II

117TH CONGRESS
2D SESSION

S. 4316

To direct the Secretary of Health and Human Services to update and clarify its rule on substances generally recognized as safe and to establish within the Center for Food Safety and Applied Nutrition of the Food and Drug Administration the Office of Food Chemical Safety Reassessment, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MAY 26, 2022

Mr. MARKEY (for himself, Mr. BLUMENTHAL, and Ms. WARREN) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To direct the Secretary of Health and Human Services to update and clarify its rule on substances generally recognized as safe and to establish within the Center for Food Safety and Applied Nutrition of the Food and Drug Administration the Office of Food Chemical Safety Reassessment, 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 ''Ensuring Safe and Toxic-Free Foods Act of 2022''.

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

(a) DEFINITIONS.—In this section:

(1) GRAS.—The term ''GRAS'', with respect to the use of a substance in food, has the meaning given the term ''generally recognized as safe for use in food'' in section 409A(a) of the Federal Food, Drug, and Cosmetic Act, as added by section 3.

(2) REPRODUCTIVE OR DEVELOPMENTAL TOXICITY.—The term ''reproductive or developmental toxicity'' has the meaning given such term in such section 409A(a).

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs.

(4) VULNERABLE HUMAN POPULATIONS.—The term ''vulnerable human population'' has the meaning given such term in such section 409A(a).

(b) DIRECTED RULEMAKING.—

(1) IN GENERAL.—The Secretary shall—

(A) not later than 1 year 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 Fed. Reg. 54960);

(B) not later than 180 days after the close of the period for public comment on the revision proposed under subparagraph (A), publish a final revision to such final rule; and

(C) not later than 180 days after the date of enactment of this Act, finalize the draft guidance titled ''Best Practices for Convening a GRAS Panel'', issued by the Food and Drug Administration in November 2017.

(2) CONTENTS.—The revision required by subparagraphs (A) and (B) of 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 made a final determination, which is conveyed to the manufacturer in writing, that the Secretary has received sufficient notice that the manufacturer has determined such substance to be GRAS under the conditions of its intended use; and

(ii) the manufacturer has provided the Secretary with supporting information sufficient to understand the basis of the determination, including—

(I) the cumulative effects of the substance, as required under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348);

(II) an adequately protective use of safety factors, as required under such section 409, including safety factors to account for the particular sensitivities of vulnerable human populations to the extent that data are available to derive safety factors for each vulnerable human population;

(III) information indicating that the weight of evidence shows the substance has not been found to induce cancer when ingested by humans or animals; and

(IV) information indicating that the weight of evidence shows the substance has not been found to induce reproductive or developmental toxicity

when ingested by humans or animals, including through an endocrine mode of action.

(B) The revision shall require—

(i) the Secretary 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;

(ii) 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 listed in subparagraph (A) and in paragraphs (3) through (5) of section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)); and

(iii) the Secretary's objection, or decision not to object, to be considered final agency action.

(C) The revision shall clarify that substances that are known (or reasonably antici-

pated) to cause cancer in humans identified by the National Toxicology Program cannot be GRAS.

(D) The revision shall clarify that substances that show clear evidence (or some evidence) of human reproductive or developmental toxicity identified by the National Toxicology Program cannot be GRAS.

(E) The revision shall clarify that any substance that was not marketed for use in foods in the United States before issuance of the revised rule cannot be GRAS and shall be approved by the Secretary through a food additive petition as required by section 409(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)) prior to being marketed in food.

(F) The revision shall—

(i) incorporate standards prohibiting conflict of interests among experts providing data for substances submitted for GRAS review; and

(ii) incorporate measures to strengthen the recommendations in the guidance described in paragraph (1)(C).

(G) The revision shall create a process that requires the Secretary to systematically reassess any substance that was determined to be GRAS if the initial determination did not meet the revised standards for such a determination, in accordance with the procedures and resources in section 409A of the Federal Food, Drug, and Cosmetic Act, as added by section 3.

SEC. 3. OFFICE OF FOOD CHEMICAL SAFETY REASSESSMENT.

Chapter IV of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341 et seq.) is amended by inserting after section 409 (21 U.S.C. 348) the following:

"SEC. 409A. OFFICE OF FOOD CHEMICAL SAFETY REASSESSMENT.

''(a) DEFINITIONS.—In this section:

''(1) FOOD CONTACT SUBSTANCE.—The term 'food contact substance' has the meaning given such term in section 409(h)(6).

''(2) GENERALLY RECOGNIZED AS SAFE FOR USE IN FOOD.—The term 'generally recognized as safe for use in food' means, with respect to the use of a substance in food, that the substance is 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).

''(3) PRIOR-SANCTIONED SUBSTANCE.—The term 'prior-sanctioned substance' means a substance described in paragraph (4) of section 201(s).

''(4) REPRODUCTIVE OR DEVELOPMENTAL TOXICITY.—The term 'reproductive or developmental toxicity' means—

''(A) adverse effects on the reproductive systems of female or male humans or animals, that may include alterations to the female or male reproductive system development, the endocrine system, fertility, pregnancy, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system; or

''(B) adverse effects on developing organisms that result from exposure prior to conception, during the prenatal period, or until the time of sexual maturity.

''(5) VULNERABLE HUMAN POPULATION.—The term 'vulnerable human population' means a human population that is subject to the potential for disproportionate exposure to, or the potential for disproportionate adverse effects from exposure to, a chemical substance or mixture, including—

''(A) infants, children, and adolescents;

''(B) pregnant or breastfeeding women;

''(C) the elderly;

''(D) individuals with preexisting medical conditions;

''(E) workers who may be exposed to chemical substances and mixtures;

''(F) residents in communities subject to disproportionate exposures or adverse effects; and

''(G) members of any other appropriate population identified by the Secretary.

''(b) ESTABLISHMENT.—Not later than 1 year after the date of the enactment of this section, the Secretary shall establish within the Center for Food Safety and Applied Nutrition of the Food and Drug Administration, an office to be known as the 'Office of Food Chemical Safety Reassessment' (referred to in this section as the 'Office'), to conduct reassessments of the safety, within the meaning

of section 409, of substances and classes of substances including food additives, food contact substances, substances generally recognized as safe for use in food, color additives, and prior-sanctioned substances.

''(c) SAFETY REASSESSMENTS.—Not less frequently than once every 3 years beginning in calendar year 2023, the Office shall—

''(1) reassess the safety of not less than 10 of the substances or classes of substances described in subsection (b); and

''(2) issue final regulations—

''(A) determining that any such substance or class of substance is safe within the meaning of section 409 and establishing the conditions of use, if any, under which any such substance or class of substances can be used safely within the meaning of such section; or

''(B) determining that any such substance or class of substances is unsafe within the meaning of such section.

''(d) CONSIDERATIONS.—In determining, for the purposes of this section, whether a substance or class of substances is unsafe within the meaning of section 409, the Secretary shall consider among other relevant factors—

''(1) the cumulative effects of the substance, as described under such section 409;

''(2) an adequately protective use of safety factors, as described under such section 409 including safety factors to account for the particular sensitivities of vulnerable human populations to the extent that data are available to derive safety factors for each vulnerable human population.

''(e) UNSAFE.—A substance or class of substances shall be deemed unsafe under this section within the meaning of section 409 if—

''(1) the substance or class has been found to induce cancer when ingested by man or animal; or

''(2) the substance or class has been found to induce reproductive or developmental toxicity when ingested by man or animal, including through an endocrine mode of action.

''(f) FIRST SUBSTANCES SUBJECT TO REASSESSMENT.—The first 10 substances or classes of substances reassessed by the Secretary under subsection (b) shall be the following:

''(1) Perfluoroalkyl substances and polyfluoroalkyl substances.

''(2) Ortho-phthalates.

''(3) The class of bisphenols.

''(4) Titanium dioxide.

''(5) Potassium bromate.

''(6) Perchlorate.

''(7) Butylated hydroxyanisole (BHA).

''(8) Butylated hydroxytoluene (BHT).

''(9) Brominated vegetable oil (BVO).

''(10) Propyl paraben.

''(g) SUBSEQUENT SUBSTANCES.—Prior to selecting subsequent substances or classes of substances to reassess in addition to those listed in subsection (f), the Secretary shall post a notice in the Federal Register requesting information and recommendations on which substances and classes should be reassessed. The information shall include substance or class name, uses, and data relating to the actual and potential hazards and impact on public health.

''(h) NOTICE PRIOR TO COMMENCEMENT.—Prior to commencing a reassessment of a substance or class of substances under subsection (f) or (g), the Secretary shall post a notice in the Federal Register requesting information on any uses of such substance or class in food, including as a prior-sanctioned substance, food contact substance, or substance that is generally recognized as safe for use in food. The information requested shall include when the uses commenced, the specific conditions of use, how they were determined to be safe, scientific evidence

relevant to the safety of the substance that has become available since its use in food commenced, and the anticipated amounts that may be found in food.

''(i) FOOD CHEMICAL COMMITTEE OF THE SCIENCE BOARD.—Not later than 180 days after the date of enactment of this section, the Secretary shall establish a standing Food Chemical Committee (referred to in this subsection as the 'Committee') within the Science Board to the Food and Drug Administration and provide resources and staffing as are necessary for the Committee to meet regularly and complete their work. The Committee shall advise the Secretary with respect to—

''(1) the standards for reassessments conducted under this section; and

''(2) the process and methods necessary to complete the work of the Office.

''(j) RULE OF CONSTRUCTION.—Nothing in this section alters the authority or duties of the Secretary with respect to the administration and enforcement of section 409.''.

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