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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.

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Toxic Free Food Act of 2021''.

SEC. 2. DIRECTED RULEMAKING REGARDING SUBSTANCES GENERALLY RECOGNIZED AS SAFE.

(a) DIRECTED RULEMAKING.—

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

(A) not later than 180 days after the date of enactment of this Act, publish a proposed revision to the final rule titled ''Substances Generally Recognized as Safe'', published by the Food and Drug Administration on August 17, 2016 (81 Federal Register 54960 et seq.); and

(B) not later than 90 days after the close of the period for public comment on the revision proposed pursuant to subparagraph (A), publish a final revision to such final rule.

(2) CONTENTS.—The revision required by paragraph (1) shall include each of the following:

(A) The revision shall prohibit a manufacturer from marketing a substance as GRAS, or manufacturing or selling food that contains a substance the manufacturer has determined to be GRAS, unless—

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

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

ficient to understand the basis of the determination, including, as required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)—

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

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

(III) application of a margin of safety to take into account the impacts of exposures during critical windows of development and on vulnerable populations.

(B) The revision shall require the Secretary—

(i) to make each determination that is submitted pursuant to subparagraph (A)(i), and the supporting information submitted pursuant to subparagraph (A)(ii), publicly available on the website of the Food and Drug Administration; and

(ii) provide a period of at least 90 days for the Secretary and the public to review each such determination and object, if

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

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

(D) The revision shall clarify that carcinogenic substances cannot be GRAS.

(E) The revision shall—

(i) prohibit the Secretary from relying on the determination of experts with conflicts of interest when determining a substance to be GRAS; and

(ii) incorporate the recommendations in the draft guidance titled ''Best Practices for Convening a GRAS Panel'', issued by the Food and Drug Administration in November, 2017, and measures to strengthen the recommendations in such guidance.

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

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

(b) FOOD ADVISORY COMMITTEE.—Not later than 180 days after the date of enactment of this Act, the Secretary shall—

(1) reestablish the Food Advisory Committee to work with the Secretary on the reassessment standards, process, and methods necessary to complete the work described in subsection (a)(2)(F); and

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

(c) DEFINITIONS.—In this subsection:

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

(2) The term ''Secretary'' means the Secretary of Health and Human Services.

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