

113TH CONGRESS
1ST SESSION

H. R. 2248

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 4, 2013

Mr. MARKEY (for himself, Mr. BLUMENAUER, Mrs. CAPPS, Ms. DEGETTE, Ms. DELAURO, Mr. ELLISON, Ms. ESHOO, Mr. FARR, Mr. GRIJALVA, Ms. LOFGREN, Mrs. LOWEY, Mrs. CAROLYN B. MALONEY of New York, Ms. MCCOLLUM, Mr. MORAN, Mr. NADLER, Ms. PINGREE of Maine, Ms. SCHAKOWSKY, Ms. SLAUGHTER, Ms. SPEIER, and Ms. TSONGAS) 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 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 2013”.

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

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

5 (1) IN GENERAL.—For purposes of applying
6 section 402(a)(6) of the Federal Food, Drug, and
7 Cosmetic Act (21 U.S.C. 342(a)(6)), a food con-
8 tainer (which for purposes of this Act includes a
9 beverage container) that is composed, in whole or in
10 part, of bisphenol A, or that can release bisphenol
11 A into food (as defined for purposes of the Federal
12 Food, Drug, and Cosmetic Act), shall be treated as
13 a container described in such section (relating to
14 containers composed, in whole or in part, of a poi-
15 sonous or deleterious substance which may render
16 the contents injurious to health).

17 (2) APPLICABILITY.—

18 (A) REUSABLE FOOD CONTAINERS.—Para-
19 graph (1) shall apply to reusable food con-
20 tainers on the date that is 180 days after the
21 date of enactment of this Act.

22 (B) OTHER FOOD CONTAINERS.—Para-
23 graph (1) shall apply to any food container that
24 is packed with food and is introduced or deliv-
25 ered for introduction into interstate commerce

1 on or after the date that is 180 days after the
2 date of enactment of this Act.

3 (b) WAIVER.—

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

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

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

20 (A) demonstrates that it is not techno-
21 logically feasible to—

22 (i) replace bisphenol A in the certain
23 type of container or containers for such
24 particular food product or products; or

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

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

8 (4) LABELING.—

9 (A) IN GENERAL.—Any product for which
10 the Secretary grants such a waiver shall display
11 a prominent warning on the label that the con-
12 tainer contains bisphenol A, in a manner that
13 the Secretary shall require.

14 (B) ADDITIONAL REQUIREMENT.—The
15 prominent warning required under subpara-
16 graph (A) shall include information to ensure
17 adequate public awareness of potential health
18 effects associated with bisphenol A.

19 (5) DURATION.—

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

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) REEXAMINATION OF APPROVED FOOD ADDI-
12 TIVES, EFFECTIVE FOOD CONTACT SUBSTANCE NOTIFI-
13 CATIONS, AND SUBSTANCES THAT ARE GENERALLY REC-
14 OGNIZED AS SAFE.—

15 (1) PLAN AND SCHEDULE.—Not later than 1
16 year after enactment of this Act, after opportunity
17 for comment, the Secretary, acting through the
18 Commissioner of Food and Drugs shall publish a
19 plan and schedule for the selection of substances
20 under paragraph (2) and the review of substances
21 under paragraph (5).

22 (2) SELECTION OF SUBSTANCES.—Not later
23 than 1 year after enactment of this Act and not less
24 than once every 3 years thereafter, the Secretary,
25 acting through the Commissioner of Food and

1 Drugs, shall, based on the factors under paragraph
2 (4), select substances to review under paragraph (5).

3 Such selection shall be made from among—

4 (A) substances authorized as a food addi-
5 tive under any regulations issued under section
6 409 of the Federal Food, Drug, and Cosmetic
7 Act;

8 (B) substances that are the subject of any
9 sanction or approval as described in section
10 201(s)(4) of the Federal Food, Drug, and Cos-
11 metic Act;

12 (C) substances that are the subject of an
13 effective food contact substance notification, as
14 described in section 409(h) of the Federal
15 Food, Drug, and Cosmetic Act;

16 (D) substances that are generally recog-
17 nized as safe, as listed in part 182 of title 21,
18 Code of Federal Regulations (or any successor
19 regulations);

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

24 (F) indirect food substances affirmed as
25 generally recognized as safe, as listed in part

1 186 of title 21, Code of Federal Regulations (or
2 any successor regulations).

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

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

9 (A) Whether, based on new scientific infor-
10 mation, the Secretary determines that there is
11 a possibility that there is no longer a reasonable
12 certainty that no harm will result from aggre-
13 gate exposure to such substance through food
14 containers composed, in whole or in part, of
15 such substance, taking into consideration—

16 (i) potential adverse effects from low
17 dose exposure; and

18 (ii) the effects of exposure on vulner-
19 able populations, including pregnant
20 women, infants, children, the elderly, and
21 populations with high exposure to such
22 substance.

23 (B) Whether, since the introduction of
24 such substance into interstate commerce, there

1 has been a significant increase in the amount of
2 such substance found in—

3 (i) sources of drinking water; or

4 (ii) products that are likely to be used
5 by vulnerable populations, including preg-
6 nant women, infants, children, the elderly,
7 and populations with high exposure to such
8 substance.

9 (5) REVIEW OF SUBSTANCES AND SECRETARIAL
10 DETERMINATION.—

11 (A) IN GENERAL.—No later than 1 year
12 after the date on which a substance is selected
13 under paragraph (2), the Secretary shall deter-
14 mine whether there is a reasonable certainty
15 that no harm will result from aggregate expo-
16 sure to such substance, taking into consider-
17 ation—

18 (i) potential adverse effects from low
19 dose exposure; and

20 (ii) the effects of exposure on vulner-
21 able populations, including pregnant
22 women, infants, children, the elderly, and
23 populations with high exposure to such
24 substance.

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

4 (6) REMEDIAL ACTION.—

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

11 (i) if the substance is not defined as
12 a food contact substance under the Federal
13 Food, Drug, and Cosmetic Act, the sub-
14 stance shall be subject to sections
15 409(a)(3) and 409(h) of the Federal Food,
16 Drug, and Cosmetic Act, subject to the
17 process under subparagraph (B); and

18 (ii) if the substance is defined as a
19 food contact substance under the Federal
20 Food, Drug, and Cosmetic Act, the sub-
21 stance shall be subject to subparagraph
22 (C).

23 (B) TREATMENT OF SUBSTANCES THAT
24 ARE NOT DEFINED AS FOOD CONTACT SUB-

1 STANCES.—The process under this subpara-
2 graph is as follows:

3 (i) One year after the determination
4 under paragraph (5) for a substance sub-
5 ject to the process under this subpara-
6 graph—

7 (I) any regulation issued under
8 section 409 of the Federal Food,
9 Drug, and Cosmetic Act that author-
10 izes any use of the substance as a
11 food additive (including sections
12 177.1580, 177.1440, 177.2280, and
13 175.300(b)(3)(viii) of title 21, Code of
14 Federal Regulations, as in effect on
15 the date of enactment of this Act);
16 and

17 (II) any sanction or approval as
18 described in section 201(s)(4) of such
19 Act regarding such substance,
20 shall be deemed revoked.

21 (ii) Upon receipt of a food contact no-
22 tification for a food contact substance con-
23 taining a substance subject to the process
24 under this subparagraph, the Secretary
25 shall review the notification under the au-

1 thority described in sections 409(a)(3) and
2 409(h) of the Federal Food, Drug, and
3 Cosmetic Act.

4 (C) TREATMENT OF SUBSTANCES DEFINED
5 AS FOOD CONTACT SUBSTANCES.—

6 (i) One year after the determination
7 under paragraph (5) for a substance that
8 is subject to this subparagraph, all effec-
9 tive notifications for the use of such sub-
10 stance under the authority described in
11 sections 409(a)(3) and 409(h) of the Fed-
12 eral Food, Drug, and Cosmetic Act shall
13 be reviewed by the Secretary.

14 (ii) Upon receipt of a food contact no-
15 tification for a food contact substance con-
16 taining a substance that is subject to this
17 subparagraph, the Secretary shall review
18 the notification under the authority de-
19 scribed in sections 409(a)(3) and 409(h) of
20 the Federal Food, Drug, and Cosmetic
21 Act.

22 (d) SAVINGS PROVISION.—Nothing in this Act shall
23 affect the right of a State, political subdivision of a State,
24 or Indian tribe to adopt or enforce any regulation, require-
25 ment, liability, or standard of performance that is more

1 stringent than a regulation, requirement, liability, or
 2 standard of performance under this Act or that—

3 (1) applies to a product category not described
 4 in this Act; or

5 (2) requires the provision of a warning of risk,
 6 illness, or injury associated with the use of food con-
 7 tainers composed, in whole or in part, of bisphenol
 8 A.

9 (e) DEFINITIONS.—For purposes of this section:

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

15 (2) SECRETARY.—The term “Secretary” means
 16 the Secretary of Health and Human Services.

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

19 Subsection (h) of section 409 of the Federal Food,
 20 Drug, and Cosmetic Act (21 U.S.C. 348(h)(1)) is amend-
 21 ed—

22 (1) in paragraph (1)—

23 (A) by striking “manufacturer or supplier
 24 for a food contact substance may” and insert-

1 ing “manufacturer or supplier for a food con-
2 tact 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, including alterations to the female or male re-
7 productive system development, the related endo-
8 crine system, fertility, pregnancy, pregnancy out-
9 comes, or modifications in other functions that are
10 dependent on the integrity of the reproductive sys-
11 tem.”.

12 **SEC. 4. REPORT TO CONGRESS.**

13 No later than two years after enactment of this Act
14 and at least once during every two year period thereafter,
15 the Secretary shall submit a report to the Committee on
16 Energy and Commerce of the House of Representatives.
17 Such report shall include—

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

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

1 (3) for each substance reviewed under section
2 2(c)(5), the outcome of such review, and the antici-
3 pated timeline for review of additional substances;
4 (4) a description of all remedial action taken
5 under section 2(c)(6); and
6 (5) for bisphenol A and any other substance de-
7 termined not to have a reasonable certainty of no
8 harm under section 2(c)(5), a review of the potential
9 alternatives to that substance that are available or
10 being developed for use in food and beverage con-
11 tainers.

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