

117TH CONGRESS  
1ST SESSION

# H. R. 3699

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.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 4, 2021

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

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## 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 2021”.

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 in 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.

