

112TH CONGRESS  
1ST SESSION

# H. R. 2521

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

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## IN THE HOUSE OF REPRESENTATIVES

JULY 13, 2011

Mr. MORAN (for himself, Mr. HINCHEY, Mr. CONNOLLY of Virginia, Ms. NORTON, Mr. GEORGE MILLER of California, Ms. RICHARDSON, Mr. GRIJALVA, Ms. SCHAKOWSKY, Mrs. LOWEY, Mr. RUSH, Mrs. CAPPS, Mr. MCGOVERN, and Mr. PRICE of North Carolina) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## 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 The Congress finds as follows:

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 animals  
8 and in humans, and those links have been further  
9 connected to numerous disorders.

10 (3) A targeted research and evaluation program  
11 on suspected endocrine-disrupting chemicals would  
12 establish greater scientific certainty with respect to  
13 the linkage of particular chemicals with endocrine  
14 system effects.

1           (4) Credible linkages established by this re-  
2 search will be the basis for regulation under authori-  
3 ties including—

4                   (A) the Federal Food, Drug, and Cosmetic  
5 Act;

6                   (B) the Toxic Substances Control Act;

7                   (C) the Safe Drinking Water Act;

8                   (D) the Food Quality Protection Act;

9                   (E) the Clean Air Act;

10                  (F) the Clean Water Act; and

11                   (G) the Federal Insecticide, Fungicide, and  
12 Rodenticide Act.

13           (5) Such research, information availability, and  
14 scientific perspective would also promote voluntary  
15 actions to reduce exposure to these harmful chemi-  
16 cals through market forces.

17           (6) There is a need to educate the public on the  
18 results of research on endocrine-disrupting chemicals  
19 so that manufacturers, processors, retailers, and in-  
20 dividual consumers can make informed decisions  
21 about potential exposure to harmful chemicals.

22           (7) People should be protected from chemicals  
23 that are found to have endocrine-disrupting effects.

24           (8) Animal testing should be reduced to the  
25 minimum necessary with the goal of transitioning to

1 a predominantly nonanimal paradigm as articulated  
2 in the 2007 National Research Council report “Tox-  
3 icity Testing in the Twenty-First Century: A Vision  
4 and a Strategy”.

5 **SEC. 4. DEFINITIONS.**

6 In this Act:

7 (1) The term “chemical” means an individual  
8 chemical, a combination of chemicals, or a mixture  
9 of chemicals.

10 (2) The term “Director” means the Director of  
11 the National Institute of Environmental Health  
12 Sciences.

13 (3) The term “endocrine-disrupting chemical”  
14 means a chemical that interrupts, alters, interferes  
15 with, disturbs, or otherwise changes the human en-  
16 docrine system or cell functioning.

17 (4) The term “Endocrine Disruption Expert  
18 Panel”, “Expert Panel”, or “Panel” means the En-  
19 docrine Disruption Expert Panel established under  
20 section 101(a)(2).

21 **SEC. 5. TIERING APPLICABLE TO LEVELS OF EVIDENCE**  
22 **AND CONCERN.**

23 In identifying, determining, or making a finding with  
24 respect to a level of evidence or a level of concern under  
25 this Act (including sections 101(a)(3), 101(a)(4),

1 101(b)(2)(C), and 201(a)(2)(B)), the Director or the Ex-  
2 pert Panel, as applicable, shall select from among the fol-  
3 lowing levels:

- 4 (1) High.
- 5 (2) Substantial.
- 6 (3) Minimal.
- 7 (4) None.

8 **TITLE I—RESEARCH ON ENDO-**  
9 **CRINE-DISRUPTING CHEMI-**  
10 **CALS**

11 **SEC. 101. NATIONAL TOXICOLOGY PROGRAM ACTIVITIES.**

12 (a) IN GENERAL.—As part of the National Toxi-  
13 cology Program, the Director, in consultation with the Na-  
14 tional Toxicology Program Board of Scientific Counselors  
15 (or any successor board or committee), shall—

16 (1) establish and implement a research program  
17 designed to strengthen the scientific basis of infor-  
18 mation used by Federal agencies to understand the  
19 effects of, and reduce human exposure to, endocrine-  
20 disrupting chemicals;

21 (2) establish (subject to subsection (b)(1)) an  
22 Endocrine Disruption Expert Panel and direct the  
23 Panel to consider and report to the Director on  
24 issues related to identification, classification, or eval-

1 uation of endocrine-disrupting chemicals as specified  
2 in subsection (b)(2);

3 (3) for each chemical determined by the Direc-  
4 tor to be a potential or actual endocrine-disrupting  
5 chemical—

6 (A) identify the level of evidence that such  
7 chemical is or may be an endocrine-disrupting  
8 chemical;

9 (B) identify the level of concern that such  
10 chemical may disrupt the human endocrine sys-  
11 tem; and

12 (C) identify the pathways of exposure to  
13 the chemical for humans and animals; and

14 (4) not later than 2 years after the date of the  
15 enactment of this Act, and every 2 years thereafter,  
16 provide to the Congress and each relevant Federal  
17 agency and make publicly available—

18 (A) an up-to-date list specifying each  
19 chemical identified by the Director to be a po-  
20 tential or actual endocrine-disrupting chemical  
21 and identifying the level of evidence that the  
22 chemical disrupts the human endocrine system,  
23 the level of concern that the chemical disrupts  
24 the human endocrine system, and the pathways

1 of exposure to the chemical for humans and  
2 animals; and

3 (B) a report on—

4 (i) the National Toxicology Program’s  
5 activities pertaining to endocrine-dis-  
6 rupting chemicals; and

7 (ii) the activities of Federal agencies  
8 with respect to endocrine-disrupting chemi-  
9 cals, including actions taken or expected to  
10 be taken pursuant to section 201.

11 (b) EXPERT PANEL.—

12 (1) APPOINTMENT.—The Director, in consulta-  
13 tion with the National Toxicology Program Board of  
14 Scientific Counselors (or any successor board or  
15 committee), shall appoint the members of the Endo-  
16 crine Disruption Expert Panel (established under  
17 subsection (a)(2)) from among individuals who—

18 (A) have established expertise in the field  
19 of endocrine disruption research by publishing  
20 research in peer-reviewed literature and have  
21 received Federal endocrine-research-related  
22 funding within the 2 years preceding appoint-  
23 ment under this subsection;

24 (B) provide assurances they will perform  
25 their duties in a manner free of conflicts of in-

1           terest, as determined by the Director, including  
2           by complying with section 208 of title 18,  
3           United States Code; and

4           (C) represent diverse disciplines, which  
5           may include endocrinology, developmental and  
6           neurological biology, embryology, biochemistry,  
7           physiology, epidemiology, endocrine-driven on-  
8           cology, in vitro and computational toxicology,  
9           and medical research.

10          (2) DUTIES.—During each of the 10 years fol-  
11         lowing the date of the enactment of this Act, the Ex-  
12         pert Panel shall—

13                 (A) consider, and report to the Director  
14                 on, issues related to identification, classifica-  
15                 tion, or evaluation of not more than 10 endo-  
16                 crine-disrupting chemicals or groups of endo-  
17                 crine-disrupting chemicals;

18                 (B) evaluate existing research aimed at un-  
19                 derstanding the biological pathways in humans  
20                 by which endocrine-disrupting chemicals operate  
21                 and identify future research priorities as appro-  
22                 priate; and

23                 (C) maintain a list that identifies chemi-  
24                 cals of concern for endocrine disruption effects



1 and includes findings, based upon peer-reviewed  
2 studies and other relevant data, regarding—

3 (i) whether a chemical is a potential  
4 or actual endocrine-disrupting chemical;

5 (ii) the level of evidence that the  
6 chemical is or may be an endocrine-dis-  
7 rupting chemical;

8 (iii) the level of concern that the  
9 chemical may disrupt the human endocrine  
10 system;

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

13 (v) the need for additional data, as-  
14 says, testing, or research to determine the  
15 level of concern associated with the chemi-  
16 cal's potential to disrupt the human endo-  
17 crine system.

18 (3) REPORT.—The Expert Panel shall provide  
19 to the Director and make publicly available a bien-  
20 nial report on the Panel's activities, including an up-  
21 to-date version of the list under paragraph (2)(C).

22 (c) PETITIONS.—

23 (1) IN GENERAL.—Any State, Tribe, local gov-  
24 ernment, Federal agency, or person may petition the  
25 Director—

1 (A) to determine whether a chemical  
2 should be identified by the National Toxicology  
3 Program to be a potential or actual endocrine-  
4 disrupting chemical and included in the list  
5 under subsection (a)(4)(A); or

6 (B) to reclassify a chemical, revise a find-  
7 ing, or amend any other determination of the  
8 National Toxicology Program based upon new  
9 information.

10 (2) RULES.—The Director shall adopt rules  
11 that provide for—

12 (A) the form and procedure for filing of  
13 petitions under paragraph (1); and

14 (B) the procedural rights of entities filing  
15 such petitions.

16 (d) NO JUDICIAL REVIEW.—A listing, finding, or  
17 other determination under this section shall not be subject  
18 to judicial review, nor to correction under section 515 of  
19 the Treasury and General Government Appropriations  
20 Act, 2001 (commonly referred to as the “Information  
21 Quality Act”).

1 **SEC. 102. RESEARCH PROGRAM OF NATIONAL INSTITUTE**  
2 **OF ENVIRONMENTAL HEALTH SCIENCES.**

3 Subpart 12 of part C of title IV of the Public Health  
4 Service Act (42 U.S.C. 2851 et seq.) is amended by adding  
5 at the end the following:

6 **“SEC. 463C. ENDOCRINE DISRUPTION RESEARCH PRO-**  
7 **GRAM.**

8 “(a) PROGRAM.—The Director of the Institute shall  
9 conduct and support a research program, to be known as  
10 the Endocrine Disruption Research Program, to improve  
11 the understanding of how chemicals can disrupt the  
12 human endocrine system. Such program shall—

13 “(1) be designed—

14 “(A) to develop the information needed by  
15 Federal agencies to understand chemical dis-  
16 ruption of the endocrine system and reduce  
17 human and animal exposure to endocrine-dis-  
18 rupting chemicals;

19 “(B) to understand the cellular pathways  
20 in humans by which endocrine-disrupting  
21 chemicals are able to cause adverse effects; and

22 “(C) to use laboratory practices that will  
23 produce data that are sufficiently accurate and  
24 reproducible to be used for regulatory decisions;

25 “(2) include research to design, develop, and  
26 validate appropriately sensitive tests to screen and

1 identify chemicals capable of disrupting the human  
2 endocrine system;

3 “(3) address the full range of possible human  
4 health impacts, including but not limited to—

5 “(A) male and female developmental and  
6 reproductive disorders;

7 “(B) brain and neurobehavioral disorders;

8 “(C) metabolic syndrome, prediabetes, dia-  
9 betes, improper glucose and fat metabolism,  
10 obesity, and cardiovascular disorders;

11 “(D) effects on the pituitary, hypothala-  
12 mus, hippocampus, thyroid, adrenal, immune,  
13 bone, cardiovascular, and other endocrine or-  
14 gans and systems throughout all life stages;

15 “(E) hormonally driven cancer; and

16 “(F) other related effects;

17 “(4) consider the potential for additive and syn-  
18 ergistic effects;

19 “(5) be carried out using a multidisciplinary ap-  
20 proach to ensure connections among multiple levels,  
21 including the molecular, organ, and whole animal or  
22 human levels;

23 “(6) refine computational modeling tools to in-  
24 tegrate cellular pathway data into a dose-response  
25 framework for risk assessment;

1           “(7) identify biomarkers of exposure and effect  
2           that can be further developed and translated for use  
3           in human epidemiological and public health studies  
4           focused on defining the role of endocrine-disrupting  
5           chemicals in disease etiology across the lifespan; and

6           “(8) ensure that research or testing involving  
7           living animals is carried out only when equally effective  
8           and reliable alternative approaches for obtaining  
9           the result sought are not readily available.

10          “(b) WORKSHOPS AND FORA.—The Director of the  
11         Institute may conduct workshops and fora and provide in-  
12         formation on the health effects associated with chemicals  
13         that may disrupt the endocrine system in order to—

14                 “(1) identify chemicals for research under sub-  
15                 section (a);

16                 “(2) strategize on approaches for the develop-  
17                 ment of sensitive tests to screen chemicals for endo-  
18                 crine-disrupting activity using assays;

19                 “(3) review the state of the science on endo-  
20                 crine-disrupting chemicals and provide recommenda-  
21                 tions for a research, testing, and training agenda;  
22                 and

23                 “(4) educate attendees about endocrine-dis-  
24                 rupting chemicals.

25          “(c) DEFINITIONS.—In this section:

1           “(1) The term ‘chemical’ means an individual  
2 chemical, a combination of chemicals, or a mixture  
3 of chemicals.

4           “(2) The term ‘endocrine-disrupting chemical’  
5 means a chemical that interrupts, alters, interferes  
6 with, disturbs, or otherwise changes the human or  
7 animal endocrine system or its functioning.”.

8 **TITLE II—REDUCING EXPOSURE**  
9 **TO ENDOCRINE-DISRUPTING**  
10 **CHEMICALS**

11 **SEC. 201. FEDERAL AGENCY ACTION.**

12 (a) RESPONSE TO LIST AND STRATEGY.—

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

19           (2) CONTENTS.—At a minimum, a Federal  
20 agency’s response under paragraph (1) shall—

21           (A) include an evaluation of the findings  
22 and determinations of the National Toxicology  
23 Program pertaining to each listed chemical sub-  
24 ject to the agency’s regulatory authority; and

1 (B) adopt or modify, as scientifically ap-  
2 propriate, each finding of the National Toxi-  
3 cology Program pertaining to—

4 (i) whether any such chemical dis-  
5 rupts or may disrupt the human endocrine  
6 system;

7 (ii) the level of concern associated  
8 with any such chemical's potential to dis-  
9 rupt the human endocrine system; and

10 (iii) the pathways of exposure to the  
11 chemical for humans and animals.

12 (b) MINIMAL LEVEL OF CONCERN.—If the Director  
13 finds under section 101(a)(3)(A) that there is at least a  
14 minimal level of concern that a chemical may disrupt the  
15 human endocrine system—

16 (1) each Federal agency with regulatory author-  
17 ity over the chemical shall—

18 (A) develop a strategy for reducing human  
19 exposure to the chemical;

20 (B) make the strategy publicly available  
21 not later than 180 days after the agency re-  
22 ceives the Director's finding; and

23 (C) include in the strategy methods to pro-  
24 mote voluntary actions by industry for reducing  
25 human exposure to the chemical; and

1           (2) each Federal agency with regulatory author-  
2           ity over the chemical shall take action under such  
3           authority, such as further testing or issuance of or-  
4           ders, regulations, or public notices, to reduce or  
5           eliminate human exposure to the chemical.

6           (c) HIGHEST LEVEL OF CONCERN.—

7           (1) PROHIBITION.—Beginning on the date that  
8           is 24 months after the Director makes publicly avail-  
9           able a finding under section 101(a)(3)(B) that there  
10          is a high level of concern that a chemical may dis-  
11          rupt the human endocrine system, it shall be unlaw-  
12          ful to use the chemical in a manner in or affecting  
13          interstate commerce unless the pathway to human  
14          exposure is mitigated before or in conjunction with  
15          such use.

16          (2) FEDERAL AGENCY ACTION.—Not later than  
17          24 months after the Director makes publicly avail-  
18          able such a finding under section 101(a)(3)(B), each  
19          Federal agency with regulatory authority over the  
20          chemical subject to the finding shall establish regu-  
21          lations or take other actions to implement the prohi-  
22          bition in paragraph (1) with respect to such chem-  
23          ical.

24          (d) AGGREGATED COMPUTATIONAL TOXICOLOGY RE-  
25          SOURCES DATABASES.—The Administrator of the Envi-



1 ronmental Protection Agency shall include the findings  
2 and determinations of the National Toxicology Program  
3 pertaining to endocrine-disrupting chemicals in the Aggre-  
4 gated Computational Toxicology Resource (ACToR) data-  
5 bases (or any successor databases) to the extent otherwise  
6 permitted by law including any restrictions on the dislo-  
7 sure of confidential business information.

8 **SEC. 202. CITIZEN SUITS.**

9 (a) **AUTHORITY TO BRING CIVIL ACTIONS.**—Any  
10 State, Tribe, local government, or person may commence  
11 a civil action to prevent or restrain a prohibited use of  
12 a chemical in violation of section 201.

13 (b) **JURISDICTION.**—The United States courts of ap-  
14 peal shall have exclusive original jurisdiction over such ac-  
15 tion.

16 **TITLE III—TRAINING**

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

19 The Director shall establish a program to support,  
20 directly or by making grants, graduate and postdoctoral  
21 training in fields related to the study and prevention of  
22 endocrine disruption.

1       **TITLE IV—MISCELLANEOUS**

2   **SEC. 401. AUTHORIZATION OF APPROPRIATIONS.**

3       To carry out this Act and the amendments made by  
4 this Act, there are authorized to be appropriated such  
5 sums as may be necessary for fiscal years 2012 through  
6 2021.

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