

119TH CONGRESS
1ST SESSION

H. R. 4306

To amend the Federal Food, Drug, and Cosmetic Act to require the Office of Food Chemical Safety, Dietary Supplements, and Innovation to conduct food chemical safety reassessments, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 10, 2025

Ms. SCHAKOWSKY (for herself, Ms. DELAURO, Ms. ADAMS, Mr. CARSON, Ms. JAYAPAL, Mr. KHANNA, Mr. KRISHNAMOORTHY, Ms. MENG, Mr. MOULTON, Mr. MULLIN, Ms. NORTON, Ms. PINGREE, Ms. TITUS, and Ms. TLAIB) 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 the Office of Food Chemical Safety, Dietary Supplements, and Innovation to conduct food chemical safety 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 “Food Chemical Reas-
5 sessment Act of 2025”.

1 **SEC. 2. FOOD SAFETY REASSESSMENTS.**

2 Section 409 of the Federal Food, Drug, and Cosmetic
3 Act (21 U.S.C. 348) is amended by adding at the end the
4 following:

5 “(l) FOOD SAFETY REASSESSMENTS.—

6 “(1) IN GENERAL.—Not less frequently than
7 once every 3 years beginning with 2026, the Office
8 of Food Chemical Safety, Dietary Supplements, and
9 Innovation (referred to in this section as the ‘Of-
10 fice’), shall systematically and continuously reassess
11 the safety of not less than a combination of 10 of
12 the following substances (or classes thereof):

13 “(A) Food additives marketed pursuant to
14 an order under subsection (c).

15 “(B) Color additives, as defined in section
16 201(t).

17 “(C) Substances generally recognized as
18 safe for use in food (as defined in section
19 201(s)).

20 “(D) Prior-sanctioned substances, or class-
21 es thereof (as described in section 201(s)(4)).

22 “(E) Food contact substances, as defined
23 in subsection (h)(6).

24 “(2) PUBLIC NOTICE.—The Secretary shall pro-
25 vide public notice of the determinations made from
26 each reassessment conducted under paragraph (1).

1 “(3) EFFECT OF REASSESSMENT.—The Sec-
2 retary shall—

3 “(A) in the case of a reassessment of a
4 substance described in subparagraph (A) of
5 paragraph (1), amend or repeal a regulation
6 under subsection (c) issued with respect to such
7 substance if such reassessment demonstrates
8 that the substance is not safe;

9 “(B) in the case of a reassessment of a
10 substance described in subparagraph (B) of
11 paragraph (1), amend or repeal a regulation
12 under section 721 issued with respect to such
13 substance if such reassessment demonstrates
14 that the substance is not safe;

15 “(C) in the case of a reassessment of a
16 substance described in subparagraph (C) of
17 paragraph (1), make public on the website of
18 the Food and Drug Administration the deter-
19 mination that—

20 “(i) any such substance is safe for
21 purposes of this subsection and estab-
22 lishing the conditions of use, if any, under
23 which any such substance or class of sub-
24 stances can be used safely; or

1 “(ii) any such substance or class of
2 substances is unsafe for purposes of this
3 section;

4 “(D) in the case of a reassessment of a
5 substance described in subparagraph (D) of
6 paragraph (1), revoke the prior-sanctioned use
7 of the substance if such reassessment dem-
8 onstrates the prior-sanctioned use of such sub-
9 stance may be injurious to health; and

10 “(E) in the case of a reassessment of a
11 substance described in subparagraph (E) of
12 paragraph (1), determine that a pre-market no-
13 tification under subsection (h) for the food con-
14 tact substance involved is no longer effective if
15 such reassessment demonstrates that the use of
16 such substance is not safe.

17 “(4) DETERMINATION OF SUBSTANCES SUB-
18 JECT TO REASSESSMENT.—

19 “(A) IN GENERAL.—In determining which
20 substances or classes of substances to reassess
21 under paragraph (1), the Secretary shall
22 prioritize substances or classes thereof by public
23 health need.

24 “(B) FIRST SUBSTANCES SUBJECT TO RE-
25 ASSESSMENT.—The Secretary may select, as

1 the first 10 substances (or classes thereof) to be
2 reassessed under this subsection, the following:

3 “(i) Tert-butylhydroquinone.

4 “(ii) Titanium dioxide.

5 “(iii) Red dye 40, yellow dye 5, yellow
6 dye 6, blue dye 01, blue dye 02, and green
7 dye 03.

8 “(iv) Perchlorate.

9 “(v) Butylated hydroxyanisole (BHA).

10 “(vi) Butylated hydroxytoluene
11 (BHT).

12 “(vii) Trichloroethylene, methylene
13 chloride, benzene, and ethylene chloride.

14 “(viii) Propyl gallate.

15 “(ix) Sodium benzoate.

16 “(x) Sodium nitrite.

17 “(5) RULE OF CONSTRUCTION.—Nothing in
18 this subsection alters the authority or duties of the
19 Secretary with respect to the administration and en-
20 forcement of the preceding provisions of this section.

21 “(6) FOOD ADVISORY COMMITTEE.—Not later
22 than 180 days after the date of enactment of the
23 Food Chemical Reassessment Act of 2025, the Sec-
24 retary shall re-establish the Food Advisory Com-
25 mittee to advise the Secretary with respect to—

1 “(A) the standards for reassessments con-
2 ducted under this section; and

3 “(B) the process and methods necessary to
4 complete the work of the Office.

5 “(7) CLASS DEFINED.—In this subsection, the
6 term ‘class’, with respect to substances referred to
7 in paragraph (1), means a group of chemicals that
8 are chemically similar or cause similar or related
9 pharmacological effects.”.

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