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

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A BILL

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

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-Disrupting Chemicals Exposure Elimination Act of 2011''.

SEC. 2. TABLE OF CONTENTS.

The table of contents of this Act is as follows:

SEC. 3. FINDINGS.

Congress finds that—

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

(2) numerous studies show links between particular chemicals and hormone functions in both animals and humans, and those links have been further connected to numerous disorders;

(3) a research and evaluation program that targets suspected endocrine-disrupting chemicals would establish greater scientific certainty with respect to the linkage of particular chemicals with endocrine system effects;

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

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

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

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

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

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

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

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

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

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

dividual consumers can make informed decisions about potential exposure to harmful chemicals;

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

(8) animal testing should be reduced to the minimum necessary with the goal of transitioning to a predominantly nonanimal paradigm as articulated in the 2007 National Research Council report entitled ''Toxicity Testing in the Twenty-First Century: A Vision and a Strategy''.

SEC. 4. DEFINITIONS.

In this Act:

(1) CHEMICAL.—The term ''chemical'' means an individual chemical, a combination of chemicals, or a mixture of chemicals.

(2) DIRECTOR.—The term ''Director'' means the Director of the National Institute of Environmental Health Sciences.

(3) ENDOCRINE-DISRUPTING CHEMICAL.—The term ''endocrine-disrupting chemical'' means a chemical that interrupts, alters, interferes with, disturbs, or otherwise changes the human endocrine system or cell functioning.

(4) ENDOCRINE DISRUPTION EXPERT PANEL; EXPERT PANEL; PANEL.—The terms ''endocrine disruption expert panel'', ''expert panel'', and ''panel'' mean the endocrine disruption expert panel established under section 101(a)(2).

SEC. 5. TIERING APPLICABLE TO LEVELS OF EVIDENCE AND CONCERN.

In identifying, determining, or making a finding with respect to a level of evidence or a level of concern under this Act (including under sections 101(a)(3), 101(a)(4), 101(b)(2)(C), and 201(a)(2)(B)), the Director or the expert panel, as applicable, shall select from among the following levels:

(1) High.

(2) Substantial.

(3) Minimal.

(4) None.

TITLE I—RESEARCH ON ENDOCRINE-DISRUPTING CHEMICALS

SEC. 101. NATIONAL TOXICOLOGY PROGRAM ACTIVITIES.

(a) IN GENERAL.—As part of the National Toxicology Program, the Director, in consultation with the National Toxicology Program Board of Scientific Counselors (or any successor board or committee), shall—

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

(2) subject to subsection (b)(1), establish an endocrine disruption expert panel and direct the panel to consider and report to the Director on issues relating to the identification, classification, or evaluation of endocrine-disrupting chemicals under subsection (b)(2);

(3) for each chemical determined by the Director to be a potential or actual endocrine-disrupting chemical identify—

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

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

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

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

(A) an up-to-date list that—

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

(ii) identifies—

(I) the level of evidence that the chemical disrupts the human endocrine system;

(II) the level of concern that the chemical disrupts the human endocrine system; and

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

(B) a report on—

(i) the activities of the National Toxicology Program pertaining to endocrine-disrupting chemicals; and

(ii) the activities of Federal agencies with respect to endocrine-disrupting chemicals, including actions taken or expected to be taken pursuant to section 201.

(b) EXPERT PANEL.—

(1) APPOINTMENT.—The Director, in consultation with the National Toxicology Program Board of Scientific Counselors (or any successor board or

committee), shall appoint the members of the endocrine disruption expert panel from among individuals who—

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

(B) have received Federal endocrine research-related funding during the 2 years preceding the date of appointment under this subsection;

(C) provide assurances that the member will carry out the duties of that member in a manner free of conflicts of interest, as determined by the Director, including by complying with section 208 of title 18, United States Code; and

(D) represent diverse disciplines, which may include endocrinology, developmental and neurological biology, embryology, biochemistry, physiology, epidemiology, endocrine-driven oncology, in vitro and computational toxicology, and medical research.

(2) DUTIES.—For each of the 10 fiscal years following the date of enactment of this Act, the expert panel shall—

(A) consider and report to the Director on issues relating to the identification, classification, or evaluation of not more than 10 endocrine-disrupting chemicals or groups of endocrine-disrupting chemicals;

(B) evaluate existing research aimed at understanding the biological pathways in humans by which endocrine-disrupting chemicals operate and as appropriate, identify future research priorities; and

(C) maintain a list that identifies chemicals of concern for endocrine disruption effects, including findings based on peer-reviewed studies and other relevant data that relate to—

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

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

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

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

(v) the need for additional data, assays, testing, or research to determine the level of concern associated with the potential of the chemical to disrupt the human endocrine system.

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

(c) PETITIONS.—

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

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

(B) to reclassify a chemical, revise a finding, or amend any other determination of the National Toxicology Program based on new information.

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

(A) the form and procedure for filing a petition under paragraph (1); and

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

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

(1) judicial review; or

(2) correction under section 515 of the Treasury and General Government Appropriations Act, 2001 (114 Stat. 2763A–153).

SEC. 102. RESEARCH PROGRAM OF NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES.

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

"SEC. 463C. ENDOCRINE DISRUPTION RESEARCH PROGRAM.

''(a) DEFINITIONS.—In this section:

''(1) CHEMICAL.—The term 'chemical' means an individual chemical, a combination of chemicals, or a mixture of chemicals.

''(2) ENDOCRINE-DISRUPTING CHEMICAL.—The term 'endocrine-disrupting chemical' means a chemical that interrupts, alters, interferes with, disturbs,

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

''(b) ENDOCRINE DISRUPTION RESEARCH PROGRAM.—

''(1) IN GENERAL.—The Director of the Institute shall conduct and support a research program, to be known as the 'Endocrine Disruption Research Program', to improve the understanding of the manner in which chemicals can disrupt the human endocrine system.

''(2) CONTENTS.—The Endocrine Disruption Research Program shall—

''(A) be designed—

''(i) to develop the information needed by Federal agencies to understand chemical disruption of the endocrine system and reduce human and animal exposure to endocrine-disrupting chemicals;

''(ii) to understand the cellular pathways in humans by which endocrine-disrupting chemicals are able to cause adverse effects; and

''(iii) to use laboratory practices that will produce data that are sufficiently ac-

curate and reproducible to be used for regulatory decisions;

''(B) include research to design, develop, and validate appropriately sensitive tests to screen and identify chemicals capable of disrupting the human endocrine system;

''(C) address the full range of potential human health impacts, including—

''(i) male and female developmental and reproductive disorders;

''(ii) brain and neurobehavioral disorders;

''(iii) metabolic syndromes, prediabetes, diabetes, improper glucose and fat metabolisms, obesity, and cardiovascular disorders;

''(iv) effects on the pituitary, hypothalamus, hippocampus, thyroid, adrenal system, immune system, bones, cardiovascular system, and other endocrine organs and systems throughout all life stages;

''(v) hormonally driven cancer; and

''(vi) other related effects;

"(D) consider the potential for additive and synergistic effects;

"(E) be carried out using a multidisciplinary approach to ensure connections among multiple levels, including the molecular, organ, and whole animal or human levels;

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

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

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

"(c) WORKSHOPS AND FORUMS.—The Director of the Institute may conduct workshops and forums and provide information on the health effects associated with chemicals that may disrupt the endocrine system—

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

''(2) to strategize on approaches for the development of sensitive tests to screen chemicals for endocrine-disrupting activity using assays;

''(3) to review the state of the science on endocrine-disrupting chemicals and provide recommendations for a research, testing, and training agenda; and

''(4) to educate attendees about endocrine-disrupting chemicals.''.

TITLE II—REDUCING EXPOSURE TO ENDOCRINE-DISRUPTING CHEMICALS

SEC. 201. FEDERAL AGENCY ACTION.

(a) RESPONSE TO LIST AND STRATEGY.—

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

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

(A) include an evaluation of the findings and determinations of the National Toxicology Program pertaining to each listed chemical subject to the regulatory authority of that Federal agency; and

(B) adopt or modify, as scientifically appropriate, each finding of the National Toxicology Program pertaining to—

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

(ii) the level of concern associated with the potential of the chemical to disrupt the human endocrine system; and

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

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

(1) develop a strategy for reducing human exposure to the chemical that—

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

(B) includes methods to promote voluntary actions by industry for reducing human exposure to the chemical; and

(2) take any necessary action under that regulatory authority, including further testing or issuance of orders, regulations, or public notices, to reduce or eliminate human exposure to the chemical.

(c) HIGHEST LEVEL OF CONCERN.—

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

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

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

(d) AGGREGATED COMPUTATIONAL TOXICOLOGY RESOURCES DATABASES.—The Administrator of the Environmental Protection Agency shall include the findings and determinations of the National Toxicology Program pertaining to endocrine-disrupting chemicals in the Aggregated Computational Toxicology Resource (ACToR) databases (or any successor databases) to the extent otherwise permitted by law, including any restrictions on the disclosure of confidential business information.

SEC. 202. CITIZEN SUITS.

(a) AUTHORITY TO BRING CIVIL ACTIONS.—Any State, local, or tribal government, or any other person, may commence a civil action to prevent or restrain a prohibited use of a chemical in violation of section 201.

(b) JURISDICTION.—The United States Court of Appeals for the circuit in which the person commencing the civil action resides shall have exclusive original jurisdiction over an action described in subsection (a).

TITLE III—TRAINING

SEC. 301. TRAINING IN FIELDS RELATED TO THE PREVENTION OF ENDOCRINE DISRUPTION.

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

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

TITLE IV—MISCELLANEOUS

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

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

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