

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

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.

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 “Ensuring Safe and
5 Toxic-Free Foods Act of 2022”.

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

2 **GENERALLY RECOGNIZED AS SAFE.**

3 (a) DEFINITIONS.—In this section:

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

9 (2) REPRODUCTIVE OR DEVELOPMENTAL TOX-
10 ICITY.—The term “reproductive or developmental
11 toxicity” has the meaning given such term in such
12 section 409A(a).

13 (3) SECRETARY.—The term “Secretary” means
14 the Secretary of Health and Human Services, acting
15 through the Commissioner of Food and Drugs.

16 (4) VULNERABLE HUMAN POPULATIONS.—The
17 term “vulnerable human population” has the mean-
18 ing given such term in such section 409A(a).

19 (b) DIRECTED RULEMAKING.—

20 (1) IN GENERAL.—The Secretary shall—

21 (A) not later than 1 year after the date of
22 enactment of this Act, publish a proposed revi-
23 sion to the final rule titled “Substances Gen-
24 erally Recognized as Safe”, published by the
25 Food and Drug Administration on August 17,
26 2016 (81 Fed. Reg. 54960);

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

5 (C) not later than 180 days after the date
6 of enactment of this Act, finalize the draft guid-
7 ance titled “Best Practices for Convening a
8 GRAS Panel”, issued by the Food and Drug
9 Administration in November 2017.

10 (2) CONTENTS.—The revision required by sub-
11 paragraphs (A) and (B) of paragraph (1) shall in-
12 clude each of the following:

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

18 (i) the Secretary has made a final de-
19 termination, which is conveyed to the man-
20 ufacturer in writing, that the Secretary
21 has received sufficient notice that the man-
22 ufacturer has determined such substance
23 to be GRAS under the conditions of its in-
24 tended use; and

1 (ii) the manufacturer has provided the
2 Secretary with supporting information suf-
3 ficient to understand the basis of the de-
4 termination, including—

5 (I) the cumulative effects of the
6 substance, as required under section
7 409 of the Federal Food, Drug, and
8 Cosmetic Act (21 U.S.C. 348);

9 (II) an adequately protective use
10 of safety factors, as required under
11 such section 409, including safety fac-
12 tors to account for the particular sen-
13 sitivities of vulnerable human popu-
14 lations to the extent that data are
15 available to derive safety factors for
16 each vulnerable human population;

17 (III) information indicating that
18 the weight of evidence shows the sub-
19 stance has not been found to induce
20 cancer when ingested by humans or
21 animals; and

22 (IV) information indicating that
23 the weight of evidence shows the sub-
24 stance has not been found to induce
25 reproductive or developmental toxicity

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

4 (B) The revision shall require—

5 (i) the Secretary to make each deter-
6 mination that is submitted pursuant to
7 subparagraph (A)(i), and the supporting
8 information submitted pursuant to sub-
9 paragraph (A)(ii), publicly available on the
10 website of the Food and Drug Administra-
11 tion;

12 (ii) a period of at least 90 days for
13 the Secretary and the public to review each
14 such determination and object, if appro-
15 priate, in order to ensure that the sub-
16 stance involved is safe taking into account
17 the factors listed in subparagraph (A) and
18 in paragraphs (3) through (5) of section
19 409(c) of the Federal Food, Drug, and
20 Cosmetic Act (21 U.S.C. 348(c)); and

21 (iii) the Secretary's objection, or deci-
22 sion not to object, to be considered final
23 agency action.

24 (C) The revision shall clarify that sub-
25 stances that are known (or reasonably antici-

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

4 (D) The revision shall clarify that sub-
5 stances that show clear evidence (or some evi-
6 dence) of human reproductive or developmental
7 toxicity identified by the National Toxicology
8 Program cannot be GRAS.

9 (E) The revision shall clarify that any sub-
10 stance that was not marketed for use in foods
11 in the United States before issuance of the re-
12 vised rule cannot be GRAS and shall be ap-
13 proved by the Secretary through a food additive
14 petition as required by section 409(c) of the
15 Federal Food, Drug, and Cosmetic Act (21
16 U.S.C. 348(c)) prior to being marketed in food.

17 (F) The revision shall—

18 (i) incorporate standards prohibiting
19 conflict of interests among experts pro-
20 viding data for substances submitted for
21 GRAS review; and

22 (ii) incorporate measures to strength-
23 en the recommendations in the guidance
24 described in paragraph (1)(C).

1 (G) The revision shall create a process that
2 requires the Secretary to systematically reassess
3 any substance that was determined to be GRAS
4 if the initial determination did not meet the re-
5 vised standards for such a determination, in ac-
6 cordance with the procedures and resources in
7 section 409A of the Federal Food, Drug, and
8 Cosmetic Act, as added by section 3.

9 **SEC. 3. OFFICE OF FOOD CHEMICAL SAFETY REASSESS-**
10 **MENT.**

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

14 **“SEC. 409A. OFFICE OF FOOD CHEMICAL SAFETY REASSESS-**
15 **MENT.**

16 “(a) DEFINITIONS.—In this section:

17 “(1) FOOD CONTACT SUBSTANCE.—The term
18 ‘food contact substance’ has the meaning given such
19 term in section 409(h)(6).

20 “(2) GENERALLY RECOGNIZED AS SAFE FOR
21 USE IN FOOD.—The term ‘generally recognized as
22 safe for use in food’ means, with respect to the use
23 of a substance in food, that the substance is gen-
24 erally recognized, among experts qualified by sci-
25 entific training and experience to evaluate its safety,

1 as having been adequately shown through scientific
2 procedures (or, in the case of a substance used in
3 food prior to January 1, 1958, through either sci-
4 entific procedures or experience based on common
5 use in food) to be safe under the conditions of its
6 intended use, as described in section 201(s).

7 “(3) PRIOR-SANCTIONED SUBSTANCE.—The
8 term ‘prior-sanctioned substance’ means a substance
9 described in paragraph (4) of section 201(s).

10 “(4) REPRODUCTIVE OR DEVELOPMENTAL TOX-
11 ICITY.—The term ‘reproductive or developmental
12 toxicity’ means—

13 “(A) adverse effects on the reproductive
14 systems of female or male humans or animals,
15 that may include alterations to the female or
16 male reproductive system development, the en-
17 docrine system, fertility, pregnancy, pregnancy
18 outcomes, or modifications in other functions
19 that are dependent on the integrity of the re-
20 productive system; or

21 “(B) adverse effects on developing orga-
22 nisms that result from exposure prior to con-
23 ception, during the prenatal period, or until the
24 time of sexual maturity.

1 “(5) VULNERABLE HUMAN POPULATION.—The
2 term ‘vulnerable human population’ means a human
3 population that is subject to the potential for dis-
4 proportionate exposure to, or the potential for dis-
5 proportionate adverse effects from exposure to, a
6 chemical substance or mixture, including—

7 “(A) infants, children, and adolescents;

8 “(B) pregnant or breastfeeding women;

9 “(C) the elderly;

10 “(D) individuals with preexisting medical
11 conditions;

12 “(E) workers who may be exposed to
13 chemical substances and mixtures;

14 “(F) residents in communities subject to
15 disproportionate exposures or adverse effects;

16 and

17 “(G) members of any other appropriate
18 population identified by the Secretary.

19 “(b) ESTABLISHMENT.—Not later than 1 year after
20 the date of the enactment of this section, the Secretary
21 shall establish within the Center for Food Safety and Ap-
22 plied Nutrition of the Food and Drug Administration, an
23 office to be known as the ‘Office of Food Chemical Safety
24 Reassessment’ (referred to in this section as the ‘Office’),
25 to conduct reassessments of the safety, within the meaning

1 of section 409, of substances and classes of substances in-
2 cluding food additives, food contact substances, substances
3 generally recognized as safe for use in food, color addi-
4 tives, and prior-sanctioned substances.

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

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

11 “(2) issue final regulations—

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

18 “(B) determining that any such substance
19 or class of substances is unsafe within the
20 meaning of such section.

21 “(d) CONSIDERATIONS.—In determining, for the pur-
22 poses of this section, whether a substance or class of sub-
23 stances is unsafe within the meaning of section 409, the
24 Secretary shall consider among other relevant factors—

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

3 “(2) an adequately protective use of safety fac-
4 tors, as described under such section 409 including
5 safety factors to account for the particular sensitivi-
6 ties of vulnerable human populations to the extent
7 that data are available to derive safety factors for
8 each vulnerable human population.

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

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

14 “(2) the substance or class has been found to
15 induce reproductive or developmental toxicity when
16 ingested by man or animal, including through an en-
17 docrine mode of action.

18 “(f) FIRST SUBSTANCES SUBJECT TO REASSESS-
19 MENT.—The first 10 substances or classes of substances
20 reassessed by the Secretary under subsection (b) shall be
21 the following:

22 “(1) Perfluoroalkyl substances and
23 polyfluoroalkyl substances.

24 “(2) Ortho-phthalates.

25 “(3) The class of bisphenols.

1 “(4) Titanium dioxide.

2 “(5) Potassium bromate.

3 “(6) Perchlorate.

4 “(7) Butylated hydroxyanisole (BHA).

5 “(8) Butylated hydroxytoluene (BHT).

6 “(9) Brominated vegetable oil (BVO).

7 “(10) Propyl paraben.

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

16 “(h) NOTICE PRIOR TO COMMENCEMENT.—Prior to
17 commencing a reassessment of a substance or class of sub-
18 stances under subsection (f) or (g), the Secretary shall
19 post a notice in the Federal Register requesting informa-
20 tion on any uses of such substance or class in food, includ-
21 ing as a prior-sanctioned substance, food contact sub-
22 stance, or substance that is generally recognized as safe
23 for use in food. The information requested shall include
24 when the uses commenced, the specific conditions of use,
25 how they were determined to be safe, scientific evidence

1 relevant to the safety of the substance that has become
2 available since its use in food commenced, and the antici-
3 pated amounts that may be found in food.

4 “(i) FOOD CHEMICAL COMMITTEE OF THE SCIENCE
5 BOARD.—Not later than 180 days after the date of enact-
6 ment of this section, the Secretary shall establish a stand-
7 ing Food Chemical Committee (referred to in this sub-
8 section as the ‘Committee’) within the Science Board to
9 the Food and Drug Administration and provide resources
10 and staffing as are necessary for the Committee to meet
11 regularly and complete their work. The Committee shall
12 advise the Secretary with respect to—

13 “(1) the standards for reassessments conducted
14 under this section; and

15 “(2) the process and methods necessary to com-
16 plete the work of the Office.

17 “(j) RULE OF CONSTRUCTION.—Nothing in this sec-
18 tion alters the authority or duties of the Secretary with
19 respect to the administration and enforcement of section
20 409.”.

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