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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

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.

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 “Ensuring Safe and
5 Toxic-Free Foods Act of 2025”.

1 **SEC. 2. SUBSTANCES GENERALLY RECOGNIZED AS SAFE.**

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

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

7 “(a) IN GENERAL.—Any substance the intended use
8 of which results or may reasonably be expected to result,
9 directly or indirectly, in its becoming a component or oth-
10 erwise affecting the characteristics of any food (including
11 any substance intended for use in producing, manufac-
12 turing, packing, processing, preparing, treating, pack-
13 aging, transporting, or holding food; and including any
14 source of radiation intended for any such use), shall, with
15 respect to any particular use or intended use, be deemed
16 to be unsafe for the purposes of the application of clause
17 (2)(C) of section 402(a), unless—

18 “(1) such substance is a food additive in com-
19 pliance with section 409;

20 “(2) subject to subsection (e)(2), the manufac-
21 turer has submitted, prior to the date of enactment
22 of the Ensuring Safe and Toxic-Free Foods Act of
23 2025, a notice to the Secretary that the manufac-
24 turer has concluded that such substance is generally
25 recognized as safe under the conditions of its in-
26 tended use, and the Secretary has not issued a re-

1 sponse or has issued a response stating that the Sec-
2 retary does not question the basis for such conclu-
3 sion; or

4 “(3)(A) the manufacturer has submitted, dur-
5 ing the period beginning on the date of enactment
6 of the Ensuring Safe and Toxic-Free Foods Act of
7 2025 and ending on the day before the effective date
8 described in section 2(d) of such Act, a notice to the
9 Secretary that the manufacturer has determined
10 such substance to be generally recognized as safe
11 under the conditions of its intended use;

12 “(B) such notice includes supporting informa-
13 tion sufficient to justify the basis of such determina-
14 tion, including full reports of investigations made
15 with respect to the safety for use of such substance,
16 including—

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

19 “(ii) information on the cumulative effects
20 of such substance;

21 “(iii) information on hazard, dose re-
22 sponse, and exposure;

23 “(iv) application of adequately protective
24 safety factors to ensure an appropriate margin
25 of safety to take into account uncertainties in

1 hazard identification, dose response, exposure,
2 and sensitivities;

3 “(v) information demonstrating that the
4 weight of the evidence analysis shows that such
5 substance has not been found to be carcino-
6 genic; and

7 “(vi) information demonstrating that the
8 weight of the evidence analysis shows that such
9 substance has not been found to induce repro-
10 ductive toxicity or developmental toxicity in hu-
11 mans or animals, including through an endo-
12 crine mode of action; and

13 “(C) the Secretary has not objected to such de-
14 termination under subsection (c).

15 “(b) PUBLIC AVAILABILITY AND COMMENT.—On re-
16 ceipt of a notice of a determination described in subsection
17 (a)(3)(A), the Secretary shall—

18 “(1) make such notice and the supporting infor-
19 mation included with such notice publicly available
20 on the website of the Food and Drug Administra-
21 tion; and

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

24 “(c) DETERMINATION OF SECRETARY.—

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

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

7 “(A) The manufacturer has submitted
8 complete documentation justifying the basis for
9 its determination as described in subsection
10 (a)(3)(B).

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

14 “(C) The available evidence adequately
15 supports a determination that the substance is
16 generally recognized as safe under the condi-
17 tions of its intended use.

18 “(3) DETERMINATION NOT TO OBJECT.—With
19 respect to a determination described in subsection
20 (a)(3)(A), if the Secretary determines that all of the
21 criteria described in paragraph (2) are met, the Sec-
22 retary shall issue a written statement that the Sec-
23 retary is not objecting to such determination de-
24 scribed in subsection (a)(3)(A).

1 “(4) ADDITIONAL INFORMATION.—Before ob-
2 jecting to a determination described in subsection
3 (a)(3)(A), the Secretary may request additional in-
4 formation from the manufacturer if the Secretary
5 determines the manufacturer has failed to submit
6 complete documentation justifying the basis for its
7 determination as described in subsection (a)(3)(B).

8 “(5) FINAL AGENCY ACTION.—The determina-
9 tion of the Secretary to object or not to object under
10 this subsection to a determination described in sub-
11 section (a)(3)(A) shall be considered to be a final
12 agency action.

13 “(6) PUBLICATION.—The Secretary shall pub-
14 lish the basis of a determination to object or to not
15 object under this subsection to a determination de-
16 scribed in subsection (a)(3)(A) on the website of the
17 Food and Drug Administration, including any chem-
18 istry and toxicology memoranda produced or relied
19 on by the Secretary in making such determination.
20 Failure to publish such a determination shall not be
21 construed as an affirmative finding by the Secretary
22 that the substance is generally recognized as safe.

23 “(7) DEFINITION OF CONFLICT OF INTER-
24 EST.—In this subsection, the term ‘conflict of inter-
25 est’ means a financial interest that could potentially

1 compromise the professional judgment or objectivity
2 of an individual in designing, conducting, reporting,
3 or reviewing research or the applicability of research,
4 potentially undermining the integrity of such re-
5 search.

6 “(d) STANDARDS FOR EXPERTS EVALUATING
7 WHETHER A SUBSTANCE IS GRAS.—Not later than 180
8 days after the date of enactment of the Ensuring Safe and
9 Toxic-Free Foods Act of 2025, the Secretary shall issue
10 guidance to strengthen the recommendations contained in
11 the December 2022 guidance of the Food and Drug Ad-
12 ministration entitled ‘Best Practices for Convening a
13 GRAS Panel’.

14 “(e) REASSESSMENT.—

15 “(1) IN GENERAL.—With respect to a sub-
16 stance for which the Secretary has determined under
17 subsection (c)(3) not to object to the manufacturer’s
18 determination under subsection (a)(3)(A) that such
19 substance is generally recognized as safe under the
20 conditions of its intended use, the Secretary may, at
21 any time—

22 “(A) reassess in accordance with sub-
23 section (c) whether such substance is generally
24 recognized as safe under the conditions of its
25 intended use; and

1 “(B) pursuant to such reassessment, with-
 2 draw the determination of the Secretary not to
 3 object under subsection (c)(3).

4 “(2) PRIOR SUBMISSIONS TO GRAS NOTIFICA-
 5 TION PROGRAM.—The Secretary may require the
 6 manufacturer of a substance described in subsection
 7 (a)(2) to submit a notice for such substance that in-
 8 cludes the information described in subsection
 9 (a)(3). The Secretary shall review such notice in ac-
 10 cordance with subsections (b) and (c).

11 “(f) TIMELINE FOR REVIEW OF GRAS SUBMIS-
 12 SIONS.—

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

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

19 “(A) with respect to a noticed described in
 20 subsection (a)(2), issue a response to such no-
 21 tice stating that, as applicable—

22 “(i) the Secretary does not question
 23 the basis for such conclusion; or

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

4 “(B) with respect to a notice described in
5 subsection (a)(3), issue a response in accord-
6 ance with, as applicable, paragraph (1) or (3)
7 of subsection (c).

8 “(g) DEFINITIONS.—In this section:

9 “(1) CARCINOGENIC.—

10 “(A) IN GENERAL.—The term ‘carcino-
11 genic’, with respect to a substance, means such
12 substance is found to induce cancer when in-
13 gested by humans or animals, or is found, after
14 tests that are appropriate for the evaluation of
15 the safety of substances, to induce cancer in hu-
16 mans or animals.

17 “(B) REQUIREMENT.—In determining
18 whether a substance is carcinogenic for pur-
19 poses of subparagraph (A), the Secretary shall
20 consider assessments conducted by authoritative
21 bodies, including the National Toxicology Pro-
22 gram, the International Agency for Research on
23 Cancer, and the Environmental Protection
24 Agency.

1 “(2) CUMULATIVE EFFECTS.—The term ‘cumu-
2 lative effects’, with respect to a substance, means
3 the combined health effects of all chemically or phar-
4 macologically related substances.

5 “(3) DEVELOPMENTAL TOXICITY.—The term
6 ‘developmental toxicity’, with respect to the effect of
7 exposure to a substance on a human or animal,
8 means an adverse effect on the development of such
9 human or animal that results from such exposure—

10 “(A) to the mother prior to conception of,
11 or during the prenatal period for, such human
12 or animal; or

13 “(B) to such human or animal before the
14 time of sexual maturity.

15 “(4) GENERALLY RECOGNIZED AS SAFE.—

16 “(A) IN GENERAL.—The term ‘generally
17 recognized as safe’, with respect to a substance,
18 means such substance is generally recognized,
19 among experts qualified by scientific training
20 and experience to evaluate its safety, as having
21 been adequately shown through scientific proce-
22 dures (or, in the case of a substance used in
23 food prior to January 1, 1958, through either
24 scientific procedures or experience based on

1 common use in food) to be safe under the con-
 2 ditions of its intended use.

3 “(B) EXCLUSIONS.—The term ‘generally
 4 recognized as safe’, with respect to a substance,
 5 does not include a substance that—

6 “(i) is carcinogenic;

7 “(ii) shows evidence of reproductive
 8 toxicity or developmental toxicity;

9 “(iii) is otherwise identified as toxic
 10 by the National Toxicology Program, the
 11 Environmental Protection Agency, the
 12 Agency for Toxic Substances and Disease
 13 Registry, or the California Office of Envi-
 14 ronmental Health Hazard Assessment;

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

19 “(v) was not synthesized, character-
 20 ized, or isolated prior to the date of enact-
 21 ment of the Ensuring Safe and Toxic-Free
 22 Foods Act of 2025.

23 “(5) REPRODUCTIVE TOXICITY.—The term ‘re-
 24 productive toxicity’, with respect to the effect of ex-
 25 posure to a substance on a human or animal, means

1 an adverse effect on the reproductive system of such
2 human or animal, which may include alterations to
3 reproductive system development, the endocrine sys-
4 tem, fertility, pregnancy, pregnancy outcomes, or
5 modifications in other functions that are dependent
6 on the integrity of the reproductive system.

7 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to carry out this section
9 such sums as are necessary.”.

10 (b) ADULTERATION.—Section 402(a)(2)(C)(i) of the
11 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
12 342(a)(2)(C)(i)) is amended by inserting “or any other
13 substance that is not generally recognized as safe in com-
14 pliance with section 409A” after “section 409”.

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

18 (1) by striking “if such substance is not gen-
19 erally recognized, among experts qualified by sci-
20 entific training and experience to evaluate its safety,
21 as having been adequately shown through scientific
22 procedures (or, in the case of a substance used in
23 food prior to January 1, 1958, through either sci-
24 entific procedures or experience based on common

1 use in food) to be safe under the conditions of its
 2 intended use;”;

3 (2) in paragraph (5), by striking “or” at the
 4 end;

5 (3) in paragraph (6), by striking the period and
 6 inserting “; or”; and

7 (4) by adding at the end the following:

8 “(7) a substance generally recognized as safe in
 9 compliance with section 409A.”.

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

13 **SEC. 3. FOOD CHEMICAL REASSESSMENT.**

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

17 **“SEC. 409B. FOOD CHEMICAL REASSESSMENT.**

18 **“(a) SAFETY REASSESSMENTS.—**

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

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

4 “(B) to establish the conditions of use, if
5 any, under which any such substance or class of
6 substances may be used safely within the mean-
7 ing of such section 409 or 409A.

8 “(2) REQUIREMENTS FOR MANUFACTURERS.—
9 The Secretary may require any manufacturer of a
10 substance or class of substances that is being reas-
11 sessed under paragraph (1) to provide data or to
12 conduct evaluations of such substance or class of
13 substances for purposes of the reassessment under
14 paragraph (1).

15 “(3) PRIORITY.—The Secretary may give pri-
16 ority to the reassessment of a substance or class of
17 substances that is the subject of—

18 “(A) a food additive petition under section
19 409(b);

20 “(B) a color additive petition under section
21 721(d); or

22 “(C) a citizen petition to request the reas-
23 sessment, restriction, or revocation of an exist-
24 ing authorization of such substance or class of
25 substances.

1 “(b) CONSIDERATIONS.—In determining, for the pur-
2 poses of this section, whether a substance or class of sub-
3 stances is unsafe within the meaning of section 409 or
4 section 409A, the Secretary shall consider the information
5 described in clauses (i) through (vi) of section
6 409A(a)(3)(B).

7 “(c) RULE OF CONSTRUCTION.—Nothing in this sec-
8 tion alters the authority or duties of the Secretary with
9 respect to the administration and enforcement of section
10 409 or section 409A.”.

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