

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.

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 “Endocrine Disruptor  
5 Screening Enhancement Act of 2011”.

6 **SEC. 2. ENDOCRINE DISRUPTOR SCREENING PROGRAM.**

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

9 “ENDOCRINE DISRUPTOR SCREENING PROGRAM

10 “SEC. 1457. (a) TESTING OF SUBSTANCES.—

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

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

9               “(A) the substance may be found in sources of  
10 drinking water; and

11               “(B) the Administrator determines that a sub-  
12 stantial population may be exposed to such sub-  
13 stance.

14       “(3) SUBSTANCES ALREADY SUBJECT TO TEST-  
15 ING.—Notwithstanding paragraph (2), a substance is not  
16 subject to testing pursuant to paragraph (1) if—

17               “(A) the substance is already subject to evalua-  
18 tion determined by the Administrator to be equiva-  
19 lent to testing pursuant to paragraph (1); or

20               “(B) the Administrator has already determined  
21 the effect of the substance on the endocrine system.

22       “(4) SUBSTANCES DERIVED FROM DEGRADATION OR  
23 METABOLISM OF ANOTHER SUBSTANCE.—If a substance  
24 subject to testing pursuant to paragraph (1) (in this para-  
25 graph referred to as the ‘covered substance’) is derived

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

6 “(b) IDENTIFICATION AND TESTING OF ENDOCRINE  
7 DISRUPTING SUBSTANCES THAT MAY BE IN DRINKING  
8 WATER.—

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

14 “(A) a plan for the identification of sub-  
15 stances for testing pursuant to subsection  
16 (a)(1); and

17 “(B) a schedule for issuing test orders for  
18 all substances by not later than 10 years after  
19 the date of the enactment of the Endocrine  
20 Disruptor Screening Enhancement Act of 2011,  
21 with the goal of testing, at a minimum and con-  
22 sistent with subsection (a), all substances that  
23 have been placed on the Drinking Water Pre-  
24 liminary Contaminant Candidate List published  
25 pursuant to section 1412(b)(1)(B)(i) and all

1 substances for which a national primary drink-  
2 ing water regulation has been promulgated pur-  
3 suant to section 1412(b)(1)(A).

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

7 “(2) PRIORITIZATION; CONSIDERATIONS.—In  
8 selecting substances for identification pursuant to  
9 the plan under paragraph (1)(A), the Adminis-  
10 trator—

11 “(A) shall prioritize the selection of sub-  
12 stances that pose the greatest public health con-  
13 cern, taking into consideration (among other  
14 factors of public health concern) the effect of  
15 such substances on subgroups that comprise a  
16 meaningful portion of the general population  
17 (such as infants, children, pregnant women, the  
18 elderly, individuals with a history of serious ill-  
19 ness, and other subpopulations) that are identi-  
20 fiable as being at greater risk of adverse health  
21 effects due to exposure to substances in drink-  
22 ing water; and

23 “(B) shall take into consideration—

1 “(i) available information on the ex-  
2 tent of potential public exposures to the  
3 substances through drinking water;

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

7 “(iii) substances for which a national  
8 primary drinking water regulation has  
9 been proposed or promulgated pursuant to  
10 1412(b)(1)(A).

11 “(c) TESTING PROTOCOL PROCESS.—

12 “(1) IN GENERAL.—Not later than 2 years  
13 after the date of the enactment of the Endocrine  
14 Disruptor Screening Enhancement Act of 2011, the  
15 Administrator shall, after opportunity for comment,  
16 and after obtaining advice and direction from the  
17 Science Advisory Board, publish guidance on devel-  
18 oping or updating protocols for testing of possible  
19 endocrine disruptors. The guidance shall specify—

20 “(A) the manner in which the Adminis-  
21 trator will evaluate and, where necessary, revise  
22 such protocols;

23 “(B) the manner in which the Adminis-  
24 trator will determine when testing of substances  
25 will be required; and

1           “(C) the procedures by which other sci-  
2           entifically relevant information can be used in  
3           lieu of some or all of the information that oth-  
4           erwise would be collected pursuant to testing  
5           under section 408(p) of the Federal Food,  
6           Drug, and Cosmetic Act.

7           “(2) MINIMUM CONTENTS.—The procedures  
8           specified pursuant to paragraph (1)(C) shall ensure  
9           that the Administrator may use information that is  
10          prepared or provided by any person (including a reg-  
11          istrant, manufacturer, or importer of a substance for  
12          which testing is required, and any other entity) and  
13          shall apply equally with respect to any such person.

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

19          “(d) REVISION OF TESTING PROTOCOLS.—Not later  
20          than 2 years after the date of the enactment of the Endo-  
21          crine Disruptor Screening Enhancement Act of 2011, the  
22          Administrator shall, after opportunity for comment, deter-  
23          mine whether sufficient scientific information has been de-  
24          veloped to warrant updating the screening protocols devel-  
25          oped under section 408(p) of the Federal Food, Drug, and

1 Cosmetic Act. Not later than 5 years after the date of  
2 the enactment of the Endocrine Disruptor Screening En-  
3 hancement Act of 2011, and every 3 years thereafter, the  
4 Administrator shall determine, consistent with the guid-  
5 ance published under subsection (c), whether to revise  
6 screening protocols under such section based on signifi-  
7 cant improvements in the sensitivity, accuracy, reliability,  
8 reproducibility, or efficiency of such protocols. In carrying  
9 out the preceding sentence the Administrator shall re-  
10 quire, where practicable, the use of screening protocols  
11 that eliminate or reduce the number of animals used.  
12 Whenever the Administrator revises such a protocol, the  
13 Administrator shall also determine, after obtaining advice  
14 and direction from the Science Advisory Board or the ad-  
15 visory panel referred to in section 25(d) of the Federal  
16 Insecticide, Fungicide, and Rodenticide Act, as appro-  
17 priate, whether any substance that has already been sub-  
18 jected to testing should be tested using the revised pro-  
19 tocol.

20 “(e) ACCELERATION OF TESTING FOR CERTAIN SUB-  
21 STANCES.—

22 “(1) IN GENERAL.—If the Administrator deter-  
23 mines that—

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

1           “(B) a substantial population is known to  
2           be exposed to the substance; and

3           “(C) the substance is either suspected to  
4           be an endocrine disruptor or has a structural  
5           similarity to a substance known to be an endo-  
6           crine disruptor;

7           the Administrator shall determine whether to require  
8           the completion of testing for such substance on an  
9           accelerated schedule, to enable the Administrator to  
10          determine the effect of such substance on the endo-  
11          crine system and ensure the protection of public  
12          health.

13          “(2) SCIENTIFICALLY RELEVANT INFORMA-  
14          TION.—The Administrator shall make any deter-  
15          mination under paragraph (1) using scientifically  
16          relevant information. In carrying out the preceding  
17          sentence, the Administrator may rely on any avail-  
18          able scientifically relevant information, prepared or  
19          provided by any person.

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

1 “(f) RESULTS OF TESTING.—

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

8 “(2) ADMINISTRATIVE ACTION.—Not later than  
9 6 months after receipt of testing results for a sub-  
10 stance, the Administrator shall—

11 “(A) determine whether to take action re-  
12 lated to the substance under section 1412(b) or  
13 1445, or other appropriate statutory authority;  
14 and

15 “(B) consistent with subsection (g), pub-  
16 lish such determination in a publicly searchable  
17 database.

18 “(3) STRUCTURED EVALUATION FRAME-  
19 WORK.—To assess the overall weight of the evidence  
20 and relevance to humans and wildlife of results of  
21 testing, the Administrator shall develop and use a  
22 structured evaluative framework consisting of  
23 science-based criteria, consistent with the protection  
24 of public health and the environment, for systemati-

1 cally evaluating endocrine mode of action and for de-  
2 termining data relevance, quality, and reliability.

3 “(g) PUBLIC DATABASE.—Beginning not later than  
4 180 days after the date of the enactment of the Endocrine  
5 Disruptor Screening Enhancement Act of 2011 and con-  
6 sistent with section 552 of title 5, United States Code,  
7 the Administrator shall publish, in electronic format, a  
8 publicly searchable database that contains information re-  
9 garding the testing program. Not later than 30 days after  
10 the date on which the information becomes available, the  
11 Administrator shall ensure that, at a minimum, the data-  
12 base—

13 “(1) identifies the substances selected for test-  
14 ing under the program; and

15 “(2) includes the documents and information  
16 pertaining to the status of testing activities for each  
17 such substance, including test orders, deadlines for  
18 submission, the Environmental Protection Agency’s  
19 data evaluation records, the Administrator’s deter-  
20 mination on whether regulatory action will be taken  
21 under subsection (f), and the summary of chemical  
22 test results.

23 “(h) PETITION FOR INCLUSION OF A SUBSTANCE IN  
24 THE PROGRAM.—

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

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

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

8           “(2) SPECIFICATION OF FACTS.—Any petition  
9 under paragraph (1) shall specify the facts that are  
10 claimed to establish that an action described in sub-  
11 paragraph (A) or (B) of paragraph (1) is warranted.

12           “(3) ADMINISTRATIVE ACTION.—Not later than  
13 90 days after the filing of a petition described under  
14 paragraph (1), the Administrator shall determine  
15 whether the petition has established that an action  
16 described in subparagraph (A) or (B) of paragraph  
17 (1) is warranted and shall grant or deny the peti-  
18 tion. If the Administrator grants such petition, the  
19 Administrator shall promptly identify the substance  
20 pursuant to the plan under subsection (b)(1)(A), or  
21 issue an order requiring testing on an accelerated  
22 basis in accordance with subsection (e), as applica-  
23 ble. If the Administrator denies the petition, the Ad-  
24 ministrator shall publish the reasons for such denial  
25 in the Federal Register.

1       “(i) COORDINATION WITH OTHER FEDERAL AGEN-  
2 CIES.—After the Administrator—

3               “(1) requires testing of a substance; or

4               “(2) based in whole or in part on the results of  
5 testing, takes action related to a substance under  
6 section 1412(b) or 1445, or other appropriate statu-  
7 tory authority;

8 the Administrator shall give notice of such testing or ac-  
9 tion to Federal agencies which are authorized by other  
10 provisions of law to regulate the substance or products,  
11 materials, medications, processes, or practices that use the  
12 substance.

13       “(j) REPORTING REQUIREMENT.—Not later than 1  
14 year after the date of the enactment of the Endocrine  
15 Disruptor Screening Enhancement Act of 2011, and every  
16 3 years thereafter, the Administrator shall provide a re-  
17 port to the Committee on Energy and Commerce of the  
18 House of Representatives and the Committee on Environ-  
19 ment and Public Works of the Senate that describes—

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

23               “(2) any change in screening or testing method-  
24 ology and evaluation or criteria for evaluating sci-  
25 entifically relevant information;

1           “(3) actions taken to ensure communication  
2           and sharing of scientific information with other Fed-  
3           eral agencies and the public; and

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

7           “(k) TESTING CONSORTIA, COMPENSATION, AND  
8 COMPLIANCE.—

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

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

14                 “(B) form (on a voluntary basis) a consor-  
15                 tium in order to satisfy the requirements of one  
16                 or more orders for such testing.

17           “(2) RELIANCE ON CONSORTIUM SUBMIS-  
18          SIONS.—Each member of a consortium described in  
19          paragraph (1)(B) shall have full rights to rely on all  
20          submissions of the consortium to satisfy the require-  
21          ments of any order for testing, but continues to be  
22          individually subject to such requirements.

23           “(3) SHARING OF COSTS.—

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

1 share the applicable costs according to appro-  
2 priate arrangements established by the consor-  
3 tium members.

4 “(B) BINDING OFFER.—Whenever, to sat-  
5 isfy the requirements of one or more orders for  
6 testing, any person offers to form or join a con-  
7 sortium described in paragraph (1)(B), or of-  
8 fers compensation to a person that has already  
9 submitted data to the Administrator satisfying  
10 an order for testing, such offer shall constitute  
11 a binding offer to share an appropriate portion  
12 of the applicable costs.

13 “(C) APPLICABLE COSTS.—In this sub-  
14 section, the term ‘applicable costs’ includes the  
15 costs—

16 “(i) incurred to generate and report  
17 information to comply with an order for  
18 testing; or

19 “(ii) associated with the organization  
20 and administration of the consortium.

21 “(4) DISPUTE RESOLUTION.—

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

1 a test order, any person involved in the dispute  
2 may initiate binding arbitration proceedings by  
3 requesting the Federal Mediation and Concilia-  
4 tion Service to appoint an arbitrator from the  
5 roster of arbitrators maintained by such Service  
6 or a hearing with a regional office of the Amer-  
7 ican Arbitration Association. A copy of the re-  
8 quest shall be sent to each person from whom  
9 the requesting party seeks compensation or who  
10 seeks compensation from that party.

11 “(B) NO REVIEW OF FINDINGS AND DE-  
12 TERMINATION.—The findings and determina-  
13 tion of the arbitrator in a dispute initiated pur-  
14 suant to subparagraph (A) shall be final and  
15 conclusive, and no official or court of the  
16 United States shall have power or jurisdiction  
17 to review any such findings and determination,  
18 except in the case of fraud, misrepresentation,  
19 or other misconduct by one of the parties to the  
20 arbitration or by the arbitrator.

21 “(C) PAYMENT OF FEE AND EXPENSES.—  
22 The parties to arbitration initiated pursuant to  
23 subparagraph (A) shall share equally in the  
24 payment of the fee and expenses of the arbi-  
25 trator.

1           “(5) ENFORCEMENT.—If the Administrator de-  
2           termines that any person seeking to comply with an  
3           order for testing by relying on a submission made by  
4           a consortium or an original data submitter has  
5           failed to make an offer in accordance with para-  
6           graph (3)(B), to participate in an arbitration pro-  
7           ceeding under paragraph (4), or to comply with the  
8           terms of an agreement or arbitration decision con-  
9           cerning sharing of applicable costs under paragraph  
10          (3), that person is deemed to have failed to comply  
11          with an order under subparagraph (A) of section  
12          408(p)(5) of the Federal Food, Drug, and Cosmetic  
13          Act for purposes of subparagraphs (B) and (C) of  
14          such section.

15          “(1) DEFINITIONS.—In this section:

16                 “(1) The term ‘endocrine disruptor’ means an  
17                 exogenous agent or mixture of agents that interferes  
18                 with or alters the synthesis, secretion, transport, me-  
19                 tabolism, binding action, or elimination of hormones  
20                 that are present in the body and are responsible for  
21                 homeostasis, growth, neurological signaling, repro-  
22                 duction and developmental process, or any other ef-  
23                 fect that the Administrator has designated as an  
24                 ‘endocrine effect’ pursuant to section 408(p)(1) of  
25                 the Federal Food, Drug, and Cosmetic Act.

1           “(2) The term ‘testing’ means the testing of a  
2           substance pursuant to the screening program under  
3           section 408(p) of the Federal Food, Drug, and Cos-  
4           metic Act, including a test of a substance that is in-  
5           tended to identify substances that have the potential  
6           to interact with the endocrine system or that is in-  
7           tended to determine the endocrine-related effects  
8           caused by such substance and obtain information  
9           about effects at various doses.

10          “(m) AUTHORIZATION OF APPROPRIATIONS.—To  
11          carry out this section, there is authorized to be appro-  
12          priated \$5,000,000 for each of fiscal years 2012 through  
13          2016.”.

○