119TH CONGRESS
1ST SESSION

S. 2341

To amend the Federal Food, Drug, and Cosmetic Act to impose requirements for substances generally recognized as safe, to require the Commissioner of Food and Drugs to reassess the safety of chemicals added to food, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 17, 2025

Mr. MARKEY (for himself, Mr. BOOKER, Ms. WARREN, and Mr. BLUMENTHAL) 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 impose requirements for substances generally recognized as safe, to require the Commissioner of Food and Drugs to reassess the safety of chemicals added to food, 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 ''Ensuring Safe and Toxic-Free Foods Act of 2025''.

SEC. 2. SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

(a) IN GENERAL.—Chapter IV of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 409 (21 U.S.C. 348) the following:

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

''(a) IN GENERAL.—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), 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) such substance is a food additive in compliance with section 409;

''(2) subject to subsection (e)(2), the manufacturer has submitted, prior to the date of enactment of the Ensuring Safe and Toxic-Free Foods Act of 2025, a notice to the Secretary that the manufacturer has concluded that such substance is generally recognized as safe under the conditions of its intended use, and the Secretary has not issued a re-

sponse or has issued a response stating that the Secretary does not question the basis for such conclusion; or

''(3)(A) the manufacturer has submitted, during the period beginning on the date of enactment of the Ensuring Safe and Toxic-Free Foods Act of 2025 and ending on the day before the effective date described in section 2(d) of such Act, a notice to the Secretary that the manufacturer has determined such substance to be generally recognized as safe under the conditions of its intended use;

''(B) such notice includes supporting information sufficient to justify the basis of such determination, including full reports of investigations made with respect to the safety for use of such substance, including—

''(i) full information as to the methods and controls used in conducting such investigations;

''(ii) information on the cumulative effects of such substance;

''(iii) information on hazard, dose response, and exposure;

''(iv) application of adequately protective safety factors to ensure an appropriate margin of safety to take into account uncertainties in

hazard identification, dose response, exposure, and sensitivities;

''(v) information demonstrating that the weight of the evidence analysis shows that such substance has not been found to be carcinogenic; and

''(vi) information demonstrating that the weight of the evidence analysis shows that such substance has not been found to induce reproductive toxicity or developmental toxicity in humans or animals, including through an endocrine mode of action; and

''(C) the Secretary has not objected to such determination under subsection (c).

''(b) PUBLIC AVAILABILITY AND COMMENT.—On receipt of a notice of a determination described in subsection (a)(3)(A), the Secretary shall—

''(1) make such notice and the supporting information included with such notice publicly available on the website of the Food and Drug Administration; and

''(2) provide an opportunity for public comment for a period of not less than 60 days.

''(c) DETERMINATION OF SECRETARY.—

''(1) IN GENERAL.—The Secretary shall issue a written statement objecting to a determination described in subsection (a)(3)(A) if 1 or more of the criteria described in paragraph (2) are not met.

''(2) CRITERIA.—The criteria described in this paragraph are the following:

''(A) The manufacturer has submitted complete documentation justifying the basis for its determination as described in subsection (a)(3)(B).

''(B) With respect to data used for such justification that was provided by an expert, such expert does not have a conflict of interest.

''(C) The available evidence adequately supports a determination that the substance is generally recognized as safe under the conditions of its intended use.

''(3) DETERMINATION NOT TO OBJECT.—With respect to a determination described in subsection (a)(3)(A), if the Secretary determines that all of the criteria described in paragraph (2) are met, the Secretary shall issue a written statement that the Secretary is not objecting to such determination described in subsection (a)(3)(A).

''(4) ADDITIONAL INFORMATION.—Before objecting to a determination described in subsection (a)(3)(A), the Secretary may request additional information from the manufacturer if the Secretary determines the manufacturer has failed to submit complete documentation justifying the basis for its determination as described in subsection (a)(3)(B).

''(5) FINAL AGENCY ACTION.—The determination of the Secretary to object or not to object under this subsection to a determination described in subsection (a)(3)(A) shall be considered to be a final agency action.

''(6) PUBLICATION.—The Secretary shall publish the basis of a determination to object or to not object under this subsection to a determination described in subsection (a)(3)(A) on the website of the Food and Drug Administration, including any chemistry and toxicology memoranda produced or relied on by the Secretary in making such determination. Failure to publish such a determination shall not be construed as an affirmative finding by the Secretary that the substance is generally recognized as safe.

''(7) DEFINITION OF CONFLICT OF INTEREST.—In this subsection, the term 'conflict of interest' means a financial interest that could potentially

compromise the professional judgment or objectivity of an individual in designing, conducting, reporting, or reviewing research or the applicability of research, potentially undermining the integrity of such research.

''(d) STANDARDS FOR EXPERTS EVALUATING WHETHER A SUBSTANCE IS GRAS.—Not later than 180 days after the date of enactment of the Ensuring Safe and Toxic-Free Foods Act of 2025, the Secretary shall issue guidance to strengthen the recommendations contained in the December 2022 guidance of the Food and Drug Administration entitled 'Best Practices for Convening a GRAS Panel'.

''(e) REASSESSMENT.—

''(1) IN GENERAL.—With respect to a substance for which the Secretary has determined under subsection (c)(3) not to object to the manufacturer's determination under subsection (a)(3)(A) that such substance is generally recognized as safe under the conditions of its intended use, the Secretary may, at any time—

''(A) reassess in accordance with subsection (c) whether such substance is generally recognized as safe under the conditions of its intended use; and

''(B) pursuant to such reassessment, withdraw the determination of the Secretary not to object under subsection (c)(3).

''(2) PRIOR SUBMISSIONS TO GRAS NOTIFICATION PROGRAM.—The Secretary may require the manufacturer of a substance described in subsection (a)(2) to submit a notice for such substance that includes the information described in subsection (a)(3). The Secretary shall review such notice in accordance with subsections (b) and (c).

''(f) TIMELINE FOR REVIEW OF GRAS SUBMISSIONS.—

''(1) IN GENERAL.—The Secretary shall review not fewer than 50 notices described in paragraphs (2) and (3) of subsection (a) each year until all such notices have been reviewed.

''(2) REQUIREMENTS.—In conducting a review described in paragraph (1), the Secretary shall—

''(A) with respect to a noticed described in subsection (a)(2), issue a response to such notice stating that, as applicable—

''(i) the Secretary does not question the basis for such conclusion; or

''(ii) the Secretary has concluded that such notice does not provide a sufficient basis for such conclusion; and

''(B) with respect to a notice described in subsection (a)(3), issue a response in accordance with, as applicable, paragraph (1) or (3) of subsection (c).

''(g) DEFINITIONS.—In this section:

''(1) CARCINOGENIC.—

''(A) IN GENERAL.—The term 'carcinogenic', with respect to a substance, means such substance is found to induce cancer when ingested by humans or animals, or is found, after tests that are appropriate for the evaluation of the safety of substances, to induce cancer in humans or animals.

''(B) REQUIREMENT.—In determining whether a substance is carcinogenic for purposes of subparagraph (A), the Secretary shall consider assessments conducted by authoritative bodies, including the National Toxicology Program, the International Agency for Research on Cancer, and the Environmental Protection Agency.

''(2) CUMULATIVE EFFECTS.—The term 'cumulative effects', with respect to a substance, means the combined health effects of all chemically or pharmacologically related substances.

''(3) DEVELOPMENTAL TOXICITY.—The term 'developmental toxicity', with respect to the effect of exposure to a substance on a human or animal, means an adverse effect on the development of such human or animal that results from such exposure—

''(A) to the mother prior to conception of, or during the prenatal period for, such human or animal; or

''(B) to such human or animal before the time of sexual maturity.

''(4) GENERALLY RECOGNIZED AS SAFE.—

''(A) IN GENERAL.—The term 'generally recognized as safe', with respect to a substance, means 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.

"(B) EXCLUSIONS.—The term 'generally recognized as safe', with respect to a substance, does not include a substance that—

"(i) is carcinogenic;

"(ii) shows evidence of reproductive toxicity or developmental toxicity;

"(iii) is otherwise identified as toxic by the National Toxicology Program, the Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry, or the California Office of Environmental Health Hazard Assessment;

"(iv) was not marketed for use in foods in the United States prior to the date of enactment of the Ensuring Safe and Toxic-Free Foods Act of 2025; or

"(v) was not synthesized, characterized, or isolated prior to the date of enactment of the Ensuring Safe and Toxic-Free Foods Act of 2025.

"(5) REPRODUCTIVE TOXICITY.—The term 'reproductive toxicity', with respect to the effect of exposure to a substance on a human or animal, means

an adverse effect on the reproductive system of such human or animal, which may include alterations to reproductive system development, the endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as are necessary.''.

(b) ADULTERATION.—Section 402(a)(2)(C)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(2)(C)(i)) is amended by inserting ''or any other substance that is not generally recognized as safe in compliance with section 409A'' after ''section 409''.

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

(1) 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;'';

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

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

(4) by adding at the end the following:

''(7) a substance generally recognized as safe in compliance with section 409A.''.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date that is 2 years after the date of enactment of this Act.

SEC. 3. FOOD CHEMICAL REASSESSMENT.

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

''SEC. 409B. FOOD CHEMICAL REASSESSMENT.

''(a) SAFETY REASSESSMENTS.—

''(1) IN GENERAL.—Not later than 3 years after the date of enactment of this section, and not less frequently than once every 3 years thereafter, the Secretary shall reassess the safety, within the meaning of section 409 or section 409A, of not less than 10 substances or classes of substances—

''(A) to determine if such substance or class of substances is safe within the meaning of section 409 or section 409A; and

''(B) to establish the conditions of use, if any, under which any such substance or class of substances may be used safely within the meaning of such section 409 or 409A.

''(2) REQUIREMENTS FOR MANUFACTURERS.—The Secretary may require any manufacturer of a substance or class of substances that is being reassessed under paragraph (1) to provide data or to conduct evaluations of such substance or class of substances for purposes of the reassessment under paragraph (1).

''(3) PRIORITY.—The Secretary may give priority to the reassessment of a substance or class of substances that is the subject of—

''(A) a food additive petition under section 409(b);

''(B) a color additive petition under section 721(d); or

''(C) a citizen petition to request the reassessment, restriction, or revocation of an existing authorization of such substance or class of substances.

''(b) CONSIDERATIONS.—In determining, for the purposes of this section, whether a substance or class of substances is unsafe within the meaning of section 409 or section 409A, the Secretary shall consider the information described in clauses (i) through (vi) of section 409A(a)(3)(B).

''(c) RULE OF CONSTRUCTION.—Nothing in this section alters the authority or duties of the Secretary with respect to the administration and enforcement of section 409 or section 409A.''.

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