

114TH CONGRESS
2D SESSION

S. 3412

To ban the use of bisphenol A in food containers, and for other purposes.

IN THE SENATE OF THE UNITED STATES

SEPTEMBER 28, 2016

Mr. MARKEY introduced the following bill; which was read twice and referred
to the Committee on Health, Education, Labor, and Pensions

A BILL

To ban the use of bisphenol A in food containers, 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.—

10 (1) IN GENERAL.—For purposes of applying
11 section 402(a)(6) of the Federal Food, Drug, and

1 Cosmetic Act (21 U.S.C. 342(a)(6)), a food con-
2 tainer (which for purposes of this Act includes a
3 beverage container) that is composed, in whole or in
4 part, of bisphenol A, or that can release bisphenol
5 A into food (as defined for purposes of the Federal
6 Food, Drug, and Cosmetic Act), shall be treated as
7 a container described in such section (relating to
8 containers composed, in whole or in part, of a poi-
9 sonous or deleterious substance which may render
10 the contents injurious to health).

11 (2) APPLICABILITY.—

12 (A) REUSABLE FOOD CONTAINERS.—Para-
13 graph (1) shall apply to reusable food con-
14 tainers on the date that is 180 days after the
15 date of enactment of this Act.

16 (B) OTHER FOOD CONTAINERS.—Para-
17 graph (1) shall apply to any food container that
18 is packed with food and is introduced or deliv-
19 ered for introduction into interstate commerce
20 on or after the date that is 180 days after the
21 date of enactment of this Act.

22 (b) WAIVER.—

23 (1) IN GENERAL.—The Secretary, after public
24 notice and opportunity for comment, may grant to
25 any facility (as that term is defined in section 415

1 of the Federal Food, Drug, and Cosmetic Act (21
2 U.S.C. 350d)) that manufactures, processes, packs,
3 holds, or sells the particular food product or prod-
4 ucts, a waiver of the treatment described in sub-
5 section (a).

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

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

14 (A) demonstrates that it is not techno-
15 logically feasible to—

16 (i) replace bisphenol A in the certain
17 type of container or containers for such
18 particular food product or products; or

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

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

1 (4) LABELING.—

2 (A) IN GENERAL.—Any product for which
3 the Secretary grants such a waiver shall display
4 a prominent warning on the label that the con-
5 tainer contains bisphenol A that states,
6 “bisphenol A (BPA) is a chemical that can
7 leach into food and may harm prenatal develop-
8 ment and the health of children and adults”.

9 (B) ADDITIONAL REQUIREMENT.—The
10 prominent warning required under subpara-
11 graph (A) shall include information to ensure
12 adequate public awareness of potential health
13 effects associated with bisphenol A.

14 (5) DURATION.—

15 (A) INITIAL WAIVER.—Any waiver granted
16 under paragraph (1) to a facility for a food con-
17 tainer or containers shall be valid for not longer
18 than 1 year after the date on which subsection
19 (a) is applicable to such food container or con-
20 tainers.

21 (B) RENEWAL OF WAIVER.—The Secretary
22 may renew any waiver granted under paragraph
23 (1) for periods of not more than 1 year, pro-
24 vided that the Secretary reaffirms that it is not
25 technologically feasible to replace bisphenol A in

1 such type of container or containers for such
2 particular food product or products or use an
3 alternative container that does not contain
4 bisphenol A for such particular food product or
5 products.

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

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

12 (2) have been found by the Environmental Pro-
13 tection Agency to be persistent, bioaccumulative, and
14 toxic;

15 (3) cause reproductive or developmental tox-
16 icity; or

17 (4) are endocrine disrupting chemicals.

18 (d) REEXAMINATION OF APPROVED FOOD ADDI-
19 TIVES, EFFECTIVE FOOD CONTACT SUBSTANCE NOTIFI-
20 CATIONS, AND SUBSTANCES THAT ARE GENERALLY REC-
21 OGNIZED AS SAFE.—

22 (1) PLAN AND SCHEDULE.—Not later than 1
23 year after the date of enactment of this Act, after
24 opportunity for comment, the Secretary, acting
25 through the Commissioner of Food and Drugs shall

1 publish a plan and schedule for the selection of sub-
2 stances under paragraph (2) and the review of sub-
3 stances under paragraph (5).

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

12 (A) substances authorized as a food addi-
13 tive under any regulations issued under section
14 409 of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 348);

16 (B) substances that are the subject of any
17 sanction or approval as described in section
18 201(s)(4) of the Federal Food, Drug, and Cos-
19 metic Act (21 U.S.C. 321(s)(4));

20 (C) substances that are the subject of an
21 effective food contact substance notification, as
22 described in section 409(h) of the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 348(h));

1 (D) substances that are generally recog-
2 nized as safe, as listed in part 182 of title 21,
3 Code of Federal Regulations (or any successor
4 regulations);

5 (E) direct food substances affirmed as gen-
6 erally recognized as safe, as listed in part 184
7 of title 21, Code of Federal Regulations (or any
8 successor regulations); and

9 (F) indirect food substances affirmed as
10 generally recognized as safe, as listed in part
11 186 of title 21, Code of Federal Regulations (or
12 any successor regulations).

13 (3) NOTICE AND COMMENT.—The selection of
14 substances under paragraph (2) shall be subject to
15 notice and comment.

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

19 (A) Whether, based on new scientific infor-
20 mation, the Secretary determines that there is
21 a possibility that there is no longer a reasonable
22 certainty that no harm will result from aggre-
23 gate exposure to such substance through food
24 containers composed, in whole or in part, of
25 such substance, taking into consideration—

1 (i) potential adverse effects from low
2 dose exposure; and

3 (ii) the effects of exposure on vulner-
4 able human populations.

5 (B) Whether, since the introduction of
6 such substance into interstate commerce, there
7 has been a significant increase in the amount of
8 such substance found in—

9 (i) sources of drinking water; or

10 (ii) products that are likely to be used
11 by vulnerable human populations.

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

15 (5) REVIEW OF SUBSTANCES AND SECRETARIAL
16 DETERMINATION.—

17 (A) IN GENERAL.—Not later than 1 year
18 after the date on which a substance is selected
19 under paragraph (2), the Secretary shall deter-
20 mine whether there is a reasonable certainty
21 that no harm will result from aggregate expo-
22 sure to such substance, taking into consider-
23 ation—

24 (i) potential adverse effects from low
25 dose exposure; and

1 (ii) the effects of exposure on vulner-
2 able human populations.

3 (B) NOTICE AND COMMENT.—The deter-
4 mination made under subparagraph (A) shall be
5 subject to notice and comment.

6 (6) REMEDIAL ACTION.—

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

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

21 (ii) if the substance is defined as a
22 food contact substance under the Federal
23 Food, Drug, and Cosmetic Act (21 U.S.C.
24 301 et seq.), the substance shall be subject
25 to subparagraph (C); and

1 (iii) the Secretary shall, to the extent
2 practicable, promote, facilitate, and
3 incentivize the use of safer alternatives as
4 replacements for such substance.

5 (B) TREATMENT OF SUBSTANCES THAT
6 ARE NOT DEFINED AS FOOD CONTACT SUB-
7 STANCES.—The process under this subpara-
8 graph is as follows:

9 (i) One year after the determination
10 under paragraph (5) for a substance sub-
11 ject to the process under this subpara-
12 graph—

13 (I) any regulation issued under
14 section 409 of the Federal Food,
15 Drug, and Cosmetic Act (21 U.S.C.
16 348) that authorizes any use of the
17 substance as a food additive (includ-
18 ing sections 177.1580, 177.1440,
19 177.2280, and 175.300(b)(3)(viii) of
20 title 21, Code of Federal Regulations,
21 as in effect on the date of enactment
22 of this Act); and

23 (II) any sanction or approval as
24 described in section 201(s)(4) of such

1 Act (21 U.S.C. 321(s)(4)) regarding
2 such substance,
3 shall be deemed revoked.

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

13 (C) TREATMENT OF SUBSTANCES DEFINED
14 AS FOOD CONTACT SUBSTANCES.—

15 (i) One year after the determination
16 under paragraph (5) for a substance that
17 is subject to this subparagraph, all effec-
18 tive notifications for the use of such sub-
19 stance under the authority described in
20 subsections (a)(3) and (h) of section 409
21 of the Federal Food, Drug, and Cosmetic
22 Act (21 U.S.C. 348(a)(3) and (h)) shall be
23 reviewed by the Secretary.

24 (ii) Upon receipt of a food contact no-
25 tification for a food contact substance con-

1 taining a substance that is subject to this
2 subparagraph, the Secretary shall review
3 the notification under the authority de-
4 scribed in subsections (a)(3) and (h) of
5 section 409 of the Federal Food, Drug,
6 and Cosmetic Act (21 U.S.C. 348(a)(3)
7 and (h)).

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

14 (1) applies to a product category not described
15 in this Act; or

16 (2) requires the provision of a warning of risk,
17 illness, or injury associated with the use of food con-
18 tainers composed, in whole or in part, of bisphenol
19 A.

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

21 (1) ENDOCRINE DISRUPTING CHEMICAL.—The
22 term “endocrine disrupting chemical” means an ex-
23 ogenous agent that causes adverse effects, such as
24 by interfering with the production, release, trans-
25 port, metabolism, binding, action, or elimination of

1 the natural hormones in the body responsible for the
2 maintenance of homeostasis and the regulation of
3 developmental processes.

4 (2) REUSABLE FOOD CONTAINER.—The term
5 “reusable food container” means a reusable food
6 container that does not contain a food item when it
7 is introduced or delivered for introduction into inter-
8 state commerce.

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

13 (A) chemical or process substitution;

14 (B) chemical or process reformulation or
15 redesign; and

16 (C) chemical or process elimination or
17 phase-out.

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

20 (5) VULNERABLE HUMAN POPULATION.—The
21 term “vulnerable human population” means a
22 human population that is subject to the potential for
23 disproportionate exposure to, or the potential for
24 disproportionate adverse effect from exposure to, a
25 chemical substance or mixture, including—

- 1 (A) infants, children, and adolescents;
- 2 (B) pregnant women;
- 3 (C) the elderly;
- 4 (D) individuals with preexisting medical
- 5 conditions;
- 6 (E) workers who may be exposed to chem-
- 7 ical substances and mixtures;
- 8 (F) residents in communities subject to
- 9 disproportionate exposures; and
- 10 (G) members of any other appropriate pop-
- 11 ulation identified by the Secretary.

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

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

16 (1) in paragraph (1)—

17 (A) by striking “manufacturer or supplier
 18 of a food contact substance may” and inserting
 19 “manufacturer or supplier of a food contact
 20 substance shall”;

21 (B) by inserting “(A)” after “notify the
 22 Secretary of”;

23 (C) by striking “, and of” and inserting “;
 24 (B)”;

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

12 (2) by striking paragraph (6) and inserting the
13 following:

14 “(6) In this section—

15 “(A) the term ‘food contact substance’ means
16 any substance intended for use as a component of
17 materials used in manufacturing, packing, pack-
18 aging, transporting, or holding food if such use is
19 not intended to have any technical effect in such
20 food; and

21 “(B) the term ‘reproductive or developmental
22 toxicity’ means biologically adverse effects on the re-
23 productive systems of female or male humans or ani-
24 mals, or on developing organisms that may result
25 from exposure prior to conception, during prenatal

1 development, or until the time of sexual maturation,
2 that may include female or male reproductive system
3 development, fertility, pregnancy, pregnancy out-
4 comes, or modifications in other functions that are
5 dependent on the integrity of the reproductive sys-
6 tem or effects on the developing organism, including
7 death, structural abnormality, altered growth, or
8 functional deficiency.”.

9 **SEC. 4. REPORT TO CONGRESS.**

10 Not later than 2 years after the date of enactment
11 of this Act and at least once during every 2-year period
12 thereafter, the Secretary shall submit a report to the Com-
13 mittee on Energy and Commerce of the House of Rep-
14 resentatives and the Committee on Health, Education,
15 Labor, and Pensions of the Senate. Such report shall in-
16 clude—

17 (1) a list of waivers granted under section
18 2(b)(1), including a description of the basis for each
19 such waiver;

20 (2) a list of substances selected for review
21 under section 2(c)(2) and the anticipated timeline
22 for future selections of additional substances;

23 (3) for each substance reviewed under section
24 2(c)(5), the outcome of such review, and the antici-
25 pated timeline for review of additional substances;

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

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

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