

119TH CONGRESS
1ST SESSION

H. R. 4958

To amend the Federal Food, Drug, and Cosmetic Act to require notification to the Food and Drug Administration prior to use of substances as generally recognized as safe, reassessment of the safety of certain substances marketed as generally recognized as safe, provide resources for reviews and reassessments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

AUGUST 12, 2025

Mr. PALLONE introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To amend the Federal Food, Drug, and Cosmetic Act to require notification to the Food and Drug Administration prior to use of substances as generally recognized as safe, reassessment of the safety of certain substances marketed as generally recognized as safe, provide resources for reviews and reassessments, 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 “Grocery Reform And
5 Safety Act” or the “GRAS Act”.

1 **SEC. 2. REMOVAL OF GRAS EXEMPTION FROM FOOD ADDI-**
2 **TIVE DEFINITION.**

3 (a) IN GENERAL.—Section 201(s) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) is
5 amended—

6 (1) by redesignating subparagraphs (1) through
7 (6) as clauses (A) through (G), respectively;

8 (2) by striking “The term ‘food additive’” and
9 inserting “(1) The term ‘food additive’”;

10 (3) by striking “, if such substance is” and all
11 that follows through “of its intended use;” and in-
12 serting “, including a substance that is generally
13 recognized as safe,”; and

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

15 “(2) The term ‘generally recognized as safe’ means,
16 with respect to a substance used in food as described in
17 subparagraph (1), that such substance is generally recog-
18 nized, among experts qualified by scientific training and
19 experience to evaluate its safety, as having been ade-
20 quately shown through scientific procedures (or, in the
21 case of a substance used in food prior to January 1, 1958,
22 through either scientific procedures or experience based on
23 common use in food) to be safe under the conditions of
24 its intended use.”.

25 (b) CONFORMING AMENDMENT.—Section 408(k)(2)
26 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

1 346a(k)(2)) is amended by striking “section 201(s)(4)”
2 and inserting “section 201(s)(1)(D)”.

3 **SEC. 3. GRAS NOTIFICATIONS.**

4 Section 409 of the Federal Food, Drug, and Cosmetic
5 Act (21 U.S.C. 348) is amended—

6 (1) in subsection (a)—

7 (A) in paragraph (2), by striking the “or”
8 at the end;

9 (B) in paragraph (3), by striking the pe-
10 riod at the end and inserting “; or”; and

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

12 “(4) the food additive is generally recognized as
13 safe, and the procedural requirements of subsection
14 (l) have been met with respect to the food additive.”;
15 and

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

17 “(1) NOTICES REGARDING USE OF GRAS SUB-
18 STANCES.—

19 “(1) IN GENERAL.—Any person that manufac-
20 tures, introduces, delivers for introduction, or re-
21 ceives a food substance in interstate commerce that
22 is intending to treat such food substance as gen-
23 erally recognized as safe (in this subsection referred
24 to as ‘GRAS’) shall, with respect to any new use of
25 such substance or use of a food substance that was

1 not marketed for use in foods in the United States
2 before the date of enactment of this subsection, sub-
3 mit to the Secretary a notice prescribing the condi-
4 tions under which such person determined such sub-
5 stance is GRAS.

6 “(2) REQUIRED INFORMATION.—A notice sub-
7 mitted under paragraph (1) with respect to a food
8 substance shall include publicly available supporting
9 data and information sufficient to demonstrate the
10 identity and composition, the manufacturing process,
11 the intended effect, and the safety of the food sub-
12 stance, used as the basis of the GRAS determina-
13 tion, including full reports of investigations made
14 with respect to the safety for use of such substance,
15 including—

16 “(A) information as to the methods and
17 controls used in conducting such investigations;

18 “(B) information on the cumulative effects
19 of such substance;

20 “(C) information on hazard, dose response,
21 and exposure;

22 “(D) information on the application of ade-
23 quately protective safety factors to ensure an
24 appropriate margin of safety to take into ac-

1 count uncertainties in hazard identification,
2 dose response, exposure, and sensitivities;

3 “(E) information demonstrating the anal-
4 ysis that the weight of the evidence shows that
5 such substance has not been found to be car-
6 cinogenic;

7 “(F) information demonstrating the anal-
8 ysis that the weight of the evidence shows that
9 such substance has not been found to induce re-
10 productive toxicity or developmental toxicity in
11 humans or animals, including through an endo-
12 crine mode of action; and

13 “(G) such other information that forms the
14 recognition of safety as the Secretary may pub-
15 licly specify.

16 “(3) FORM OF NOTICE.—A notice submitted
17 under paragraph (1) with respect to a food sub-
18 stance shall be submitted in such form and manner
19 as specified in subpart E of part 170 of title 21,
20 Code of Federal Regulations (or successor regula-
21 tions).

22 “(4) STATEMENT NOT TO OBJECT TO USE.—A
23 person may use a substance subject to a notice
24 under paragraph (1) only if the Secretary has issued
25 a written statement to not object to the determina-

1 tion that the substance is GRAS under the condi-
2 tions prescribed in the notice.

3 “(5) STATEMENT TO OBJECT.—The Secretary
4 shall issue a written statement objecting to use of a
5 substance subject to a notice under paragraph (1) if
6 the Secretary determines that—

7 “(A) the notice does not contain the sup-
8 porting data and information described in para-
9 graph (2);

10 “(B) with respect to any such supporting
11 data and information that was provided by an
12 expert, such expert appears to have a conflict of
13 interest, as determined pursuant to guidance
14 issued by the Secretary; or

15 “(C) such supporting data and information
16 does not adequately support a determination
17 that the substance is GRAS under the condi-
18 tions prescribed in the notice.

19 “(6) DETERMINATION TIMELINE.—

20 “(A) IN GENERAL.—The Secretary shall—

21 “(i) not later than 180 days after the
22 acceptance of a notice under paragraph
23 (1), issue a written statement under para-
24 graph (4) or (5); or

1 “(ii) provide written notice to extend
2 the 180-day period described in subpara-
3 graph (A) for one additional 90-day period,
4 as specified in regulations.

5 “(B) CORRECTIONS.—The timeline set
6 forth in subparagraph (A) shall not be con-
7 strued to limit the authority of the Secretary to
8 correct a statement of the Secretary to not ob-
9 ject to the determination that the substance is
10 GRAS if new evidence is subsequently pre-
11 sented or discovered.

12 “(7) PUBLIC AVAILABILITY AND COMMENT.—
13 The Secretary shall—

14 “(A) upon acceptance of a notice under
15 paragraph (1)—

16 “(i) make such notice, and the sup-
17 porting data and information described in
18 paragraph (2), publicly available in a sin-
19 gle location on the website of the Food and
20 Drug Administration; and

21 “(ii) provide an opportunity for public
22 comment for a period of not less than 60
23 days; and

24 “(B) upon close of the comment period,
25 make any written statement issued under para-

1 graph (4) or (5) publicly available in the same
2 location.

3 “(8) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated such sums as
5 may be necessary to carry out this subsection.”.

6 **SEC. 4. REASSESSMENTS.**

7 Section 409 of the Federal Food, Drug, and Cosmetic
8 Act (21 U.S.C. 348), as amended by section 3, is further
9 amended by adding at the end the following:

10 “(m) REASSESSMENTS.—

11 “(1) IN GENERAL.—Not later than 3 years
12 after the date of enactment of this subsection, and
13 at least every 3 years thereafter, the Secretary shall
14 systematically reassess the safety (including the
15 safety of conditions of use), within the meaning of
16 section 409, of at least 10 of the following sub-
17 stances (or classes thereof):

18 “(A) Food additives marketed pursuant to
19 an order under subsection (c).

20 “(B) Any substance which was, before the
21 date of the enactment of this subsection, con-
22 sidered generally recognized as safe.

23 “(C) Color additives.

1 “(D) Prior-sanctioned substances (as de-
2 scribed in subparagraph (D) of section
3 201(s)(1)).

4 “(E) Food contact substances.

5 “(2) SAFETY EVALUATIONS.—In conducting the
6 reassessments under this subsection, the Secretary
7 may require any person that manufactures, intro-
8 duces, delivers for introduction, or receives a food
9 substance described in paragraph (1) in interstate
10 commerce to conduct, and submit to the Secretary,
11 safety evaluations of such substance. Such a safety
12 evaluation shall include, with respect to such sub-
13 stance, updated information on—

14 “(A) estimates of dietary exposure among
15 the United States population;

16 “(B) the cumulative effects of such sub-
17 stance;

18 “(C) hazard, dose response, and exposure;

19 “(D) the application of adequately protec-
20 tive safety factors to ensure an appropriate
21 margin of safety to take into account uncertain-
22 ties in hazard identification, dose response, ex-
23 posure, and sensitivities;

1 “(E) whether the weight of the evidence
2 shows that such substance has not been found
3 to be carcinogenic;

4 “(F) whether the weight of the evidence
5 shows that such substance has not been found
6 to induce reproductive toxicity or developmental
7 toxicity in humans or animals, including
8 through an endocrine mode of action; and

9 “(G) such other information as the Sec-
10 retary may specify in regulation.

11 “(3) REVOKING STATEMENT TO NOT OBJECT.—
12 If the Secretary determines, with respect to a sub-
13 stance described in paragraph (1)(B), based on in-
14 formation received under paragraph (2) and publicly
15 available information, that a concern about the safe-
16 ty of the substance, or the intended use of the sub-
17 stance, exists, the Secretary—

18 “(A) may revoke a written statement pre-
19 viously issued by the Secretary to not object to
20 a determination that the substance is generally
21 recognized as safe; and

22 “(B) shall post such revocation in the loca-
23 tion on the website of the Food and Drug Ad-
24 ministration referred to in subsection (1)(7).

1 “(4) NOTICES OF SUBSTANCES MARKETED AS
2 GRAS.—The Secretary may require a person that
3 manufactures, introduces, delivers for introduction,
4 or receives a food substance described in paragraph
5 (1) in interstate commerce that was marketed as
6 generally recognized as safe before, on, and after the
7 date of enactment of this subsection to submit to the
8 Secretary a notification that such person so mar-
9 keted the substance as generally recognized as safe.

10 “(5) CIVIL MONETARY PENALTIES.—In the case
11 of a violation of this subsection, the Secretary shall
12 assess a civil penalty in accordance with section 307.

13 “(6) AUTHORIZATION OF APPROPRIATIONS.—
14 There is authorized to be appropriated such sums as
15 may be necessary to carry out this subsection.”.

16 **SEC. 5. DEFINITIONS.**

17 (a) IN GENERAL.—Section 409 of the Federal Food,
18 Drug, and Cosmetic Act (21 U.S.C. 348), as amended by
19 sections 3 and 4, is further amended by adding at the end
20 the following:

21 “(n) DEFINITIONS.—In this section:

22 “(1) CARCINOGENIC.—The term ‘carcinogenic’
23 means, with respect to a substance, that such sub-
24 stance has been found—

1 “(A) to induce cancer when ingested by
2 humans or animals; or

3 “(B) after evaluation through appropriate
4 testing methods, by research or assessment con-
5 ducted by an authoritative scientific body (such
6 as the Environmental Protection Agency, the
7 International Agency for Research on Cancer,
8 or the National Toxicology Program), to induce
9 cancer in humans or animals.

10 “(2) CLASS.—The term ‘class’, with respect to
11 a substance, means a group of chemicals that are
12 chemically similar or cause similar or related phar-
13 macological effects.

14 “(3) CONFLICT OF INTEREST.—The term ‘con-
15 flict of interest’ means a personal or financial inter-
16 est that could potentially compromise the profes-
17 sional judgment or objectivity of an individual in de-
18 signing, conducting, reporting, or reviewing research
19 or the applicability of research, potentially under-
20 mining the integrity of such research.

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

1 “(5) DEVELOPMENTAL TOXICITY.—The term
2 ‘developmental toxicity’ means, with respect to the
3 effect of exposure to a substance on a human or ani-
4 mal, an adverse effect on the development of such
5 human or animal that results from such exposure—

6 “(A) to the mother prior to conception of,
7 or during the prenatal period for, such human
8 or animal; or

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

11 “(6) FOOD CONTACT SUBSTANCE.—The term
12 ‘food contact substance’ means any substance in-
13 tended for use as a component of materials used in
14 manufacturing, packing, packaging, transporting, or
15 holding food if such use is not intended to have any
16 technical effect in such food.

17 “(7) NEW USE.—The term ‘new use’ means a
18 use other than—

19 “(A) a use of a substance generally recog-
20 nized as safe before, on, and after the date of
21 enactment of this subsection;

22 “(B) a use of a substance treated as gen-
23 erally recognized as safe under subsection (1);
24 or

1 “(C) a use of a prior-sanctioned substance
2 (as described in subparagraph (D) of section
3 201(s)(1)).

4 “(8) REPRODUCTIVE TOXICITY.—The term ‘re-
5 productive toxicity’ means, with respect to the effect
6 of exposure to a substance on a human or animal,
7 an adverse effect on the reproductive system of such
8 human or animal, which may include alterations to
9 reproductive system development, the endocrine sys-
10 tem, fertility, pregnancy, pregnancy outcomes, or
11 modifications in other functions that are dependent
12 on the integrity of the reproductive system.”.

13 (b) CONFORMING AMENDMENTS.—

14 (1) Section 201(q)(1)(B)(ii) of the Federal
15 Food, Drug, and Cosmetic Act (21 U.S.C.
16 321(q)(1)(B)(ii)) is amended by striking “section
17 409(h)(6)” and inserting “section 409(n)”.

18 (2) Section 409(h) of the Federal Food, Drug,
19 and Cosmetic Act (21 U.S.C. 348(h)) is amended by
20 striking paragraph (6).

21 **SEC. 6. FOOD ADDITIVE AND GRAS SUBSTANCE FEES.**

22 Section 743 of the Federal Food, Drug, and Cosmetic
23 Act (21 U.S.C. 379j–31) is amended—

24 (1) in subsection (a)(1)—

1 (A) in subparagraph (C), by striking
2 “and” at the end;

3 (B) in subparagraph (D), by striking the
4 period at the end and inserting a semicolon;
5 and

6 (C) by adding at the end the following:

7 “(E) each person filing a petition or sub-
8 mitting a notice with respect to a food additive,
9 for purposes of issuing regulations or reviewing
10 notices under section 409 prescribing the condi-
11 tions under which such food additive may be
12 safely used; and

13 “(F) each person that manufactures, intro-
14 duces, delivers for introduction, or receives a
15 food substance in interstate commerce that is
16 subject to a reassessment under subsection (m)
17 of section 409, for purposes of conducting such
18 reassessment.”;

19 (2) in subsection (b)—

20 (A) in paragraph (2)(A)—

21 (i) in clause (iii), by striking “and” at
22 the end;

23 (ii) in clause (iv), by striking the pe-
24 riod at the end and inserting “; and”; and

1 (iii) by adding at the end the fol-
2 lowing:

3 “(v) under subparagraph (E) or (F)
4 of subsection (a)(1) for a fiscal year shall
5 be based on the Secretary’s estimate of
6 100 percent of the costs of the activities
7 described in such subparagraph (E) or (F)
8 for such year.”; and

9 (B) in paragraph (3), by striking “clause
10 (i), (ii), (iii), and (iv)” each place it appears
11 and inserting “clause (i), (ii), (iii), (iv), and
12 (v)”;

13 (3) in subsection (c)—

14 (A) in paragraph (1)—

15 (i) by striking “fiscal year 2010” and
16 inserting “fiscal year 2026”; and

17 (ii) by striking “fiscal year 2009” and
18 inserting “fiscal year 2025”; and

19 (B) in paragraph (3)(B), by striking “fis-
20 cal year 2009” and inserting “fiscal year
21 2025”.

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