

112TH CONGRESS
1ST SESSION

S. 1361

To reduce human exposure to endocrine-disrupting chemicals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 13, 2011

Mr. KERRY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

A BILL

To reduce human exposure to endocrine-disrupting chemicals, 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 “Endocrine-Disrupting
5 Chemicals Exposure Elimination Act of 2011”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents of this Act is as follows:

- Sec. 1. Short title.
- Sec. 2. Table of contents.
- Sec. 3. Findings.
- Sec. 4. Definitions.
- Sec. 5. Tiering applicable to levels of evidence and concern.

TITLE I—RESEARCH ON ENDOCRINE-DISRUPTING CHEMICALS

Sec. 101. National toxicology program activities.

Sec. 102. Research program of national institute of environmental health sciences.

TITLE II—REDUCING EXPOSURE TO ENDOCRINE-DISRUPTING
CHEMICALS

Sec. 201. Federal agency action.

Sec. 202. Citizen suits.

TITLE III—TRAINING

Sec. 301. Training in fields related to the prevention of endocrine disruption.

TITLE IV—MISCELLANEOUS

Sec. 401. Authorization of appropriations.

1 **SEC. 3. FINDINGS.**

2 Congress finds that—

3 (1) there is growing evidence that the human
4 endocrine system is extremely sensitive to particular
5 chemicals;

6 (2) numerous studies show links between par-
7 ticular chemicals and hormone functions in both ani-
8 mals and humans, and those links have been further
9 connected to numerous disorders;

10 (3) a research and evaluation program that tar-
11 gets suspected endocrine-disrupting chemicals would
12 establish greater scientific certainty with respect to
13 the linkage of particular chemicals with endocrine
14 system effects;

15 (4) credible linkages established by the research
16 described in paragraph (3) would establish a basis
17 for regulation under authorities that include—

1 (A) the Federal Insecticide, Fungicide, and
2 Rodenticide Act (7 U.S.C. 136 et seq.);

3 (B) the Food Quality Protection Act of
4 1996 (7 U.S.C. 136 note; Public Law 104–
5 170);

6 (C) the Toxic Substances Control Act (15
7 U.S.C. 2601 et seq.);

8 (D) the Federal Food, Drug, and Cosmetic
9 Act (21 U.S.C. 301 et seq.);

10 (E) the Federal Water Pollution Control
11 Act (33 U.S.C. 1251 et seq.);

12 (F) the Safe Drinking Water Act (42
13 U.S.C. 300f et seq.); and

14 (G) the Clean Air Act (42 U.S.C. 7401 et
15 seq.);

16 (5) the research described in paragraph (3), as
17 well as availability of information and the scientific
18 perspective derived from that research, would pro-
19 mote voluntary actions to reduce exposure to those
20 harmful endocrine-disrupting chemicals through
21 market forces;

22 (6) there is a need to educate the public on the
23 results of research on endocrine-disrupting chemicals
24 so that manufacturers, processors, retailers, and in-

1 individual consumers can make informed decisions
2 about potential exposure to harmful chemicals;

3 (7) people should be protected from chemicals
4 that are found to have endocrine-disrupting effects;
5 and

6 (8) animal testing should be reduced to the
7 minimum necessary with the goal of transitioning to
8 a predominantly nonanimal paradigm as articulated
9 in the 2007 National Research Council report enti-
10 tled “Toxicity Testing in the Twenty-First Century:
11 A Vision and a Strategy”.

12 **SEC. 4. DEFINITIONS.**

13 In this Act:

14 (1) **CHEMICAL.**—The term “chemical” means
15 an individual chemical, a combination of chemicals,
16 or a mixture of chemicals.

17 (2) **DIRECTOR.**—The term “Director” means
18 the Director of the National Institute of Environ-
19 mental Health Sciences.

20 (3) **ENDOCRINE-DISRUPTING CHEMICAL.**—The
21 term “endocrine-disrupting chemical” means a
22 chemical that interrupts, alters, interferes with, dis-
23 turbs, or otherwise changes the human endocrine
24 system or cell functioning.

1 (1) establish and implement a research program
2 designed to strengthen the scientific basis of infor-
3 mation used by Federal agencies to understand the
4 effects of, and reduce human exposure to, endocrine-
5 disrupting chemicals;

6 (2) subject to subsection (b)(1), establish an en-
7 docrine disruption expert panel and direct the panel
8 to consider and report to the Director on issues re-
9 lating to the identification, classification, or evalua-
10 tion of endocrine-disrupting chemicals under sub-
11 section (b)(2);

12 (3) for each chemical determined by the Direc-
13 tor to be a potential or actual endocrine-disrupting
14 chemical identify—

15 (A) the level of evidence that the chemical
16 is or may be an endocrine-disrupting chemical;

17 (B) the level of concern that the chemical
18 may disrupt the human endocrine system; and

19 (C) the pathways of exposure to the chem-
20 ical for humans and animals; and

21 (4) not later than 2 years after the date of en-
22 actment of this Act and every 2 years thereafter,
23 make publicly available and submit to Congress and
24 each relevant Federal agency—

25 (A) an up-to-date list that—

1 (i) specifies each chemical identified
2 by the Director to be a potential or actual
3 endocrine-disrupting chemical; and

4 (ii) identifies—

5 (I) the level of evidence that the
6 chemical disrupts the human endo-
7 crine system;

8 (II) the level of concern that the
9 chemical disrupts the human endo-
10 crine system; and

11 (III) the pathways of exposure to
12 the chemical for humans and animals;
13 and

14 (B) a report on—

15 (i) the activities of the National Toxi-
16 cology Program pertaining to endocrine-
17 disrupting chemicals; and

18 (ii) the activities of Federal agencies
19 with respect to endocrine-disrupting chemi-
20 cals, including actions taken or expected to
21 be taken pursuant to section 201.

22 (b) EXPERT PANEL.—

23 (1) APPOINTMENT.—The Director, in consulta-
24 tion with the National Toxicology Program Board of
25 Scientific Counselors (or any successor board or

1 committee), shall appoint the members of the endo-
2 crine disruption expert panel from among individuals
3 who—

4 (A) have established expertise in the field
5 of endocrine disruption research by publishing
6 research in peer-reviewed literature;

7 (B) have received Federal endocrine re-
8 search-related funding during the 2 years pre-
9 ceeding the date of appointment under this sub-
10 section;

11 (C) provide assurances that the member
12 will carry out the duties of that member in a
13 manner free of conflicts of interest, as deter-
14 mined by the Director, including by complying
15 with section 208 of title 18, United States
16 Code; and

17 (D) represent diverse disciplines, which
18 may include endocrinology, developmental and
19 neurological biology, embryology, biochemistry,
20 physiology, epidemiology, endocrine-driven on-
21 cology, in vitro and computational toxicology,
22 and medical research.

23 (2) DUTIES.—For each of the 10 fiscal years
24 following the date of enactment of this Act, the ex-
25 pert panel shall—

1 (A) consider and report to the Director on
2 issues relating to the identification, classifica-
3 tion, or evaluation of not more than 10 endo-
4 crine-disrupting chemicals or groups of endo-
5 crine-disrupting chemicals;

6 (B) evaluate existing research aimed at un-
7 derstanding the biological pathways in humans
8 by which endocrine-disrupting chemicals operate
9 and as appropriate, identify future research pri-
10 orities; and

11 (C) maintain a list that identifies chemi-
12 cals of concern for endocrine disruption effects,
13 including findings based on peer-reviewed stud-
14 ies and other relevant data that relate to—

15 (i) whether a chemical is a potential
16 or actual endocrine-disrupting chemical;

17 (ii) the level of evidence that the
18 chemical is or may be an endocrine-dis-
19 rupting chemical;

20 (iii) the level of concern that the
21 chemical may disrupt the human endocrine
22 system;

23 (iv) the pathways of exposure to the
24 chemical for humans and animals; and

1 (v) the need for additional data, as-
2 says, testing, or research to determine the
3 level of concern associated with the poten-
4 tial of the chemical to disrupt the human
5 endocrine system.

6 (3) REPORT.—The expert panel shall submit to
7 the Director and make publicly available a biennial
8 report on the activities of the panel, including an up-
9 to-date version of the list under paragraph (2)(C).

10 (c) PETITIONS.—

11 (1) IN GENERAL.—Any Federal agency, State,
12 local, or tribal government, or person may petition
13 the Director—

14 (A) to determine whether a chemical
15 should be identified by the National Toxicology
16 Program to be a potential or actual endocrine-
17 disrupting chemical and included in the list
18 under subsection (a)(4)(A); or

19 (B) to reclassify a chemical, revise a find-
20 ing, or amend any other determination of the
21 National Toxicology Program based on new in-
22 formation.

23 (2) RULES.—The Director shall adopt rules
24 that provide for—

1 (A) the form and procedure for filing a pe-
2 tition under paragraph (1); and

3 (B) the procedural rights of an entity that
4 files a petition under paragraph (1).

5 (d) NO JUDICIAL REVIEW.—A listing, finding, or
6 other determination under this section shall not be subject
7 to—

8 (1) judicial review; or

9 (2) correction under section 515 of the Treas-
10 ury and General Government Appropriations Act,
11 2001 (114 Stat. 2763A–153).

12 **SEC. 102. RESEARCH PROGRAM OF NATIONAL INSTITUTE**
13 **OF ENVIRONMENTAL HEALTH SCIENCES.**

14 Subpart 12 of part C of title IV of the Public Health
15 Service Act (42 U.S.C. 281 et seq.) is amended by adding
16 at the end the following:

17 **“SEC. 463C. ENDOCRINE DISRUPTION RESEARCH PRO-**
18 **GRAM.**

19 “(a) DEFINITIONS.—In this section:

20 “(1) CHEMICAL.—The term ‘chemical’ means
21 an individual chemical, a combination of chemicals,
22 or a mixture of chemicals.

23 “(2) ENDOCRINE-DISRUPTING CHEMICAL.—The
24 term ‘endocrine-disrupting chemical’ means a chem-
25 ical that interrupts, alters, interferes with, disturbs,

1 or otherwise changes the human or animal endocrine
2 system or its functioning.

3 “(b) ENDOCRINE DISRUPTION RESEARCH PRO-
4 GRAM.—

5 “(1) IN GENERAL.—The Director of the Insti-
6 tute shall conduct and support a research program,
7 to be known as the ‘Endocrine Disruption Research
8 Program’, to improve the understanding of the man-
9 ner in which chemicals can disrupt the human endo-
10 crine system.

11 “(2) CONTENTS.—The Endocrine Disruption
12 Research Program shall—

13 “(A) be designed—

14 “(i) to develop the information needed
15 by Federal agencies to understand chem-
16 ical disruption of the endocrine system and
17 reduce human and animal exposure to en-
18 docrine-disrupting chemicals;

19 “(ii) to understand the cellular path-
20 ways in humans by which endocrine-dis-
21 rupting chemicals are able to cause adverse
22 effects; and

23 “(iii) to use laboratory practices that
24 will produce data that are sufficiently ac-

1 curate and reproducible to be used for reg-
2 ulatory decisions;

3 “(B) include research to design, develop,
4 and validate appropriately sensitive tests to
5 screen and identify chemicals capable of dis-
6 rupting the human endocrine system;

7 “(C) address the full range of potential
8 human health impacts, including—

9 “(i) male and female developmental
10 and reproductive disorders;

11 “(ii) brain and neurobehavioral dis-
12 orders;

13 “(iii) metabolic syndromes,
14 prediabetes, diabetes, improper glucose and
15 fat metabolisms, obesity, and cardio-
16 vascular disorders;

17 “(iv) effects on the pituitary,
18 hypothalamus, hippocampus, thyroid, adre-
19 nal system, immune system, bones, cardio-
20 vascular system, and other endocrine or-
21 gans and systems throughout all life
22 stages;

23 “(v) hormonally driven cancer; and

24 “(vi) other related effects;

1 “(D) consider the potential for additive
2 and synergistic effects;

3 “(E) be carried out using a multidisci-
4 plinary approach to ensure connections among
5 multiple levels, including the molecular, organ,
6 and whole animal or human levels;

7 “(F) refine computational modeling tools
8 to integrate cellular pathway data into a dose-
9 response framework for risk assessment;

10 “(G) identify biomarkers of exposure and
11 effect that can be further developed and trans-
12 lated for use in human epidemiological and pub-
13 lic health studies focused on defining the role of
14 endocrine-disrupting chemicals in disease eti-
15 ology across the lifespan; and

16 “(H) ensure that research or testing in-
17 volving living animals is carried out only when
18 equally effective and reliable alternative ap-
19 proaches for obtaining the result sought are not
20 readily available.

21 “(c) WORKSHOPS AND FORUMS.—The Director of
22 the Institute may conduct workshops and forums and pro-
23 vide information on the health effects associated with
24 chemicals that may disrupt the endocrine system—

1 “(1) to identify chemicals for research under
2 subsection (b);

3 “(2) to strategize on approaches for the devel-
4 opment of sensitive tests to screen chemicals for en-
5 docrine-disrupting activity using assays;

6 “(3) to review the state of the science on endo-
7 crine-disrupting chemicals and provide recommenda-
8 tions for a research, testing, and training agenda;
9 and

10 “(4) to educate attendees about endocrine-dis-
11 rupting chemicals.”.

12 **TITLE II—REDUCING EXPOSURE**
13 **TO ENDOCRINE-DISRUPTING**
14 **CHEMICALS**

15 **SEC. 201. FEDERAL AGENCY ACTION.**

16 (a) RESPONSE TO LIST AND STRATEGY.—

17 (1) IN GENERAL.—Not later than 90 days after
18 receiving each biennial list, strategy, and report
19 under section 101(a)(4), each Federal agency with
20 regulatory authority over any chemical included on
21 the list shall prepare and publish a written response
22 to the list and strategy.

23 (2) CONTENTS.—At a minimum, the response
24 of a Federal agency under paragraph (1) shall—

1 (A) include an evaluation of the findings
2 and determinations of the National Toxicology
3 Program pertaining to each listed chemical sub-
4 ject to the regulatory authority of that Federal
5 agency; and

6 (B) adopt or modify, as scientifically ap-
7 propriate, each finding of the National Toxi-
8 cology Program pertaining to—

9 (i) whether the chemical disrupts or
10 may disrupt the human endocrine system;

11 (ii) the level of concern associated
12 with the potential of the chemical to dis-
13 rupt the human endocrine system; and

14 (iii) the pathways of exposure to the
15 chemical for humans and animals.

16 (b) MINIMAL LEVEL OF CONCERN.—If the Director
17 finds under section 101(a)(3)(A) that there is at least a
18 minimal level of concern that a chemical may disrupt the
19 human endocrine system each Federal agency with regu-
20 latory authority over the chemical shall—

21 (1) develop a strategy for reducing human ex-
22 posure to the chemical that—

23 (A) is made publicly available not later
24 than 180 days after the date on which the
25 agency receives the finding of the Director; and

1 (B) includes methods to promote voluntary
2 actions by industry for reducing human expo-
3 sure to the chemical; and

4 (2) take any necessary action under that regu-
5 latory authority, including further testing or
6 issuance of orders, regulations, or public notices, to
7 reduce or eliminate human exposure to the chemical.

8 (c) HIGHEST LEVEL OF CONCERN.—

9 (1) PROHIBITION.—Beginning on the date that
10 is 2 years after the date on which the Director
11 makes publicly available a finding under section
12 101(a)(3)(B) that there is a high level of concern
13 that a chemical may disrupt the human endocrine
14 system, it shall be unlawful to use the chemical in
15 interstate commerce or in a manner that affects
16 interstate commerce, unless the pathway to human
17 exposure is mitigated before or in conjunction with
18 that use.

19 (2) FEDERAL AGENCY ACTION.—Not later than
20 the date that is 2 years after the date on which the
21 Director makes publicly available a finding described
22 in paragraph (1), each Federal agency with regu-
23 latory authority over the chemical subject to the
24 finding shall establish regulations or take other ap-

1 appropriate actions to implement paragraph (1) with
2 respect to the chemical.

3 (d) **AGGREGATED COMPUTATIONAL TOXICOLOGY RE-**
4 **SOURCES DATABASES.**—The Administrator of the Envi-
5 ronmental Protection Agency shall include the findings
6 and determinations of the National Toxicology Program
7 pertaining to endocrine-disrupting chemicals in the Aggre-
8 gated Computational Toxicology Resource (ACToR) data-
9 bases (or any successor databases) to the extent otherwise
10 permitted by law, including any restrictions on the disclo-
11 sure of confidential business information.

12 **SEC. 202. CITIZEN SUITS.**

13 (a) **AUTHORITY TO BRING CIVIL ACTIONS.**—Any
14 State, local, or tribal government, or any other person,
15 may commence a civil action to prevent or restrain a pro-
16 hibited use of a chemical in violation of section 201.

17 (b) **JURISDICTION.**—The United States Court of Ap-
18 peals for the circuit in which the person commencing the
19 civil action resides shall have exclusive original jurisdiction
20 over an action described in subsection (a).

21 **TITLE III—TRAINING**

22 **SEC. 301. TRAINING IN FIELDS RELATED TO THE PREVEN-**
23 **TION OF ENDOCRINE DISRUPTION.**

24 The Director shall establish a program to support,
25 either directly or by making grants, graduate and

1 postdoctoral training in fields relating to the study and
2 prevention of endocrine disruption.

3 **TITLE IV—MISCELLANEOUS**

4 **SEC. 401. AUTHORIZATION OF APPROPRIATIONS.**

5 There are authorized to be appropriated to carry out
6 this Act and the amendments made by this Act such sums
7 as are necessary for each of fiscal years 2012 through
8 2021.

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