119TH CONGRESS
1ST SESSION

S. 3122

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

NOVEMBER 6, 2025

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 Health, Education, Labor, and Pensions

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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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Better Food Disclosure Act of 2025'' or the ''Better FDA Act of 2025''.

SEC. 2. MANDATORY REPORTING OF SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

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

"SEC. 409A. FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

''(a) IN GENERAL.—Beginning on the date that is 2 years after the date of enactment of the Better Food Disclosure Act of 2025, a food substance generally recognized as safe shall, with respect to any particular use or intended use, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

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

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

''(b) NOTICE TO FDA.—

''(1) IN GENERAL.—Any person may, with respect to any intended use of a food substance generally recognized as safe, file with the Secretary a notice proposing inclusion of such food substance on the list described in subsection (c).

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

''(A) With respect to a food substance used in food offered in interstate commerce as of the date of enactment of the Better Food Disclosure Act of 2025, and, as of such date of enactment, considered to be a food substance generally recognized as safe, not later than 2 years after such date of enactment.

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

''(c) REGULATIONS.—Not later than 2 years after the date of enactment of the Better Food Disclosure Act of 2025, the Secretary shall promulgate regulations to establish the procedures to establish and maintain a publicly accessible list of food substances generally recognized as safe.

''(d) FDA LISTING.—

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

''(A) add the food substance to the list described in subsection (c); or

''(B) subject to subsection (e), make a preliminary determination to exclude the food substance from such list.

''(2) EFFECTIVENESS OF NOTICE.—If the Secretary does not make a preliminary determination to exclude a food substance under subparagraph (B) of paragraph (1) by the deadline described in such paragraph, such food substance shall be deemed to be added to the list described in subsection (c).

''(e) EXCLUDED OR DELISTED SUBSTANCES.—

''(1) IN GENERAL.—If the Secretary makes a preliminary determination under subsection (d)(1)(B) to exclude a food substance for which a notice was submitted under subsection (b)(1) from the list described in subsection (c), or removes a food substance from such list after reevaluation in accordance with section 409B, the Secretary shall require any person using such food substance in food to submit to the Secretary, not later than 180 days after issuance of an preliminary or removal determination, at the option of such person—

''(A) a request for the Secretary to reconsider such preliminary determination or removal determination, including any additional information the Secretary may request in order to

make a final determination of whether the food substance is a food substance generally recognized as safe;

"(B) a food additive petition under section 409; or

"(C) a plan for phasing out use of the food substance.

"(2) FINAL DETERMINATIONS.—If a person requests under paragraph (1)(A) that the Secretary reconsider a preliminary determination under subsection (d)(1)(B) to exclude a food substance for which a notice was submitted under subsection (b)(1) from the list described in subsection (c) or the removal of a food substance from such list after reevaluation in accordance with section 409B, not later than 180 days after receiving sufficient information paragraph (1)(A), the Secretary shall make a final determination of whether the food substance is a food substance generally recognized as safe.".

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

(1) in paragraph (s)—

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

its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use'';

(B) in paragraph (5), by striking ''or'' at the end;

(C) in paragraph (6), by striking the period and inserting ''; or''; and

(D) by adding at the end the following:

''(7) a food substance generally recognized as safe, as defined in paragraph (tt).''; and

(2) by adding at the end the following:

''(tt) The term 'food substance generally recognized as safe' means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having

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

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

''(2) any article described in subparagraphs (1) through (6) of paragraph (s).''.

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

(1) by striking ''or (ii) a new'' and inserting ''(ii) a new''; and

(2) by inserting ''or (iii) a food substance generally recognized as safe that is not included on the list maintained by the Secretary pursuant to section 409A(c) or is under review pursuant to section 409A(e);'' after ''section 512;''.

(d) CONFORMING AMENDMENTS.—

(1) Section 301(ll)(3)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(ll)(3)(A)) is amended by inserting '', or the requirements of section 409A, as applicable'' before the semicolon.

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

(3) Section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(b)(4)) is amended by striking ''while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s)'' and inserting ''if it is included on the list maintained by the Secretary pursuant to section 409A(c)''.

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

(5) Section 803(c)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 383(c)(2)) is amended by striking ''and color additives'' and inserting ''color additives, and food substances generally recognized as safe''.

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

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

"SEC. 409B. POSTMARKET ASSESSMENT OF FOOD ADDITIVES, COLOR ADDITIVES, AND FOOD SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

''(a) IN GENERAL.—If the Secretary receives a citizen petition or a notice from a State governmental official regarding concerns about the safety of a food additive for which 1 or more regulations prescribing conditions of safe use have been issued under section 409, a color additive used in accordance with the requirements of section 721, or a food substance generally recognized as safe included on the list described in section 409A(c), or if the Secretary determines through the Secretary's initiative that such a concern exists, the Secretary may reevaluate the additive or substance in accordance with section 409, 721, or 409A, as applicable, and, as appropriate—

''(1) with respect to a food additive, amend or revoke the 1 or more regulations issued under section 409 with respect to the food additive;

''(2) with respect to a color additive, amend or revoke the 1 or more regulations issued under section 409 with respect to the food additive; and

''(3) with respect to a food substance generally recognized as safe—

''(A) determine the food substance to be a food additive subject to the requirements of section 409; and

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

''(b) PRIORITY CONSIDERATIONS.—In considering citizen petitions and notices from State governmental officials received under subsection (a), the Secretary shall give priority to petitions and notices regarding food additives, color additives, and food substances generally recognized as safe for which clear and convincing scientific evidence supports the concerns raised in the petition or notice.

''(c) SAFETY INFORMATION.—The Secretary shall publish in the Federal Register a request for safety information for any food substance subject to reevaluation under subsection (a).

''(d) REVIEW REQUIREMENTS.—

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

''(A) review and recommendation by individuals serving in positions in the Food and Drug Administration under career appointments and who have relevant scientific and regulatory expertise; and

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

''(2) LIMITATION.—The Secretary may not delegate the review under paragraph (1)(A) to—

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

''(B) an individual who is not serving in a position in the Food and Drug Administration under a career appointment.''.

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