

119TH CONGRESS
1ST SESSION

S. _____

To amend the Federal Food, Drug, and Cosmetic Act to require notifications to the Food and Drug Administration regarding food substances generally recognized as safe, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. MARSHALL (for himself, Mrs. BRITT, and Mr. SCOTT of Florida) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require notifications to the Food and Drug Administration regarding food substances generally recognized as safe, and for other purposes.

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 “Better Food Disclosure
5 Act of 2025” or the “Better FDA Act of 2025”.

1 **SEC. 2. MANDATORY REPORTING OF SUBSTANCES GEN-**
2 **ERALLY RECOGNIZED AS SAFE.**

3 (a) IN GENERAL.— Chapter IV of the Federal Food,
4 Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amend-
5 ed by inserting after section 409 the following:

6 **“SEC. 409A. FOOD SUBSTANCES GENERALLY RECOGNIZED**
7 **AS SAFE.**

8 “(a) IN GENERAL.—Beginning on the date that is 2
9 years after the date of enactment of the Better Food Dis-
10 closure Act of 2025, a food substance generally recognized
11 as safe shall, with respect to any particular use or in-
12 tended use, be deemed to be unsafe for the purposes of
13 the application of clause (2)(C) of section 402(a), unless—

14 “(1) the Secretary includes the food substance
15 on the list described in subsection (c); or

16 “(2) the food substance is under review under
17 subsection (e)(1)(A) and the Secretary has not yet
18 made a final determination under subsection (e)(2).

19 “(b) NOTICE TO FDA.—

20 “(1) IN GENERAL.—Any person may, with re-
21 spect to any intended use of a food substance gen-
22 erally recognized as safe, file with the Secretary a
23 notice proposing inclusion of such food substance on
24 the list described in subsection (c).

25 “(2) TIMEFRAMES.—The timeframes for filing
26 of a notice under paragraph (1) are as follows:

1 “(A) With respect to a food substance used
2 in food offered in interstate commerce as of the
3 date of enactment of the Better Food Disclo-
4 sure Act of 2025, and, as of such date of enact-
5 ment, considered to be a food substance gen-
6 erally recognized as safe, not later than 2 years
7 after such date of enactment.

8 “(B) With respect to a food substance first
9 used in food offered in interstate commerce
10 after the date of enactment of the Better Food
11 Disclosure Act of 2025, not later than 120 days
12 before the first use of the food substance in
13 such food.

14 “(c) REGULATIONS.—Not later than 2 years after the
15 date of enactment of the Better Food Disclosure Act of
16 2025, the Secretary shall promulgate regulations to estab-
17 lish the procedures to establish and maintain a publicly
18 accessible list of food substances generally recognized as
19 safe.

20 “(d) FDA LISTING.—

21 “(1) IN GENERAL.—Not later than 180 days
22 after receiving a notice under subsection (b)(1), the
23 Secretary shall accept such notice and—

24 “(A) add the food substance to the list de-
25 scribed in subsection (c); or

1 “(B) subject to subsection (e), make a pre-
2 liminary determination to exclude the food sub-
3 stance from such list.

4 “(2) EFFECTIVENESS OF NOTICE.—If the Sec-
5 retary does not make a preliminary determination to
6 exclude a food substance under subparagraph (B) of
7 paragraph (1) by the deadline described in such
8 paragraph, such food substance shall be deemed to
9 be added to the list described in subsection (c).

10 “(e) EXCLUDED OR DELISTED SUBSTANCES.—

11 “(1) IN GENERAL.—If the Secretary makes a
12 preliminary determination under subsection
13 (d)(1)(B) to exclude a food substance for which a
14 notice was submitted under subsection (b)(1) from
15 the list described in subsection (c), or removes a
16 food substance from such list after reevaluation in
17 accordance with section 409B, the Secretary shall
18 require any person using such food substance in
19 food to submit to the Secretary, not later than 180
20 days after issuance of an preliminary or removal de-
21 termination, at the option of such person—

22 “(A) a request for the Secretary to recon-
23 sider such preliminary determination or removal
24 determination, including any additional infor-
25 mation the Secretary may request in order to

1 make a final determination of whether the food
2 substance is a food substance generally recog-
3 nized as safe;

4 “(B) a food additive petition under section
5 409; or

6 “(C) a plan for phasing out use of the food
7 substance.

8 “(2) FINAL DETERMINATIONS.—If a person re-
9 quests under paragraph (1)(A) that the Secretary
10 reconsider a preliminary determination under sub-
11 section (d)(1)(B) to exclude a food substance for
12 which a notice was submitted under subsection
13 (b)(1) from the list described in subsection (c) or the
14 removal of a food substance from such list after re-
15 evaluation in accordance with section 409B, not
16 later than 180 days after receiving sufficient infor-
17 mation paragraph (1)(A), the Secretary shall make
18 a final determination of whether the food substance
19 is a food substance generally recognized as safe.”.

20 (b) DEFINITIONS.—Section 201 of the Federal Food,
21 Drug, and Cosmetic Act (21 U.S.C. 321) is amended—

22 (1) in paragraph (s)—

23 (A) by striking “, if such substance is not
24 generally recognized, among experts qualified
25 by scientific training and experience to evaluate

1 its safety, as having been adequately shown
2 through scientific procedures (or, in the case of
3 a substance used in food prior to January 1,
4 1958, through either scientific procedures or ex-
5 perience based on common use in food) to be
6 safe under the conditions of its intended use”;

7 (B) in paragraph (5), by striking “or” at
8 the end;

9 (C) in paragraph (6), by striking the pe-
10 riod and inserting “; or”; and

11 (D) by adding at the end the following:

12 “(7) a food substance generally recognized as
13 safe, as defined in paragraph (tt).”; and

14 (2) by adding at the end the following:

15 “(tt) The term ‘food substance generally recognized
16 as safe’ means any substance the intended use of which
17 results or may reasonably be expected to result, directly
18 or indirectly, in its becoming a component or otherwise
19 affecting the characteristics of any food (including any
20 substance intended for use in producing, manufacturing,
21 packing, processing, preparing, treating, packaging, trans-
22 porting, or holding food; and including any source of radi-
23 ation intended for any such use), if such substance is gen-
24 erally recognized, among experts qualified by scientific
25 training and experience to evaluate its safety, as having

1 been adequately shown through scientific procedures (or,
2 in the case of a substance used in food prior to January
3 1, 1958, through either scientific procedures or experience
4 based on common use in food) to be safe under the condi-
5 tions of its intended use, except that such term does not
6 include—

7 “(1) food additives, as defined in paragraph (s),
8 that are subject to section 409;or

9 “(2) any article described in subparagraphs (1)
10 through (6) of paragraph (s).”.

11 (c) ADULTERATED FOOD.—Section 402(a)(2)(C) of
12 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
13 342(a)(2)(C)) is amended—

14 (1) by striking “or (ii) a new” and inserting
15 “(ii) a new”; and

16 (2) by inserting “or (iii) a food substance gen-
17 erally recognized as safe that is not included on the
18 list maintained by the Secretary pursuant to section
19 409A(c) or is under review pursuant to section
20 409A(e);” after “section 512;”.

21 (d) CONFORMING AMENDMENTS.—

22 (1) Section 301(ll)(3)(A) of the Federal Food,
23 Drug, and Cosmetic Act (21 U.S.C. 331(ll)(3)(A)) is
24 amended by inserting “, or the requirements of sec-
25 tion 409A, as applicable” before the semicolon.

1 (2) Section 408(l)(5)(B) of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 346a(l)(5)(B))
3 is amended by inserting “listing of a food substance
4 generally recognized as safe under section 409A(c),”
5 after “food additive regulation”.

6 (3) Section 721(b)(4) of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 379e(b)(4)) is
8 amended by striking “while there is in effect a pub-
9 lished finding of the Secretary declaring such sub-
10 stance exempt from the term ‘food additive’ because
11 of its being generally recognized by qualified experts
12 as safe for its intended use, as provided in section
13 201(s)” and inserting “if it is included on the list
14 maintained by the Secretary pursuant to section
15 409A(c)”.

16 (4) Section 801(d) of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 381(d)) is amended by
18 inserting “food substance generally recognized as
19 safe,” after “color additive,” each place such term
20 appears.

21 (5) Section 803(c)(2) of the Federal Food,
22 Drug, and Cosmetic Act (21 U.S.C. 383(c)(2)) is
23 amended by striking “and color additives” and in-
24 serting “color additives, and food substances gen-
25 erally recognized as safe”.

1 **SEC. 3. POSTMARKET ASSESSMENT OF FOOD ADDITIVES,**
2 **COLOR ADDITIVES, AND FOOD SUBSTANCES**
3 **GENERALLY RECOGNIZED AS SAFE.**

4 Chapter IV of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 341 et seq.) is amended by adding after
6 section 409A (as added by section 2) the following:

7 **“SEC. 409B. POSTMARKET ASSESSMENT OF FOOD ADDI-**
8 **TIVES, COLOR ADDITIVES, AND FOOD SUB-**
9 **STANCES GENERALLY RECOGNIZED AS SAFE.**

10 “(a) IN GENERAL.—If the Secretary receives a cit-
11 izen petition or a notice from a State governmental official
12 regarding concerns about the safety of a food additive for
13 which 1 or more regulations prescribing conditions of safe
14 use have been issued under section 409, a color additive
15 used in accordance with the requirements of section 721,
16 or a food substance generally recognized as safe included
17 on the list described in section 409A(c), or if the Secretary
18 determines through the Secretary’s initiative that such a
19 concern exists, the Secretary may reevaluate the additive
20 or substance in accordance with section 409, 721, or
21 409A, as applicable, and, as appropriate—

22 “(1) with respect to a food additive, amend or
23 revoke the 1 or more regulation issued under section
24 409 with respect to the food additive;

1 “(2) with respect to a color additive, amend or
2 revoke the 1 or more regulations issued under sec-
3 tion 409 with respect to the food additive; and

4 “(3) with respect to a food substance generally
5 recognized as safe—

6 “(A) determine the food substance to be a
7 food additive subject to the requirements of sec-
8 tion 409; and

9 “(B) by rulemaking under section 553 of
10 title 5, United States Code, remove the food
11 substance from the list described in subsection
12 409A(c).

13 “(b) PRIORITY CONSIDERATIONS.—In considering
14 citizen petitions and notices from State governmental offi-
15 cials received under subsection (a), the Secretary shall give
16 priority to petitions and notices regarding food additives,
17 color additives, and food substances generally recognized
18 as safe for which clear and convincing scientific evidence
19 supports the concerns raised in the petition or notice.

20 “(c) SAFETY INFORMATION.—The Secretary shall
21 publish in the Federal Register a request for safety infor-
22 mation for any food substance subject to reevaluation
23 under subsection (a).

24 “(d) REVIEW REQUIREMENTS.—

1 “(1) IN GENERAL.—Any determination, re-
2 evaluation, or final action taken by the Secretary
3 under this section regarding the safety, exclusion,
4 delisting, or reclassification of a food additive, color
5 additive, or food substance generally recognized as
6 safe shall be subject to—

7 “(A) review and recommendation by indi-
8 viduals serving in positions in the Food and
9 Drug Administration under career appoint-
10 ments and who have relevant scientific and reg-
11 ulatory expertise; and

12 “(B) the notice and comment rulemaking
13 procedures under section 553 of title 5, United
14 States Code.

15 “(2) LIMITATION.—The Secretary may not del-
16 egate the review under paragraph (1)(A) to—

17 “(A) an individual occupying a position for
18 which appointment is made by the President; or

19 “(B) an individual who is not serving in a
20 position in the Food and Drug Administration
21 under a career appointment.”.