasurer monthly, and the entire amount would be credited to the Food Safety Fee Fund. All expenditures of this fund would be made in accordance with appropriation acts upon warrants of the Director of Accounts and Reports issued pursuant to vouchers approved by the Secretary, or the Secretary's designee.

Inspection of Licensed Dealer Premises

The Secretary would be required to inspect or cause to be inspected the premises of every licensed dealer. If, upon inspection, the Secretary determines the premises does not comply with the Act, or rules and regulations adopted under the Act, the Secretary would be required to give written or electronic notice to the owner, proprietor, or agent in charge of the licensed premises and could allow for correction within ten days or provide for any other civil remedy established by the Act or rules and regulations adopted under the Act.

The bill would state the Secretary shall have access at all reasonable hours to any location in which products are manufactured, sold, prepared, produced, distributed, maintained, or advertised and to enter any vehicle being used to transport or hold products in commerce, for the following purposes:

- To inspect any location, products, or equipment subject to the provisions of this Act and rules and regulations adopted under the Act;
- To inspect or sample any product reported to be adulterated, misbranded, or a threat to public health;
- To inspect or investigate complaints of violation of the provisions of the Act and rules and regulations adopted under the Act;
- To inspect the records concerning the place of origin or the sale of any product;
- To open any package containing or suspected of containing any product that is exposed or offered for sale; and
- To take samples of the contents of any product for examination.

The bill would specify that, if the Secretary is denied access to any location where access is sought for the purposes described above, the Secretary could apply to any court of competent jurisdiction for a search warrant authorizing access to such location for such purposes. The court would be required to issue a search warrant upon such application and a showing of cause.

Inspections and Sampling of Products

The Secretary, or duly authorized representative, would be required to inspect and sample products at such time, in such places, and to such extent as the Secretary or representative considers advisable. The Secretary, or representative, could stop further sale or movement of any products found to be in violation of the provisions of the Act or of any rules and regulations adopted or any orders issued under the Act.

It would be the duty of the Secretary, or a duly authorized representative, to enforce and administer the provisions of the Act and sample, inspect, make analysis of, and test products transported, sold, offered for sale, or exposed for sale within the state at such time and place and to the extent considered necessary to determine whether such products are in compliance with the Act and any rules and regulations adopted under the Act.

Violations

The bill would authorize the Secretary to issue and enforce a written or printed "stop sale" order to the owner or custodian of any product the Secretary, or duly authorized representative, determines to be in violation of the Act or rules and regulations adopted under the Act. Any such stop sale order would prohibit further sale, processing, and movement of the product subject to the order unless the Secretary was provided with evidence of compliance with the Act and a release from the order is issued.

If the Secretary were to find the public health or safety is endangered by the continued operation of a dealer, the Secretary could temporarily suspend a dealer's license or order the temporary closure of the dealer's premises without notice or hearing in accordance with the emergency provisions of KAPA. Such temporary suspension or closure order could not be effective for more than 90 days.

Upon expiration of a suspension or stop sale order, the bill would require the licensee to be reinstated to full licensure or allowed to reopen their business, unless the dealer's license had expired or the Secretary denied, suspended, or revoked the dealer's license or obtained an injunction against the licensee.

After notice and opportunity for a hearing in accordance with KAPA, the bill would allow the Secretary to deny, suspend, modify, revoke, or refuse to renew any license if the Secretary determines the applicant has:

- Been convicted of or pleaded guilty to a criminal violation of any provision of the Act;
- Failed to comply with any provision or requirement of the Act or any rules and regulations adopted pursuant to the Act;
- Interfered with the Secretary's ability to carry out inspections or the administration of the Act; or
- Denied the Secretary access to any premises required to be inspected under the Act.

Unlawful Acts

The bill would establish it would be unlawful for:

- Any person without a license from the Secretary to manufacture, sell, prepare, produce, distribute, maintain, advertise, or represent that such person manufactures, sells, prepare, produces, distributes, maintains, or advertises kratom products;
- Any dealer to manufacture, sell, prepare, produce, distribute, maintain, or otherwise provide any product that is adulterated or misbranded; and

- Any dealer to distribute, sell, or otherwise provide any product to an individual under 18 years of age.

Violation of any of the above provisions would be a class C misdemeanor.

Civil Penalties

The bill would authorize the Secretary to impose a civil penalty in an amount not to exceed \$1,000 per violation of the Act or of rules and regulations or orders adopted under the Act, in addition to other corrective actions ordered and other penalties provided by law. The bill would require, in the case of a continuing violation, each day a violation continued to be deemed a separate violation. Such civil penalties could be assessed only after notice and an opportunity for a hearing under KAPA.

Any person aggrieved by an order of a civil penalty by the Secretary could appeal such order to the district court as provided by the Kansas Judicial Review Act.

Any civil penalty recovered would be remitted to the State Treasurer and the entire amount deposited in the Compliance Education Fee Fund of the Department of Agriculture (Department).

Advertisements

The bill would deem any advertisement for a product as a false claim if the advertisement is false or misleading in any particular aspect of such product, including, but not limited to, any claims not authorized by the federal Food and Drug Administration (FDA) or the Secretary.

Rules and Regulations Authority

The Secretary would be required to adopt rules and regulations for administering the provisions of the Act, including, but not limited to, the format, size, and placement of product labels and the information required to be included on the labels; the fees necessary for carrying out the provisions of the bills; all safety and sanitary standards required; and any other provisions necessary to effectuate the Act.

Technical Changes

The bill would make technical amendments to ensure consistency in statutory phrasing.

Background

The bill was introduced by the House Committee on Federal and State Affairs at the request of Representative Eplee.

[*Note:* HB 2056 contains provisions similar to those of 2020 Sub. for HB 2400, as recommended by the House Committee on Federal and State Affairs.]

House Committee on Federal and State Affairs

In the House Committee hearing, **proponent** testimony was provided by a representative of the American Kratom Association and a private citizen.

Opponent testimony was provided by a representative of the Department. No other testimony was provided.

Fiscal Information

According to the fiscal note prepared by the Division of the Budget on the bill, the Department reports enactment of the bill would significantly broaden the authority and scope of the Department's Food Safety Program. The Department estimates approximately 300 kratom dealers exist within the state. With a one-time application fee of \$100 and a yearly license fee of \$285, revenue of \$115,500 would be generated in the first year the legislation is in effect and \$93,000 in each subsequent year. Expenditures would include the cost to conduct inspections and lab tests, administrative costs, and overhead. The agency indicates the largest expense would be for testing, with lab testing supplies costing nearly \$450 per sample. The testing would be performed every three years for each licensee.

Any fiscal effect associated with the bill is not reflected in *The FY 2022 Governor's Budget Report*.

Kratom; Kansas Food, Drug and Cosmetic Act; rules and regulations