I

112TH CONGRESS
1ST SESSION

H. R. 553

To amend the Safe Drinking Water Act regarding an endocrine disruptor screening program.

IN THE HOUSE OF REPRESENTATIVES

FEBRUARY 8, 2011

Mr. MARKEY (for himself, Mr. GRIJALVA, Mr. MORAN, and Ms. NORTON) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To amend the Safe Drinking Water Act regarding an endocrine disruptor screening program.

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 ''Endocrine Disruptor Screening Enhancement Act of 2011''.

SEC. 2. ENDOCRINE DISRUPTOR SCREENING PROGRAM.

Section 1457 of the Safe Drinking Water Act (42 U.S.C. 300j–17) is amended to read as follows:

''ENDOCRINE DISRUPTOR SCREENING PROGRAM

''SEC. 1457. (a) TESTING OF SUBSTANCES.—

''(1) IN GENERAL.—In carrying out the screening program under section 408(p) of the Federal Food, Drug, and Cosmetic Act, the Administrator shall provide for the testing of substances described in paragraph (2) in addition to the substances described in section 408(p)(3) of such Act.

''(2) COVERED SUBSTANCES.—A substance is subject to testing pursuant to paragraph (1) if—

''(A) the substance may be found in sources of drinking water; and

''(B) the Administrator determines that a substantial population may be exposed to such substance.

''(3) SUBSTANCES ALREADY SUBJECT TO TESTING.—Notwithstanding paragraph (2), a substance is not subject to testing pursuant to paragraph (1) if—

''(A) the substance is already subject to evaluation determined by the Administrator to be equivalent to testing pursuant to paragraph (1); or

''(B) the Administrator has already determined the effect of the substance on the endocrine system.

''(4) SUBSTANCES DERIVED FROM DEGRADATION OR METABOLISM OF ANOTHER SUBSTANCE.—If a substance subject to testing pursuant to paragraph (1) (in this paragraph referred to as the 'covered substance') is derived

from the degradation or metabolism of another substance, or is used in or generated by the manufacture of another substance, the Administrator shall provide for such testing of the covered substance by the importer or manufacturer of the other substance.

''(b) IDENTIFICATION AND TESTING OF ENDOCRINE DISRUPTING SUBSTANCES THAT MAY BE IN DRINKING WATER.—

''(1) IDENTIFICATION.—Not later than 1 year after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, after opportunity for comment, the Administrator shall publish—

''(A) a plan for the identification of substances for testing pursuant to subsection (a)(1); and

''(B) a schedule for issuing test orders for all substances by not later than 10 years after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, with the goal of testing, at a minimum and consistent with subsection (a), all substances that have been placed on the Drinking Water Preliminary Contaminant Candidate List published pursuant to section 1412(b)(1)(B)(i) and all

substances for which a national primary drinking water regulation has been promulgated pursuant to section 1412(b)(1)(A).

In publishing the plan and schedule required by this paragraph, the Administrator shall obtain advice and direction from the Science Advisory Board.

''(2) PRIORITIZATION; CONSIDERATIONS.—In selecting substances for identification pursuant to the plan under paragraph (1)(A), the Administrator—

''(A) shall prioritize the selection of substances that pose the greatest public health concern, taking into consideration (among other factors of public health concern) the effect of such substances on subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, and other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to substances in drinking water; and

''(B) shall take into consideration—

"(i) available information on the extent of potential public exposures to the substances through drinking water;

"(ii) the Drinking Water Preliminary Contaminant Candidate List published pursuant to section 1412(b)(1)(B)(i); and

"(iii) substances for which a national primary drinking water regulation has been proposed or promulgated pursuant to 1412(b)(1)(A).

"(c) TESTING PROTOCOL PROCESS.—

"(1) IN GENERAL.—Not later than 2 years after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, the Administrator shall, after opportunity for comment, and after obtaining advice and direction from the Science Advisory Board, publish guidance on developing or updating protocols for testing of possible endocrine disruptors. The guidance shall specify—

"(A) the manner in which the Administrator will evaluate and, where necessary, revise such protocols;

"(B) the manner in which the Administrator will determine when testing of substances will be required; and

"(C) the procedures by which other scientifically relevant information can be used in lieu of some or all of the information that otherwise would be collected pursuant to testing under section 408(p) of the Federal Food, Drug, and Cosmetic Act.

"(2) MINIMUM CONTENTS.—The procedures specified pursuant to paragraph (1)(C) shall ensure that the Administrator may use information that is prepared or provided by any person (including a registrant, manufacturer, or importer of a substance for which testing is required, and any other entity) and shall apply equally with respect to any such person.

"(3) AMENDMENTS.—The Administrator may, after opportunity for comment, and after obtaining advice and direction from the Science Advisory Board, amend any guidance published pursuant to this subsection.

"(d) REVISION OF TESTING PROTOCOLS.—Not later than 2 years after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, the Administrator shall, after opportunity for comment, determine whether sufficient scientific information has been developed to warrant updating the screening protocols developed under section 408(p) of the Federal Food, Drug, and

Cosmetic Act. Not later than 5 years after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, and every 3 years thereafter, the Administrator shall determine, consistent with the guidance published under subsection (c), whether to revise screening protocols under such section based on significant improvements in the sensitivity, accuracy, reliability, reproducibility, or efficiency of such protocols. In carrying out the preceding sentence the Administrator shall require, where practicable, the use of screening protocols that eliminate or reduce the number of animals used. Whenever the Administrator revises such a protocol, the Administrator shall also determine, after obtaining advice and direction from the Science Advisory Board or the advisory panel referred to in section 25(d) of the Federal Insecticide, Fungicide, and Rodenticide Act, as appropriate, whether any substance that has already been subjected to testing should be tested using the revised protocol.

''(e) ACCELERATION OF TESTING FOR CERTAIN SUBSTANCES.—

''(1) IN GENERAL.—If the Administrator determines that—

''(A) a substance is known to be found in sources of drinking water;

''(B) a substantial population is known to be exposed to the substance; and

''(C) the substance is either suspected to be an endocrine disruptor or has a structural similarity to a substance known to be an endocrine disruptor;

the Administrator shall determine whether to require the completion of testing for such substance on an accelerated schedule, to enable the Administrator to determine the effect of such substance on the endocrine system and ensure the protection of public health.

''(2) SCIENTIFICALLY RELEVANT INFORMATION.—The Administrator shall make any determination under paragraph (1) using scientifically relevant information. In carrying out the preceding sentence, the Administrator may rely on any available scientifically relevant information, prepared or provided by any person.

''(3) GUIDANCE.—Not later than 1 year after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, the Administrator shall, after opportunity for comment, publish guidance on how the Administrator will make determinations under paragraph (1).

''(f) RESULTS OF TESTING.—

''(1) PUBLICATION OF DATA EVALUATION RECORDS.—Not later than 6 months after receipt of testing results for a substance, the Administrator shall prepare and, consistent with subsection (g), publish data evaluation records for such results in a publicly searchable database.

''(2) ADMINISTRATIVE ACTION.—Not later than 6 months after receipt of testing results for a substance, the Administrator shall—

''(A) determine whether to take action related to the substance under section 1412(b) or 1445, or other appropriate statutory authority; and

''(B) consistent with subsection (g), publish such determination in a publicly searchable database.

''(3) STRUCTURED EVALUATION FRAMEWORK.—To assess the overall weight of the evidence and relevance to humans and wildlife of results of testing, the Administrator shall develop and use a structured evaluative framework consisting of science-based criteria, consistent with the protection of public health and the environment, for systemati-

cally evaluating endocrine mode of action and for determining data relevance, quality, and reliability.

''(g) PUBLIC DATABASE.—Beginning not later than 180 days after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011 and consistent with section 552 of title 5, United States Code, the Administrator shall publish, in electronic format, a publicly searchable database that contains information regarding the testing program. Not later than 30 days after the date on which the information becomes available, the Administrator shall ensure that, at a minimum, the database—

''(1) identifies the substances selected for testing under the program; and

''(2) includes the documents and information pertaining to the status of testing activities for each such substance, including test orders, deadlines for submission, the Environmental Protection Agency's data evaluation records, the Administrator's determination on whether regulatory action will be taken under subsection (f), and the summary of chemical test results.

''(h) PETITION FOR INCLUSION OF A SUBSTANCE IN THE PROGRAM.—

''(1) IN GENERAL.—Any person may submit a petition to the Administrator to—

''(A) identify a substance pursuant to the plan under subsection (b)(1)(A); or

''(B) issue a test order requiring that a substance be tested on an accelerated basis in accordance with subsection (e).

''(2) SPECIFICATION OF FACTS.—Any petition under paragraph (1) shall specify the facts that are claimed to establish that an action described in subparagraph (A) or (B) of paragraph (1) is warranted.

''(3) ADMINISTRATIVE ACTION.—Not later than 90 days after the filing of a petition described under paragraph (1), the Administrator shall determine whether the petition has established that an action described in subparagraph (A) or (B) of paragraph (1) is warranted and shall grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly identify the substance pursuant to the plan under subsection (b)(1)(A), or issue an order requiring testing on an accelerated basis in accordance with subsection (e), as applicable. If the Administrator denies the petition, the Administrator shall publish the reasons for such denial in the Federal Register.

''(i) COORDINATION WITH OTHER FEDERAL AGENCIES.—After the Administrator—

''(1) requires testing of a substance; or

''(2) based in whole or in part on the results of testing, takes action related to a substance under section 1412(b) or 1445, or other appropriate statutory authority;

the Administrator shall give notice of such testing or action to Federal agencies which are authorized by other provisions of law to regulate the substance or products, materials, medications, processes, or practices that use the substance.

''(j) REPORTING REQUIREMENT.—Not later than 1 year after the date of the enactment of the Endocrine Disruptor Screening Enhancement Act of 2011, and every 3 years thereafter, the Administrator shall provide a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works of the Senate that describes—

''(1) progress made in identifying, testing, and regulating endocrine disruptors as well as plans for future activities;

''(2) any change in screening or testing methodology and evaluation or criteria for evaluating scientifically relevant information;

''(3) actions taken to ensure communication and sharing of scientific information with other Federal agencies and the public; and

''(4) any deviations from the plan or schedule published under subsections (b)(1)(A) and (b)(1)(B) as well as the reasons therefor.

''(k) TESTING CONSORTIA, COMPENSATION, AND COMPLIANCE.—

''(1) IN GENERAL.—Any person required by the Administrator to conduct testing of an endocrine disruptor may—

''(A) submit, on its own, data in response to an order for such testing; and

''(B) form (on a voluntary basis) a consortium in order to satisfy the requirements of one or more orders for such testing.

''(2) RELIANCE ON CONSORTIUM SUBMISSIONS.—Each member of a consortium described in paragraph (1)(B) shall have full rights to rely on all submissions of the consortium to satisfy the requirements of any order for testing, but continues to be individually subject to such requirements.

''(3) SHARING OF COSTS.—

''(A) IN GENERAL.—Each member of a consortium described in paragraph (1)(B) shall

share the applicable costs according to appropriate arrangements established by the consortium members.

''(B) BINDING OFFER.—Whenever, to satisfy the requirements of one or more orders for testing, any person offers to form or join a consortium described in paragraph (1)(B), or offers compensation to a person that has already submitted data to the Administrator satisfying an order for testing, such offer shall constitute a binding offer to share an appropriate portion of the applicable costs.

''(C) APPLICABLE COSTS.—In this subsection, the term 'applicable costs' includes the costs—

''(i) incurred to generate and report information to comply with an order for testing; or

''(ii) associated with the organization and administration of the consortium.

''(4) DISPUTE RESOLUTION.—

''(A) IN GENERAL.—In the event of any dispute about an appropriate share or a fair method of determining an appropriate share of applicable costs of the testing requirements in

a test order, any person involved in the dispute may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service or a hearing with a regional office of the American Arbitration Association. A copy of the request shall be sent to each person from whom the requesting party seeks compensation or who seeks compensation from that party.

''(B) NO REVIEW OF FINDINGS AND DETERMINATION.—The findings and determination of the arbitrator in a dispute initiated pursuant to subparagraph (A) shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except in the case of fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or by the arbitrator.

''(C) PAYMENT OF FEE AND EXPENSES.—The parties to arbitration initiated pursuant to subparagraph (A) shall share equally in the payment of the fee and expenses of the arbitrator.

''(5) ENFORCEMENT.—If the Administrator determines that any person seeking to comply with an order for testing by relying on a submission made by a consortium or an original data submitter has failed to make an offer in accordance with paragraph (3)(B), to participate in an arbitration proceeding under paragraph (4), or to comply with the terms of an agreement or arbitration decision concerning sharing of applicable costs under paragraph (3), that person is deemed to have failed to comply with an order under subparagraph (A) of section 408(p)(5) of the Federal Food, Drug, and Cosmetic Act for purposes of subparagraphs (B) and (C) of such section.

''(l) DEFINITIONS.—In this section:

''(1) The term 'endocrine disruptor' means an exogenous agent or mixture of agents that interferes with or alters the synthesis, secretion, transport, metabolism, binding action, or elimination of hormones that are present in the body and are responsible for homeostasis, growth, neurological signaling, reproduction and developmental process, or any other effect that the Administrator has designated as an 'endocrine effect' pursuant to section 408(p)(1) of the Federal Food, Drug, and Cosmetic Act.

''(2) The term 'testing' means the testing of a substance pursuant to the screening program under section 408(p) of the Federal Food, Drug, and Cosmetic Act, including a test of a substance that is intended to identify substances that have the potential to interact with the endocrine system or that is intended to determine the endocrine-related effects caused by such substance and obtain information about effects at various doses.

''(m) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2012 through 2016.''.

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