

INTERIM STUDY PROPOSAL 2023-004

State of Arkansas
94th General Assembly
Regular Session, 2023

A Bill

JMB/JMB
SENATE BILL

By: Senators J. Boyd, G. Leding, Irvin
By: Representative Eubanks

Filed with: Senate Committee on Public Health, Welfare, and Labor
pursuant to A.C.A. §10-3-217.

For An Act To Be Entitled

AN ACT TO ESTABLISH THE ARKANSAS KRATOM CONSUMER
PROTECTION ACT; TO REMOVE MITRAGYNINE AND 7-
HYDROXYMITRAGYNINE, ALSO KNOWN AS KRATOM, FROM THE
CONTROLLED SUBSTANCES LIST IN ARKANSAS; AND FOR OTHER
PURPOSES.

Subtitle

TO ESTABLISH THE ARKANSAS KRATOM CONSUMER
PROTECTION ACT; AND TO REMOVE MITRAGYNINE
AND 7-HYDROXYMITRAGYNINE, ALSO KNOWN AS
KRATOM, FROM THE CONTROLLED SUBSTANCES
LIST IN ARKANSAS.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

SECTION 1. Arkansas Code Title 20, Chapter 56, is amended to add an
additional subchapter to read as follows:

Subchapter 4 – Arkansas Kratom Consumer Protection Act

20-56-401. Title.

This subchapter shall be known and may be cited as the “Arkansas Kratom
Consumer Protection Act”.

20-56-402. Legislative Findings.

1 The General Assembly finds that:

2 (1) On February 1, 2016, the Department of Health added
3 mitragynine and 7-hydroxymitragynine, which are two (2) constituent compounds
4 of the kratom plant, as Schedule I substances;

5 (2) The department justified this action on the basis that
6 mitragynine and 7-hydroxymitragynine exhibit opioid-like activity when
7 consumed, and included kratom as a Schedule I substance since it has no
8 approved medical use by the United States Food and Drug Administration;

9 (3)(A) The United States Food and Drug Administration had
10 encouraged every state to ban kratom on the premise that it would be
11 scheduled by the United States Drug Enforcement Administration as a
12 controlled substance in 2016, and that Alabama, Wisconsin, Indiana, and
13 Vermont had already classified kratom as a Schedule I substance.

14 (B) Rhode Island also banned kratom in 2017 based on
15 information provided by the United State Food and Drug Administration;

16 (4) Since 2016, the United States Drug Enforcement
17 Administration withdrew the United States Food and Drug Administration's
18 scheduling recommendation for kratom on October 13, 2016, citing insufficient
19 evidence to meet the requirements for classifying mitragynine and 7-
20 hydroxymitragynine as Schedule I substances;

21 (5) On August 16, 2018, the Assistant Secretary of Health at the
22 United States Department of Health and Human Services withdrew the United
23 State Food and Drug Administration's second scheduling recommendation for
24 mitragynine and 7-hydroxymitragynine as Schedule I substances citing
25 "disappointingly poor evidence and data and a failure to consider overall
26 public health";

27 (6) On December 1, 2021, the Expert Committee on Drug Dependence
28 at the United Nations Commission on Narcotic Drugs rejected the
29 recommendation for international scheduling of mitragynine and 7-
30 hydroxymitragynine citing insufficient evidence to support that action;

31 (7) On February 21, 2023, the Indiana House of Representatives,
32 on a vote of 53-40, passed a repeal of the kratom ban and replacing it with
33 the Kratom Consumer Protection Act;

34 (8)(A) On March 1, 2023, the Vermont Department of Health
35 accepted a petition by the American Kratom Association to remove the kratom
36 ban.

1 (B) Upon completion of the planned rule making of the
2 Vermont Department of Health, the number of banned states is reduced to five
3 (5) states;

4 (9) On March 10, 2023, the Wisconsin Controlled Substances Board
5 passed a motion affirming to the State Legislature that kratom does not meet
6 the statutorily mandated eight factors established by the Controlled
7 Substances Act for scheduling despite their view kratom should not be removed
8 from scheduling until more research is available;

9 (10) The Rhode Island Legislature is proceeding with the Kratom
10 Consumer Protection Act after the Interim Director of the Department of
11 Health acknowledged kratom does not meet the criteria for scheduling;

12 (11)(A) At this time, seven (7) states, including Utah, Georgia,
13 Arizona, Nevada, Oregon, Colorado, and Oklahoma, have passed the Kratom
14 Consumer Protection Act between 2019 and 2022.

15 (B) Two (2) additional states have passed the Kratom
16 Consumer Protection Act during the current 2023 legislative session and they
17 are now awaiting the Governor’s signature in Virginia and West Virginia.

18 (12) On March 16, 2022, United States Department of Health and
19 Human Services Secretary Becerra, in a letter to Senator Mike Lee and
20 Representative Mark Pocan, acknowledged “knowledge gaps” on kratom and that
21 “kratom-involved overdose deaths have occurred after use of adulterated
22 kratom products or taking kratom with other substances”;

23 (13) On December 29, 2022, President Joe Biden signed the FY23
24 Omnibus with kratom report language commending the National Institute on Drug
25 Abuse for funding studies on kratom that “may provide help for some Americans
26 struggling with addictions, given its analgesic and less addictive properties
27 as compared to opioids”;

28 (14)(A) Data from the Department of Health shows that fatal
29 opioid overdoses have been on the rise in recent years.

30 (B) In 2021, the Department of Health reported there were
31 six hundred twenty-eight (628) drug overdose deaths in Arkansas; and

32 (15)(A) On May 17, 2022, the Director of the National Institute
33 on Drug Abuse, Dr. Nora Volkow, testified regarding the drug overdose crisis
34 at a hearing of the United States Senate Subcommittee on Labor, Health and
35 Human Services.

1 (B) When asked about overdose prevention strategies, Dr.
2 Volkow stated: "There's also interest in the community to test other products
3 that may serve as harm reduction. For example, the use of kratom, which is
4 sold as tea and that contains a drug molecule that has effects that are
5 similar to a dose of buprenorphine but could be utilized also for decreasing
6 withdrawal or depression."

7
8 20-56-403. Definitions.

9 As used in this subchapter:

10 (1) "Food" means a food, food product, food ingredient, dietary
11 ingredient, dietary supplement, or beverage for human consumption;

12 (2)(A) "Kratom product" means a food product or dietary
13 ingredient containing any part of the leaf of the plant mitragyna speciosa or
14 an extract of the plant mitragyna speciosa.

15 (B) A "kratom product" may be manufactured as a powder,
16 capsule, pill, beverage, extract, or other edible form;

17 (3) "Kratom extract" means a food product or dietary ingredient
18 containing any part of the leaf of the plant mitragyna speciosa that has been
19 extracted in order to provide more standardized dosing;

20 (4) "Processor" means a person that sells, prepares,
21 manufactures, distributes, or maintains kratom products, or advertises,
22 represents, or holds itself out as selling, preparing, or maintaining kratom
23 products; and

24 (5) "Retailer" means any person that sells, distributes,
25 advertises, represents, or holds itself out as selling or maintaining kratom
26 products.

27
28 20-56-404. Kratom product limitations.

29 A processor shall not prepare, distribute, sell, or expose for sale any
30 of the following:

31 (1) A kratom product that:

32 (A)(i) Is adulterated with a dangerous non-kratom
33 substance.

34 (ii) A kratom product is adulterated with a
35 dangerous non-kratom substance if the kratom product is mixed or packed with
36 a non-kratom substance and that substance affects the quality or strength of

1 the kratom product to such a degree as to render the kratom product injurious
2 to a consumer;

3 (B)(i) Is contaminated with a dangerous non-kratom
4 substance.

5 (ii) A kratom product is contaminated with a
6 dangerous non-kratom substance if the kratom product contains a poisonous or
7 otherwise deleterious non-kratom ingredient, including without limitation the
8 substances listed in the state's controlled substances list;

9 (C) Contains:

10 (i) A level of 7-hydroxymitragynine in the alkaloid
11 fraction that is greater than one percent (1%) of the overall alkaloid
12 composition of the product; or

13 (ii) Any synthetic alkaloids including synthetic
14 mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically
15 derived compounds of the kratom plant;

16 (2) A kratom extract that contains levels of residual solvents
17 higher than is allowed in the U.S. Pharmacopeia Chapter 467; or

18 (3) A kratom product or kratom extract that does not provide
19 adequate labeling directions necessary for safe use by consumers, including a
20 recommended serving size, the recommended number of servings per day, and the
21 number of servings in the package that is sold.

22
23 20-56-405. Age limits.

24 A processor shall not distribute, sell, or expose for sale a kratom
25 product to an individual under eighteen (18) years of age.

26
27 20-56-406. Processor registration.

28 (a)(1) A processor shall register annually with the Department of
29 Agriculture any kratom product intended to be offered for sale to an end
30 consumer that is in an approved kratom delivery form and pay a fee that is
31 adjusted annually to cover all administrative costs for processing and
32 administering the registrations.

33 (2) The registration shall include a certificate of analysis
34 from a certified independent third-party laboratory showing compliance with
35 the requirements for kratom products in this subchapter.

1 (b)(1) Upon receipt of a credible violation report of non-compliance
2 with this subchapter on a kratom product offered for sale, the Department of
3 Agriculture shall require the processor to produce an updated and current
4 certificate of analysis in a reasonable time frame from a certified
5 independent third-party laboratory showing compliance with the requirements
6 of this subchapter for safe kratom products.

7 (2) If the processor does not provide the certificate of
8 analysis in the specified time frame, the registration for that product shall
9 be revoked.

10 (c)(1) Upon receipt of any adverse event related to a registered
11 kratom product, the processor shall be required to submit a copy via
12 certified mail to the department of their adverse event report that is
13 required to be submitted to the United States Food and Drug Administration
14 under Section 761 of the Federal Food Drug & Cosmetic Act.

15 (2) The department may revoke the kratom product's registration
16 for any documented failure to report an adverse event to the department.

17 (d)(1) If the department has a reasonable basis to require an
18 independent third-party test of a registered kratom product by a laboratory
19 of the department's choice, the processor shall be required to submit payment
20 for the test within a reasonable time frame.

21 (2) If the processor does not tender payment to the department
22 within a set time period upon receipt of the invoice for the testing, the
23 department shall revoke the registration for that product.

24
25 20-56-407. Violations.

26 (a)(1) A processor that violates this subchapter is subject to an
27 administrative fine of not more than five hundred dollars (\$500) for the
28 first offense and not more than one thousand dollars (\$1,000) for a second or
29 subsequent offense.

30 (2) Upon the request of a person to whom an administrative fine
31 is issued, the Secretary of the Department of Agriculture shall conduct a
32 hearing in accordance with the Arkansas Administrative Procedure Act, § 25-
33 15-201 et seq.

34 (b) A retailer does not violate this subchapter if it is shown by a
35 preponderance of the evidence that the retailer relied in good faith upon the

1 representations of a manufacturer, processor, packer, or distributor of food
2 represented to be a kratom product.

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Referred by Senator J. Boyd

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