

112TH CONGRESS
1ST SESSION

H. R. 432

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

IN THE HOUSE OF REPRESENTATIVES

JANUARY 25, 2011

Mr. MARKEY (for himself, Ms. SLAUGHTER, Ms. SCHAKOWSKY, and Mr. MORAN) 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 2011”.

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

13 (2) APPLICABILITY.—

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

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

24 (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

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

5 (4) LABELING.—

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

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

16 (5) DURATION.—

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

23 (B) RENEWAL OF WAIVER.—The Secretary
24 may renew any waiver granted under paragraph
25 (1) for periods of not more than 1 year, pro-

1 vided that the Secretary reaffirms that it is not
2 technologically feasible to replace bisphenol A in
3 such type of container or containers for such
4 particular food product or products or use an
5 alternative container that does not contain
6 bisphenol A for such particular food product or
7 products.

8 (c) REEXAMINATION OF APPROVED FOOD ADDI-
9 TIVES, EFFECTIVE FOOD CONTACT SUBSTANCE NOTIFI-
10 CATIONS, AND SUBSTANCES THAT ARE GENERALLY REC-
11 OGNIZED AS SAFE.—

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

19 (2) SELECTION OF SUBSTANCES.—Not later
20 than 1 year after enactment of this Act and not less
21 than once every 3 years thereafter, the Secretary,
22 acting through the Commissioner of Food and
23 Drugs, shall, based on the factors under paragraph
24 (4), select substances to review under paragraph (5).
25 Such selection shall be made from among—

1 (A) substances authorized as a food addi-
2 tive under any regulations issued under section
3 409 of the Federal Food, Drug, and Cosmetic
4 Act;

5 (B) substances that are the subject of any
6 sanction or approval as described in section
7 201(s)(4) of the Federal Food, Drug, and Cos-
8 metic Act;

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

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

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

21 (F) indirect food substances affirmed as
22 generally recognized as safe, as listed in part
23 186 of title 21, Code of Federal Regulations (or
24 any successor regulations).

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

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

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

14 (i) potential adverse effects from low
15 dose exposure; and

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

21 (B) Whether, since the introduction of
22 such substance into interstate commerce, there
23 has been a significant increase in the amount of
24 such substance found in—

25 (i) sources of drinking water; or

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

6 (5) REVIEW OF SUBSTANCES AND SECRETARIAL
7 DETERMINATION.—

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

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

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

22 (B) NOTICE AND COMMENT.—The deter-
23 mination made under subparagraph (A) shall be
24 subject to notice and comment.

25 (6) REMEDIAL ACTION.—

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

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

14 (ii) if the substance is defined as a
15 food contact substance under the Federal
16 Food, Drug, and Cosmetic Act, the sub-
17 stance shall be subject to subparagraph
18 (C).

19 (B) TREATMENT OF SUBSTANCES THAT
20 ARE NOT DEFINED AS FOOD CONTACT SUB-
21 STANCES.—The process under this subpara-
22 graph is as follows:

23 (i) One year after the determination
24 under paragraph (5) for a substance sub-

1 ject to the process under this subpara-
2 graph—

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

13 (II) any sanction or approval as
14 described in section 201(s)(4) of such
15 Act regarding such substance,

16 shall be deemed revoked.

17 (ii) Upon receipt of a food contact no-
18 tification for a food contact substance con-
19 taining a substance subject to the process
20 under this subparagraph, the Secretary
21 shall review the notification under the au-
22 thority described in sections 409(a)(3) and
23 409(h) of the Federal Food, Drug, and
24 Cosmetic Act.

1 (C) TREATMENT OF SUBSTANCES DEFINED
2 AS FOOD CONTACT SUBSTANCES.—

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

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

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

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

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

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

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

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

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

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

20 (1) in paragraph (1)—

21 (A) by striking “manufacturer or supplier
22 for a food contact substance may” and insert-
23 ing “manufacturer or supplier for a food con-
24 tact substance shall”;

1 (B) by inserting “(A)” after “notify the
2 Secretary of”;

3 (C) by striking “, and of” and inserting “;
4 (B)”;

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

16 (2) by striking paragraph (6) and inserting the
17 following:

18 “(6) In this section—

19 “(A) the term ‘food contact substance’
20 means any substance intended for use as a
21 component of materials used in manufacturing,
22 packing, packaging, transporting, or holding
23 food if such use is not intended to have any
24 technical effect in such food; and

1 “(B) the term ‘reproductive or develop-
2 mental toxicity’ means biologically adverse ef-
3 fects on the reproductive systems of female or
4 male humans or animals, including alterations
5 to the female or male reproductive system de-
6 velopment, the related endocrine system, fer-
7 tility, pregnancy, pregnancy outcomes, or modi-
8 fications in other functions that are dependent
9 on the integrity of the reproductive system.”.

10 **SEC. 4. REPORT TO CONGRESS.**

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

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

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

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

1 (4) a description of all remedial action taken
2 under section 2(e)(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(e)(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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