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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Ban Poisonous Additives Act of 2016''.

SEC. 2. BAN ON USE OF BISPHENOL A IN FOOD AND BEVERAGE CONTAINERS.

(a) TREATMENT OF BISPHENOL A AS ADULTERATING 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) IN GENERAL.—The Secretary, after public notice and opportunity for comment, may grant to any facility (as that term is defined in section 415

of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350d)) that manufactures, processes, packs, holds, or sells the particular food product or products, a waiver of the treatment described in subsection (a).

(2) APPLICABILITY.—A waiver granted to a facility under paragraph (1) may only be applicable to a certain type of food container or containers, as used for a particular food product or group of similar products containing similar foods.

(3) REQUIREMENT FOR WAIVER.—The Secretary may only grant a waiver under paragraph (1) to a facility, if such facility—

(A) demonstrates that it is not technologically feasible to—

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

(ii) use an alternative container that does not contain bisphenol A for such particular 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.

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

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

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

(1) are known or are likely human carcinogens;

(2) have been found by the Environmental Protection Agency to be persistent, bioaccumulative, and toxic;

(3) cause reproductive or developmental toxicity; or

(4) are endocrine disrupting chemicals.

(d) REEXAMINATION OF APPROVED FOOD ADDITIVES, EFFECTIVE FOOD CONTACT SUBSTANCE NOTIFICATIONS, AND SUBSTANCES THAT ARE GENERALLY RECOGNIZED AS SAFE.—

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

publish a plan and schedule for the selection of substances under paragraph (2) and the review of substances under paragraph (5).

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

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

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

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

(D) substances that are generally recognized as safe, as listed in part 182 of title 21, Code of Federal Regulations (or any successor regulations);

(E) direct food substances affirmed as generally recognized as safe, as listed in part 184 of title 21, Code of Federal Regulations (or any successor regulations); and

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

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

(4) PRIORITIES.—In selecting substances under paragraph (2), the Secretary shall take into consideration the following factors:

(A) Whether, based on new scientific information, the Secretary determines that there is a possibility that there is no longer a reasonable certainty that no harm will result from aggregate exposure to such substance through food containers composed, in whole or in part, of such substance, taking into consideration—

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

(ii) the effects of exposure on vulnerable human populations.

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

(i) sources of drinking water; or

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

(C) Whether such substance has been approved by the Food and Drug Administration to be used in the lining of canned food.

(5) REVIEW OF SUBSTANCES AND SECRETARIAL DETERMINATION.—

(A) IN GENERAL.—Not later than 1 year after the date on which a substance is selected under paragraph (2), the Secretary shall determine whether there is a reasonable certainty that no harm will result from aggregate exposure to such substance, taking into consideration—

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

(ii) the effects of exposure on vulnerable human populations.

(B) NOTICE AND COMMENT.—The determination made under subparagraph (A) shall be subject to notice and comment.

(6) REMEDIAL ACTION.—

(A) IN GENERAL.—Upon a determination under paragraph (5) that there is not a reasonable certainty that no harm will result from aggregate exposure to a substance through food containers composed, in whole or in part, of such substance—

(i) if the substance is not defined as a food contact substance under the Federal Food, Drug, and Cosmetic Act, the substance shall be subject to subsections (a)(3) and (h) of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)(3) and (h)), subject to the process under subparagraph (B);

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

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

(B) TREATMENT OF SUBSTANCES THAT ARE NOT DEFINED AS FOOD CONTACT SUBSTANCES.—The process under this subparagraph is as follows:

(i) One year after the determination under paragraph (5) for a substance subject to the process under this subparagraph—

(I) any regulation issued under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) that authorizes any use of the substance as a food additive (including sections 177.1580, 177.1440, 177.2280, and 175.300(b)(3)(viii) of title 21, Code of Federal Regulations, as in effect on the date of enactment of this Act); and

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

Act (21 U.S.C. 321(s)(4)) regarding such substance,

shall be deemed revoked.

(ii) Upon receipt of a food contact notification for a food contact substance containing a substance subject to the process under this subparagraph, the Secretary shall review the notification under the authority described in subsections (a)(3) and (h) of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)(3) and (h)).

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

(i) One year after the determination under paragraph (5) for a substance that is subject to this subparagraph, all effective notifications for the use of such substance under the authority described in subsections (a)(3) and (h) of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)(3) and (h)) shall be reviewed by the Secretary.

(ii) Upon receipt of a food contact notification for a food contact substance con-

taining a substance that is subject to this subparagraph, the Secretary shall review the notification under the authority described in subsections (a)(3) and (h) of section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(a)(3) and (h)).

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

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

(2) requires the provision of a warning of risk, illness, or injury associated with the use of food containers composed, in whole or in part, of bisphenol A.

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

(1) ENDOCRINE DISRUPTING CHEMICAL.—The term ''endocrine disrupting chemical'' means an exogenous agent that causes adverse effects, such as by interfering with the production, release, transport, metabolism, binding, action, or elimination of

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

(2) REUSABLE FOOD CONTAINER.—The term ''reusable food container'' means a reusable food container that does not contain a food item when it is introduced or delivered for introduction into interstate commerce.

(3) SAFER ALTERNATIVE.—The term ''safer alternative'' means an option, that is safer for humans and the environment than the existing chemical or process, including—

(A) chemical or process substitution;

(B) chemical or process reformulation or redesign; and

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

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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

(A) infants, children, and adolescents;

(B) pregnant women;

(C) the elderly;

(D) individuals with preexisting medical conditions;

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

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

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

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

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

(1) in paragraph (1)—

(A) by striking ''manufacturer or supplier of a food contact substance may'' and inserting ''manufacturer or supplier of a food contact substance shall'';

(B) by inserting ''(A)'' after ''notify the Secretary of'';

(C) by striking '', and of'' and inserting ''; (B)''; and

(D) by striking the period after ''subsection (c)(3)(A)'' and inserting ''; (C) the determination of the manufacturer or supplier that no adverse health effects result from low-dose exposures to the food contact substance; and (D) the determination of the manufacturer or supplier that the substance has not been shown, after tests which are appropriate for the evaluation of the safety of food contact substances, to cause reproductive or developmental toxicity in humans or animals.''; and

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

''(6) In this section—

''(A) the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food; and

''(B) the term 'reproductive or developmental toxicity' means biologically adverse effects on the reproductive systems of female or male humans or animals, or on developing organisms that may result from exposure prior to conception, during prenatal

development, or until the time of sexual maturation, that may include female or male reproductive system development, fertility, pregnancy, pregnancy outcomes, or modifications in other functions that are dependent on the integrity of the reproductive system or effects on the developing organism, including death, structural abnormality, altered growth, or functional deficiency.''.

SEC. 4. REPORT TO CONGRESS.

Not later than 2 years after the date of enactment of this Act and at least once during every 2-year period thereafter, the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate. Such report shall include—

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

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

(3) for each substance reviewed under section 2(c)(5), the outcome of such review, and the anticipated timeline for review of additional substances;

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

(5) for bisphenol A and any other substance determined not to have a reasonable certainty of no harm under section 2(c)(5), a review of the potential alternatives to that substance that are available or being developed for use in food and beverage containers.

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