

118TH CONGRESS
1ST SESSION

H. R. 5905

To protect access to kratom.

IN THE HOUSE OF REPRESENTATIVES

OCTOBER 6, 2023

Mr. POCAN (for himself and Mr. BERGMAN) introduced the following bill

OCTOBER 25, 2023

Referred to the Committee on Energy and Commerce

A BILL

To protect access to kratom.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Federal Kratom Con-
5 sumer Protection Act”.

6 **SEC. 2. ACCESS TO KRATOM.**

7 (a) OPENNESS IN RESEARCH.—

8 (1) IN GENERAL.—During the period that be-
9 gins 30 days after the date of enactment of this Act
10 and ends 90 days after such date of enactment, the
11 Secretary, acting through the Commissioner, shall

1 hold at least one hearing that provides an open
2 forum for the discussion on the current scientific
3 data and information about safety and use of prod-
4 ucts containing kratom or kratom-derived products
5 marketed as a food, dietary ingredient, or dietary
6 supplement.

7 (2) HEARING REQUIREMENTS.—The hearing
8 under paragraph (1) shall—

9 (A) include input from leading scientific
10 researchers on kratom and kratom-derived
11 products; and

12 (B) consider—

13 (i) how many individuals in the
14 United States consume kratom and
15 kratom-derived products;

16 (ii) the scope, scale, and degree of de-
17 pendence or addiction associated with
18 kratom, mitragynine, and 7-
19 hydroxymitragynine;

20 (iii) the causality of deaths in which
21 kratom or kratom-derived products are as-
22 sociated, including instances in which—

23 (I) a kratom-containing product
24 or kratom-derived product was con-

1 sumed together with legal or illegal
2 drugs; or

3 (II) the kratom-containing prod-
4 uct or kratom-derived product con-
5 sumed was contaminated with a dif-
6 ferent non-drug adulterant known to
7 endanger health;

8 (iv) whether use of kratom or kratom-
9 derived products is directly linked to the
10 use of more dangerous scheduled sub-
11 stances;

12 (v) any adverse health impacts that
13 could be expected if kratom or kratom-de-
14 rived were no longer available; and

15 (vi) the potential health and wellness
16 benefits of kratom and kratom-derived
17 products.

18 (3) PUBLIC DOCKET.—Not later than 30 days
19 after the date of enactment of this Act, the Sec-
20 retary shall open a public docket for submission of
21 public comments for consideration at the hearing
22 under paragraph (1). The Secretary shall leave such
23 public docket open for comments for not fewer than
24 30 days before the hearing takes place.

1 (4) PUBLICATION OF INFORMATION.—The Sec-
2 retary shall publish on the website of the Food and
3 Drug Administration the transcripts of all hearings
4 conducted pursuant to paragraph (1), subject to sec-
5 tion 552(b) of title 5, United States Code.

6 (b) TASK FORCE.—

7 (1) ESTABLISHMENT.—Not later than 30 days
8 after the date of enactment of this Act, the Sec-
9 retary shall convene a task force, to be known as the
10 “Kratom Research Task Force”, to coordinate
11 kratom-related research conducted or supported by
12 the Federal Government.

13 (2) REPORTS ON KRATOM RESEARCH.—

14 (A) INITIAL REPORT.—Not later than 90
15 days after the date of enactment of this Act,
16 the Kratom Research Task Force shall submit
17 to Congress, the Secretary, and the Commis-
18 sioner a report that details all federally funded
19 kratom-related research that has begun or been
20 completed prior to such date of enactment.

21 (B) SUBSEQUENT QUARTERLY REPORTS.—

22 Not later than 90 days after submission of the
23 report under subparagraph (A), and quarterly
24 thereafter, the Kratom Research Task Force

1 shall submit to Congress, the Secretary, and the
2 Commissioner a report that includes—

3 (i) a progress report on all federally
4 funded kratom-related research and find-
5 ings made during the applicable quarter;
6 and

7 (ii) an analysis of the results of all
8 such research.

9 (3) PUBLIC MEETINGS.—The Kratom Research
10 Task Force shall convene public meetings with ap-
11 propriate experts and stakeholders to increase public
12 awareness concerning the current state of kratom-re-
13 lated research.

14 (4) PUBLICLY AVAILABLE INFORMATION.—The
15 Secretary shall—

16 (A) publish the report submitted under
17 paragraph (2)(A) on the website of the Food
18 and Drug Administration; and

19 (B) update such website in accordance
20 with the quarterly reports submitted under
21 paragraph (2)(B), upon receipt of each such re-
22 port.

23 (5) TERMINATION OF TASK FORCE.—On the
24 date that is 2 years after the initial report is sub-
25 mitted by the Kratom Research Task Force under

1 paragraph (2)(A), such task force shall be termi-
2 nated.

3 (c) PROTECTION OF KRATOM FROM CURRENT REGU-
4 LATIONS.—The Secretary shall not—

5 (1) impose requirements on kratom or kratom-
6 derived products that are more restrictive than the
7 requirements for food, dietary supplements, and die-
8 tary ingredients that apply under The Federal Food,
9 Drug, and Cosmetic Act (21 U.S.C. 301 et seq.);

10 (2) treat kratom, or any product derived from
11 or containing kratom, as an adulterated dietary sup-
12 plement—

13 (A) for containing a new dietary ingredient
14 as described in subparagraph (B) of section
15 402(f)(1) of the Federal Food, Drug, and Cos-
16 metic Act (21 U.S.C. 342(f)(1)); or

17 (B) pursuant to subparagraph (C) of such
18 section 402(f)(1); or

19 (3) require kratom to undergo requirements for
20 notification as a new dietary ingredient under sec-
21 tion 413 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 350b).

23 (d) PROTECTION FROM FUTURE ADMINISTRATIVE
24 ACTION.—

1 (1) IN GENERAL.—Any rulemaking the Sec-
2 retary initiates to regulate kratom shall—

3 (A) comply with formal rulemaking re-
4 quirements under section 552(a) of title 5,
5 United States Code; and

6 (B) require public, in-person hearings.

7 (2) PUBLICATION OF INFORMATION.—The Sec-
8 retary shall publish on the website of the Food and
9 Drug Administration the transcripts of all hearings
10 conducted pursuant to paragraph (1)(B), subject to
11 section 552(b) of title 5, United States Code.

12 (e) IMPORT ALERT REQUIREMENTS.—The Secretary
13 may not issue, implement, or enforce an import alert for
14 a kratom or kratom-derived product unless the Secretary
15 determines that there is a history of such kratom or
16 kratom-derived product being adulterated as described in
17 section 402(f)(1)(A) of the Federal Food, Drug, and Cos-
18 metic Act (21 U.S.C. 342(f)(1)(A)), or evidence that such
19 kratom or kratom-derived product is adulterated as de-
20 scribed in such section.

21 (f) NONPREEMPTION.—Nothing in this section shall
22 preempt any State law.

23 (g) DEFINITIONS.—In this section:

24 (1) SECRETARY.—The term “Secretary” means
25 the Secretary of Health and Human Services.

1 (2) COMMISSIONER.—The term “Commis-
2 sioner” means the Commissioner of Food and
3 Drugs.

4 (3) DIETARY SUPPLEMENT.—The term “dietary
5 supplement” has the meaning given such term in
6 section 201(ff) of the Federal Food, Drug, and Cos-
7 metic Act (21 U.S.C. 321(ff)).

8 (4) DIETARY INGREDIENT.—The term “dietary
9 ingredient” means a dietary ingredient as such term
10 is used in section 201(ff)(1) of the Federal Food,
11 Drug, and Cosmetic Act (21 U.S.C. 321(ff)(1)).

12 (5) FOOD.—The term “food” has the meaning
13 given such term in section 201(f) of the Federal
14 Food, Drug, and Cosmetic Act (21 U.S.C. 321(f)).

15 (6) KRATOM.—The term “kratom” means the
16 botanical *Mitragyna speciosa*.

17 (7) NEW DIETARY INGREDIENT.—The term
18 “new dietary ingredient” has the meaning given
19 such term in section 413(d) of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C. 350b(d)).

○