

114TH CONGRESS
2D SESSION

H. R. 6269

To ban the use of bisphenol A in food containers and the replacement of bisphenol A in such containers with unsafe alternatives, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2016

Ms. MENG (for herself and Mr. TED LIEU of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To ban the use of bisphenol A in food containers and the replacement of bisphenol A in such containers with unsafe alternatives, 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 “Ban Poisonous Addi-
5 tives Act of 2016”.

6 **SEC. 2. BAN ON USE OF BISPHENOL A IN FOOD AND BEV-**
7 **ERAGE CONTAINERS.**

8 (a) TREATMENT OF BISPHENOL A AS ADULTER-
9 ATING THE FOOD OR BEVERAGE.—

(1) IN GENERAL.—For purposes of applying section 402(a)(6) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(6)), a food container (which for purposes of this Act includes a beverage container) that is composed, in whole or in part, of bisphenol A, or that can release bisphenol A into food (as defined for purposes of the Federal Food, Drug, and Cosmetic Act), shall be treated as a container described in such section (relating to containers composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health).

(2) APPLICABILITY.—

(A) REUSABLE FOOD CONTAINERS.—Paragraph (1) shall apply to reusable food containers on the date that is 180 days after the date of enactment of this Act.

(B) OTHER FOOD CONTAINERS.—Paragraph (1) shall apply to any food container that is packed with food and is introduced or delivered for introduction into interstate commerce on or after the date that is 180 days after the date of enactment of this Act.

(b) WAIVER.—

1 (1) IN GENERAL.—The Secretary, after public
2 notice and opportunity for comment, may grant to
3 any facility (as that term is defined in section 415
4 of the Federal Food, Drug, and Cosmetic Act (21
5 U.S.C. 350d)) that manufactures, processes, packs,
6 holds, or sells the particular food product or prod-
7 ucts, a waiver of the treatment described in sub-
8 section (a).

9 (2) APPLICABILITY.—A waiver granted to a fa-
10 cility under paragraph (1) may only be applicable to
11 a certain type of food container or containers, as
12 used for a particular food product or group of simi-
13 lar products containing similar foods.

14 (3) REQUIREMENT FOR WAIVER.—The Sec-
15 retary may only grant a waiver under paragraph (1)
16 to a facility, if such facility—

17 (A) demonstrates that it is not techno-
18 logically feasible to—

19 (i) replace bisphenol A in the certain
20 type of container or containers for such
21 particular food product or products; or

22 (ii) use an alternative container that
23 does not contain bisphenol A for such par-
24 ticular food product or products; and

(B) submits to the Secretary a plan and timeline for removing bisphenol A from such type of container or containers for that food product or products.

(4) LABELING.—

(A) IN GENERAL.—Any product for which the Secretary grants such a waiver shall display a prominent warning on the label that the container contains bisphenol A that states, “bisphenol A (BPA) is a chemical that can leach into food and may harm prenatal development and the health of children and adults”.

(B) ADDITIONAL REQUIREMENT.—The prominent warning required under subparagraph (A) shall include information to ensure adequate public awareness of potential health effects associated with bisphenol A.

(5) DURATION.—

(A) INITIAL WAIVER.—Any waiver granted under paragraph (1) to a facility for a food container or containers shall be valid for not longer than 1 year after the date on which subsection (a) is applicable to such food container or containers.

1 (B) RENEWAL OF WAIVER.—The Secretary
2 may renew any waiver granted under paragraph
3 (1) for periods of not more than 1 year, pro-
4 vided that the Secretary reaffirms that it is not
5 technologically feasible to replace bisphenol A in
6 such type of container or containers for such
7 particular food product or products or use an
8 alternative container that does not contain
9 bisphenol A for such particular food product or
10 products.

11 (c) SUBSTANCES USED TO REPLACE BISPHENOL
12 A.—The Secretary shall, to the extent possible, promote,
13 facilitate, and incentivize the use of safer alternatives to
14 replace bisphenol A, and as such bisphenol A shall not
15 be replaced in food containers with substances that—

16 (1) are known or are likely human carcinogens;

17 (2) have been found by the Environmental Pro-
18 tection Agency to be persistent, bioaccumulative, and
19 toxic;

20 (3) cause reproductive or developmental tox-
21 icity; or

22 (4) are endocrine disrupting chemicals.

23 (d) REEXAMINATION OF APPROVED FOOD ADDI-
24 TIVES, EFFECTIVE FOOD CONTACT SUBSTANCE NOTIFI-

1 CATIONS, AND SUBSTANCES THAT ARE GENERALLY REC-
2 OGNIZED AS SAFE.—

3 (1) PLAN AND SCHEDULE.—Not later than 1
4 year after the date of enactment of this Act, after
5 opportunity for comment, the Secretary, acting
6 through the Commissioner of Food and Drugs shall
7 publish a plan and schedule for the selection of sub-
8 stances under paragraph (2) and the review of sub-
9 stances under paragraph (5).

10 (2) SELECTION OF SUBSTANCES.—Not later
11 than 1 year after the date of enactment of this Act
12 and not less than once every 3 years thereafter, the
13 Secretary, acting through the Commissioner of Food
14 and Drugs, shall, based on the factors under para-
15 graph (4), select substances to review under para-
16 graph (5). Such selection shall be made from
17 among—

18 (A) substances authorized as a food addi-
19 tive under any regulations issued under section
20 409 of the Federal Food, Drug, and Cosmetic
21 Act (21 U.S.C. 348);

22 (B) substances that are the subject of any
23 sanction or approval as described in section
24 201(s)(4) of the Federal Food, Drug, and Cos-
25 metic Act (21 U.S.C. 321(s)(4));

1 (C) substances that are the subject of an
2 effective food contact substance notification, as
3 described in section 409(h) of the Federal
4 Food, Drug, and Cosmetic Act (21 U.S.C.
5 348(h));

6 (D) substances that are generally recog-
7 nized as safe, as listed in part 182 of title 21,
8 Code of Federal Regulations (or any successor
9 regulations);

10 (E) direct food substances affirmed as gen-
11 erally recognized as safe, as listed in part 184
12 of title 21, Code of Federal Regulations (or any
13 successor regulations); and

14 (F) indirect food substances affirmed as
15 generally recognized as safe, as listed in part
16 186 of title 21, Code of Federal Regulations (or
17 any successor regulations).

18 (3) NOTICE AND COMMENT.—The selection of
19 substances under paragraph (2) shall be subject to
20 notice and comment.

21 (4) PRIORITIES.—In selecting substances under
22 paragraph (2), the Secretary shall take into consid-
23 eration the following factors:

24 (A) Whether, based on new scientific infor-
25 mation, the Secretary determines that there is

1 a possibility that there is no longer a reasonable
2 certainty that no harm will result from aggre-
3 gate exposure to such substance through food
4 containers composed, in whole or in part, of
5 such substance, taking into consideration—

6 (i) potential adverse effects from low
7 dose exposure; and

8 (ii) the effects of exposure on vulner-
9 able human populations.

10 (B) Whether, since the introduction of
11 such substance into interstate commerce, there
12 has been a significant increase in the amount of
13 such substance found in—

14 (i) sources of drinking water; or

15 (ii) products that are likely to be used
16 by vulnerable human populations.

17 (C) Whether such substance has been ap-
18 proved by the Food and Drug Administration to
19 be used in the lining of canned food.

20 (5) REVIEW OF SUBSTANCES AND SECRETARIAL
21 DETERMINATION.—

22 (A) IN GENERAL.—Not later than 1 year
23 after the date on which a substance is selected
24 under paragraph (2), the Secretary shall deter-
25 mine whether there is a reasonable certainty

1 that no harm will result from aggregate expo-
2 sure to such substance, taking into consider-
3 ation—

4 (i) potential adverse effects from low
5 dose exposure; and

6 (ii) the effects of exposure on vulner-
7 able human populations.

8 (B) NOTICE AND COMMENT.—The deter-
9 mination made under subparagraph (A) shall be
10 subject to notice and comment.

11 (6) REMEDIAL ACTION.—

12 (A) IN GENERAL.—Upon a determination
13 under paragraph (5) that there is not a reason-
14 able certainty that no harm will result from ag-
15 gregate exposure to a substance through food
16 containers composed, in whole or in part, of
17 such substance—

18 (i) if the substance is not defined as
19 a food contact substance under the Federal
20 Food, Drug, and Cosmetic Act, the sub-
21 stance shall be subject to subsections
22 (a)(3) and (h) of section 409 of the Fed-
23 eral Food, Drug, and Cosmetic Act (21
24 U.S.C. 348(a)(3) and (h)), subject to the
25 process under subparagraph (B);

1 (ii) if the substance is defined as a
2 food contact substance under the Federal
3 Food, Drug, and Cosmetic Act (21 U.S.C.
4 301 et seq.), the substance shall be subject
5 to subparagraph (C); and

6 (iii) the Secretary shall, to the extent
7 practicable, promote, facilitate, and
8 incentivize the use of safer alternatives as
9 replacements for such substance.

10 (B) TREATMENT OF SUBSTANCES THAT
11 ARE NOT DEFINED AS FOOD CONTACT SUB-
12 STANCES.—The process under this subpara-
13 graph is as follows:

14 (i) One year after the determination
15 under paragraph (5) for a substance sub-
16 ject to the process under this subpara-
17 graph—

18 (I) any regulation issued under
19 section 409 of the Federal Food,
20 Drug, and Cosmetic Act (21 U.S.C.
21 348) that authorizes any use of the
22 substance as a food additive (includ-
23 ing sections 177.1580, 177.1440,
24 177.2280, and 175.300(b)(3)(viii) of
25 title 21, Code of Federal Regulations,

1 as in effect on the date of enactment
2 of this Act); and

3 (II) any sanction or approval as
4 described in section 201(s)(4) of such
5 Act (21 U.S.C. 321(s)(4)) regarding
6 such substance,

7 shall be deemed revoked.

8 (ii) Upon receipt of a food contact no-
9 tification for a food contact substance con-
10 taining a substance subject to the process
11 under this subparagraph, the Secretary
12 shall review the notification under the au-
13 thority described in subsections (a)(3) and
14 (h) of section 409 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C.
16 348(a)(3) and (h)).

17 (C) TREATMENT OF SUBSTANCES DEFINED
18 AS FOOD CONTACT SUBSTANCES.—

19 (i) One year after the determination
20 under paragraph (5) for a substance that
21 is subject to this subparagraph, all effec-
22 tive notifications for the use of such sub-
23 stance under the authority described in
24 subsections (a)(3) and (h) of section 409
25 of the Federal Food, Drug, and Cosmetic

1 Act (21 U.S.C. 348(a)(3) and (h)) shall be
2 reviewed by the Secretary.

3 (ii) Upon receipt of a food contact no-
4 tification for a food contact substance con-
5 taining a substance that is subject to this
6 subparagraph, the Secretary shall review
7 the notification under the authority de-
8 scribed in subsections (a)(3) and (h) of
9 section 409 of the Federal Food, Drug,
10 and Cosmetic Act (21 U.S.C. 348(a)(3)
11 and (h)).

12 (e) SAVINGS PROVISION.—Nothing in this Act shall
13 affect the right of a State, political subdivision of a State,
14 or Indian tribe to adopt or enforce any regulation, require-
15 ment, liability, or standard of performance that is more
16 stringent than a regulation, requirement, liability, or
17 standard of performance under this Act or that—

18 (1) applies to a product category not described
19 in this Act; or

20 (2) requires the provision of a warning of risk,
21 illness, or injury associated with the use of food con-
22 tainers composed, in whole or in part, of bisphenol
23 A.

24 (f) DEFINITIONS.—For purposes of this section:

1 (1) ENDOCRINE DISRUPTING CHEMICAL.—The
2 term “endocrine disrupting chemical” means an ex-
3 ogenous agent that causes adverse effects, such as
4 by interfering with the production, release, trans-
5 port, metabolism, binding, action, or elimination of
6 the natural hormones in the body responsible for the
7 maintenance of homeostasis and the regulation of
8 developmental processes.

9 (2) REUSABLE FOOD CONTAINER.—The term
10 “reusable food container” means a reusable food
11 container that does not contain a food item when it
12 is introduced or delivered for introduction into inter-
13 state commerce.

14 (3) SAFER ALTERNATIVE.—The term “safer al-
15 ternative” means an option, that is safer for humans
16 and the environment than the existing chemical or
17 process, including—

18 (A) chemical or process substitution;

19 (B) chemical or process re-formulation or
20 re-design; and

21 (C) chemical or process elimination or
22 phase-out.

23 (4) SECRETARY.—The term “Secretary” means
24 the Secretary of Health and Human Services.

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

7 (A) infants, children, and adolescents;

8 (B) pregnant women;

9 (C) the elderly;

10 (D) individuals with preexisting medical
11 conditions;

12 (E) workers who may be exposed to chem-
13 ical substances and mixtures;

14 (F) residents in communities subject to
15 disproportionate exposures; and

16 (G) members of any other appropriate pop-
17 ulation identified by the Secretary.

18 **SEC. 3. AMENDMENTS TO SECTION 409 OF THE FEDERAL**
19 **FOOD, DRUG, AND COSMETIC ACT.**

20 Section 409(h) of the Federal Food, Drug, and Cos-
21 metic Act (21 U.S.C. 348(h)) is amended—

22 (1) in paragraph (1)—

23 (A) by striking “manufacturer or supplier
24 of a food contact substance may” and inserting

1 “manufacturer or supplier of a food contact
2 substance shall”;

3 (B) by inserting “(A)” after “notify the
4 Secretary of”;

5 (C) by striking “, and of” and inserting “;
6 (B)”;

7 (D) by striking the period after “sub-
8 section (c)(3)(A)” and inserting “; (C) the de-
9 termination of the manufacturer or supplier
10 that no adverse health effects result from low-
11 dose exposures to the food contact substance;
12 and (D) the determination of the manufacturer
13 or supplier that the substance has not been
14 shown, after tests which are appropriate for the
15 evaluation of the safety of food contact sub-
16 stances, to cause reproductive or developmental
17 toxicity in humans or animals.”;

18 (2) by striking paragraph (6) and inserting the
19 following:

20 “(6) In this section—

21 “(A) the term ‘food contact substance’ means
22 any substance intended for use as a component of
23 materials used in manufacturing, packing, pack-
24 aging, transporting, or holding food if such use is

1 not intended to have any technical effect in such
2 food; and

3 “(B) the term ‘reproductive or developmental
4 toxicity’ means biologically adverse effects on the re-
5 productive systems of female or male humans or ani-
6 mals, or on developing organisms that may result
7 from exposure prior to conception, during prenatal
8 development, or until the time of sexual maturation,
9 that may include female or male reproductive system
10 development, fertility, pregnancy, pregnancy out-
11 comes, or modifications in other functions that are
12 dependent on the integrity of the reproductive sys-
13 tem or effects on the developing organism, including
14 death, structural abnormality, altered growth, or
15 functional deficiency.”.

16 **SEC. 4. REPORT TO CONGRESS.**

17 Not later than 2 years after the date of enactment
18 of this Act and at least once during every 2-year period
19 thereafter, the Secretary shall submit a report to the Com-
20 mittee on Energy and Commerce of the House of Rep-
21 resentatives and the Committee on Health, Education,
22 Labor, and Pensions of the Senate. Such report shall in-
23 clude—

1 (1) a list of waivers granted under section
2 2(b)(1), including a description of the basis for each
3 such waiver;

4 (2) a list of substances selected for review
5 under section 2(c)(2) and the anticipated timeline
6 for future selections of additional substances;

7 (3) for each substance reviewed under section
8 2(c)(5), the outcome of such review, and the antici-
9 pated timeline for review of additional substances;

10 (4) a description of all remedial action taken
11 under section 2(c)(6); and

12 (5) for bisphenol A and any other substance de-
13 termined not to have a reasonable certainty of no
14 harm under section 2(c)(5), a review of the potential
15 alternatives to that substance that are available or
16 being developed for use in food and beverage con-
17 tainers.

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