

118TH CONGRESS
2D SESSION

H. R. 9817

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to update and clarify its rule on substances generally recognized as safe, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2024

Ms. DELAURO introduced the following bill; which was referred to the
Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, to update and clarify its rule on substances generally recognized as safe, 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 “Toxic Free Food Act
5 of 2024”.

6 **SEC. 2. DIRECTED RULEMAKING REGARDING SUBSTANCES**

7 **GENERALLY RECOGNIZED AS SAFE.**

8 (a) DIRECTED RULEMAKING.—

1 (1) IN GENERAL.—The Secretary of Health and
2 Human Services, acting through the Commissioner
3 of Food and Drugs, shall—

4 (A) not later than 180 days after the date
5 of enactment of this Act, publish a proposed re-
6 vision to the final rule titled “Substances Gen-
7 erally Recognized as Safe”, published by the
8 Food and Drug Administration on August 17,
9 2016 (81 Federal Register 54960 et seq.); and

10 (B) not later than 90 days after the close
11 of the period for public comment on the revision
12 proposed pursuant to subparagraph (A), pub-
13 lish a final revision to such final rule.

14 (2) CONTENTS.—The revision required by para-
15 graph (1) shall include each of the following:

16 (A) The revision shall prohibit a manufac-
17 turer from marketing a substance as GRAS, or
18 manufacturing or selling food that contains a
19 substance the manufacturer has determined to
20 be GRAS, unless—

21 (i) the Secretary has received notice
22 that the manufacturer has determined
23 such substance to be GRAS; and

24 (ii) the manufacturer has provided the
25 Secretary with supporting information suf-

1 ficient to understand the basis of the de-
2 termination, including, as required by the
3 Federal Food, Drug, and Cosmetic Act (21
4 U.S.C. 301 et seq.)—

5 (I) the cumulative effects of the
6 substance, as required under section
7 409 of such Act (21 U.S.C. 348);

8 (II) an adequately protective use
9 of safety factors; and

10 (III) application of a margin of
11 safety to take into account the im-
12 pacts of exposures during critical win-
13 dows of development and on vulner-
14 able populations.

15 (B) The revision shall require the Sec-
16 retary—

17 (i) to make each determination that is
18 submitted pursuant to subparagraph
19 (A)(i), and the supporting information sub-
20 mitted pursuant to subparagraph (A)(ii),
21 publicly available on the website of the
22 Food and Drug Administration; and

23 (ii) provide a period of at least 90
24 days for the Secretary and the public to re-
25 view each such determination and object, if

1 appropriate, in order to ensure that the
2 substance involved is safe taking into ac-
3 count the factors listed in section
4 409(c)(5) of the Federal Food, Drug, and
5 Cosmetic Act (21 U.S.C. 348(c)(5)).

6 (C) The revision shall clarify that newly
7 synthesized or novel chemical substances cannot
8 be GRAS.

9 (D) The revision shall clarify that carcino-
10 genic substances cannot be GRAS.

11 (E) The revision shall—

12 (i) prohibit the Secretary from relying
13 on the determination of experts with con-
14 flicts of interest when determining a sub-
15 stance to be GRAS; and

16 (ii) incorporate the recommendations
17 in the draft guidance titled “Best Practices
18 for Convening a GRAS Panel”, issued by
19 the Food and Drug Administration in No-
20 vember, 2017, and measures to strengthen
21 the recommendations in such guidance.

22 (F) The revision shall create a process that
23 requires the Secretary to systematically reassess
24 any substance that was determined to be GRAS

1 if such determination did not meet the revised
2 standards for such a determination.

3 (b) FOOD ADVISORY COMMITTEE.—Not later than
4 180 days after the date of enactment of this Act, the Sec-
5 retary shall—

6 (1) reestablish the Food Advisory Committee to
7 work with the Secretary on the reassessment stand-
8 ards, process, and methods necessary to complete
9 the work described in subsection (a)(2)(F); and

10 (2) provide such Committee with such staffing
11 and resources as are necessary to complete such
12 work.

13 (c) DEFINITIONS.—In this subsection:

14 (1) The term “GRAS” means, with respect to
15 a substance, generally recognized, among experts
16 qualified by scientific training and experience to
17 evaluate its safety, as having been adequately shown
18 through scientific procedures (or, in the case of a
19 substance used in food prior to January 1, 1958,
20 through either scientific procedures or experience
21 based on common use in food) to be safe under the
22 conditions of its intended use, as described in section
23 201(s) of the Federal Food, Drug, and Cosmetic Act
24 (21 U.S.C. 321).

- 1 (2) The term “Secretary” means the Secretary
2 of Health and Human Services.

