

111TH CONGRESS
2D SESSION

H. R. 5210

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

IN THE HOUSE OF REPRESENTATIVES

MAY 5, 2010

Mr. MARKEY of Massachusetts (for himself and Mr. MORAN of Virginia) 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 2010”.

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 2010,
12 after opportunity for comment, the Administrator
13 shall publish—

14 “(A) a list of no fewer than 100 sub-
15 stances for testing pursuant to subsection
16 (a)(1) (in accordance with the schedule speci-
17 fied in paragraph (3)); and

18 “(B) a plan for the identification of addi-
19 tional substances for testing pursuant to sub-
20 section (a)(1), and a schedule for issuing test
21 orders for all such additional substances by not
22 later than 10 years after the date of the enact-
23 ment of the Endocrine Disruptor Screening En-
24 hancement Act of 2010, with the goal of test-
25 ing, at a minimum and consistent with sub-

1 section (a), all substances that have been placed
2 on the Drinking Water Preliminary Contami-
3 nant Candidate List published pursuant to sec-
4 tion 1412(b)(1)(B)(i).

5 In publishing the plan and schedule required by sub-
6 paragraph (B), the Administrator shall obtain advice
7 and direction from the Science Advisory Board.

8 “(2) PRIORITIZATION; CONSIDERATIONS.—In
9 selecting substances for listing under paragraph
10 (1)(A) or identification pursuant to the plan under
11 paragraph (1)(B), the Administrator—

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

24 “(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; and

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

7 “(3) SCHEDULE.—After publication of the list
8 under paragraph (1)(A), the Administrator shall
9 issue test orders for—

10 “(A) at least 25 substances on the list by
11 the end of each year during the 4-year period
12 following the date of the enactment of the En-
13 docrine Disruptor Screening Enhancement Act
14 of 2010; and

15 “(B) all substances on the list by the end
16 of such 4-year period.

17 “(c) TESTING PROTOCOL PROCESS.—

18 “(1) IN GENERAL.—Not later than 2 years
19 after the date of the enactment of the Endocrine
20 Disruptor Screening Enhancement Act of 2010, the
21 Administrator shall, after opportunity for comment,
22 and after obtaining advice and direction from the
23 Science Advisory Board, publish guidance on devel-
24 oping and updating protocols for testing of possible
25 endocrine disruptors. The guidance shall specify—

1 “(A) the manner in which the Adminis-
2 trator will evaluate and, where necessary, revise
3 such protocols;

4 “(B) the manner in which the Adminis-
5 trator will determine when testing of substances
6 will be required; and

7 “(C) the procedures by which other sci-
8 entifically relevant information can be used in
9 lieu of some or all of the information that oth-
10 erwise would be collected pursuant to testing
11 under section 408(p) of the Federal Food,
12 Drug, and Cosmetic Act.

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

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

1 “(d) REVISION OF TESTING PROTOCOLS.—Not later
2 than 2 years after the date of the enactment of the Endo-
3 crine Disruptor Screening Enhancement Act of 2010, the
4 Administrator shall, after opportunity for comment, deter-
5 mine whether sufficient scientific information has been de-
6 veloped to warrant updating the screening protocols devel-
7 oped under section 408(p) of the Federal Food, Drug, and
8 Cosmetic Act. Not later than 5 years after the date of
9 the enactment of the Endocrine Disruptor Screening En-
10 hancement Act of 2010 and every 3 years thereafter, the
11 Administrator shall determine, consistent with the guid-
12 ance published under subsection (c), whether to revise
13 screening protocols under such section based on signifi-
14 cant improvements in the sensitivity, accuracy, reliability,
15 reproducibility, or efficiency of such protocols. Whenever
16 the Administrator revises such a protocol, the Adminis-
17 trator shall also determine, after obtaining advice and di-
18 rection from the Science Advisory Board or the advisory
19 panel referred to in section 25(d) of the Federal Insecti-
20 cide, Fungicide, and Rodenticide Act, as appropriate,
21 whether any substance that has already been subjected to
22 testing should be tested using the revised protocol.

23 “(e) ACCELERATION OF TESTING FOR CERTAIN SUB-
24 STANCES.—

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

3 “(A) a substance is known to be found in
4 sources of drinking water,

5 “(B) a substantial population is known to
6 be exposed to the substance, and

7 “(C) the substance is either suspected to
8 be an endocrine disruptor or has a structural
9 similarity to a substance known to be an endo-
10 crine disruptor,

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

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

24 “(3) GUIDANCE.—Not later than 1 year after
25 the date of the enactment of the Endocrine

1 Disruptor Screening Enhancement Act of 2010, the
2 Administrator shall, after opportunity for comment,
3 publish guidance on how the Administrator will
4 make determinations under paragraph (1).

5 “(f) RESULTS OF TESTING.—

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

12 “(2) ADMINISTRATIVE ACTION.—Not later than
13 6 months after receipt of testing results for a sub-
14 stance, the Administrator shall—

15 “(A) determine whether to take action re-
16 lated to the substance under section 1412(b) or
17 1445, or other appropriate statutory authority;
18 and

19 “(B) consistent with subsection (g), pub-
20 lish such determination in a publicly searchable
21 database.

22 “(3) STRUCTURED EVALUATION FRAME-
23 WORK.—To assess the overall weight of the evidence
24 and relevance to humans and wildlife of results of
25 testing, the Administrator shall develop and use a

1 structured evaluative framework consisting of
2 science-based criteria, consistent with the protection
3 of public health and the environment, for systemati-
4 cally evaluating endocrine mode of action and for de-
5 termining data relevance, quality, and reliability.

6 “(g) PUBLIC DATABASE.—Beginning not later than
7 180 days after the date of the enactment of the Endocrine
8 Disruptor Screening Enhancement Act of 2010 and con-
9 sistent with section 552 of title 5, United States Code,
10 the Administrator shall publish, in electronic format, a
11 publicly searchable database that contains information re-
12 garding the testing program. Not later than 30 days after
13 the date on which the information becomes available, the
14 Administrator shall ensure that, at a minimum, the data-
15 base—

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

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

1 “(h) PETITION FOR INCLUSION OF A SUBSTANCE IN
2 THE PROGRAM.—

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

5 “(A) add a substance to the list under sub-
6 section (b)(1)(A) or identify a substance pursu-
7 ant to the plan under subsection (b)(1)(B); or

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

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

15 “(3) ADMINISTRATIVE ACTION.—Not later than
16 90 days after the filing of a petition described under
17 paragraph (1), the Administrator shall determine
18 whether the petition has established that an action
19 described in subparagraph (A) or (B) of paragraph
20 (1) is warranted and shall grant or deny the peti-
21 tion. If the Administrator grants such petition, the
22 Administrator shall promptly add the substance to
23 the list under subsection (b)(1)(A), identify the sub-
24 stance pursuant to the plan under subsection
25 (b)(1)(B), or issue an order requiring testing on an

1 accelerated basis in accordance with subsection (e),
2 as applicable. If the Administrator denies the peti-
3 tion, the Administrator shall publish the reasons for
4 such denial in the Federal Register.

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

7 “(1) requires testing of a substance, or

8 “(2) based in whole or in part on the results of
9 testing, takes action related to a substance under
10 section 1412(b) or 1445 or other appropriate statu-
11 tory authority,

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

17 “(j) REPORTING REQUIREMENT.—Not later than 1
18 year after the date of the enactment of the Endocrine
19 Disruptor Screening Enhancement Act of 2010 and every
20 3 years thereafter, the Administrator shall provide a re-
21 port to the Committee on Energy and Commerce of the
22 House of Representatives and the Committee on Environ-
23 ment and Public Works of the Senate that describes—

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

4 “(2) any change in screening or testing method-
5 ology and evaluation or criteria for evaluating sci-
6 entifically relevant information; and

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

10 “(4) any deviations from the plan or schedule
11 published under subsection (b)(1)(B) as well as the
12 reasons therefor.

13 “(k) TESTING CONSORTIA, COMPENSATION, AND
14 COMPLIANCE.—

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

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

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

23 “(2) RELIANCE ON CONSORTIUM SUBMIS-
24 SIONS.—Each member of a consortium described in
25 paragraph (1)(B) shall have full rights to rely on all

1 submissions of the consortium to satisfy the require-
2 ments of any order for testing, but continues to be
3 individually subject to such requirements.

4 “(3) SHARING OF COSTS.—

5 “(A) IN GENERAL.—Each member of a
6 consortium described in paragraph (1)(B) shall
7 share the applicable costs according to appro-
8 priate arrangements established by the consor-
9 tium members.

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

19 “(C) APPLICABLE COSTS.—In this sub-
20 section, the term ‘applicable costs’ includes the
21 costs—

22 “(i) incurred to generate and report
23 information to comply with an order for
24 testing; or

1 “(ii) associated with the organization
2 and administration of the consortium.

3 “(4) DISPUTE RESOLUTION.—

4 “(A) IN GENERAL.—In the event of any
5 dispute about an appropriate share or a fair
6 method of determining an appropriate share of
7 applicable costs of the testing requirements in
8 a test order, any person involved in the dispute
9 may initiate binding arbitration proceedings by
10 requesting the Federal Mediation and Concilia-
11 tion Service to appoint an arbitrator from the
12 roster of arbitrators maintained by such Service
13 or a hearing with a regional office of the Amer-
14 ican Arbitration Association. A copy of the re-
15 quest shall be sent to each person from whom
16 the requesting party seeks compensation or who
17 seeks compensation from that party.

18 “(B) NO REVIEW OF FINDINGS AND DE-
19 TERMINATION.—The findings and determina-
20 tion of the arbitrator in a dispute initiated pur-
21 suant to subparagraph (A) shall be final and
22 conclusive, and no official or court of the
23 United States shall have power or jurisdiction
24 to review any such findings and determination,
25 except in the case of fraud, misrepresentation,

1 or other misconduct by one of the parties to the
2 arbitration or by the arbitrator.

3 “(C) PAYMENT OF FEE AND EXPENSES.—

4 The parties to arbitration initiated pursuant to
5 subparagraph (A) shall share equally in the
6 payment of the fee and expenses of the arbi-
7 trator.

8 “(5) ENFORCEMENT.—If the Administrator de-
9 termines that any person seeking to comply with an
10 order for testing by relying on a submission made by
11 a consortium or an original data submitter has
12 failed to make an offer in accordance with para-
13 graph (3)(B), to participate in an arbitration pro-
14 ceeding under paragraph (4), or to comply with the
15 terms of an agreement or arbitration decision con-
16 cerning sharing of applicable costs under paragraph
17 (3), that person is deemed to have failed to comply
18 with an order under subparagraph (A) of section
19 408(p)(5) of the Federal Food, Drug, and Cosmetic
20 Act for purposes of subparagraphs (B) and (C) of
21 such section.

22 “(1) DEFINITIONS.—In this section:

23 “(1) The term ‘endocrine disruptor’ means an
24 exogenous agent or mixture of agents that interferes
25 or alters the synthesis, secretion, transport, metabo-

1 lism, binding action, or elimination of hormones that
2 are present in the body and are responsible for ho-
3 meostasis, growth, neurological signaling, reproduc-
4 tion and developmental process, or any other effect
5 that the Administrator has designated as an ‘endo-
6 crine effect’ pursuant to section 408(p)(1) of the
7 Federal Food, Drug, and Cosmetic Act.

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

17 “(m) AUTHORIZATION OF APPROPRIATIONS.—To
18 carry out this section, there is authorized to be appro-
19 priated \$5,000,000 for each of fiscal years 2011 through
20 2015.”.

