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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Mr. MORAN introduced the following bill; which was referred to the Committee on _____

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.

The Congress finds as follows:

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

(3) A targeted research and evaluation program on 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 this research will be the basis for regulation under authorities including—

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

(B) the Toxic Substances Control Act;

(C) the Safe Drinking Water Act;

(D) the Food Quality Protection Act;

(E) the Clean Air Act;

(F) the Clean Water Act; and

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

(5) Such research, information availability, and scientific perspective would also promote voluntary actions to reduce exposure to these harmful 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 individual 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.

(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 ''Toxicity Testing in the Twenty-First Century: A Vision and a Strategy''.

SEC. 4. DEFINITIONS.

In this Act:

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

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

(3) 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) The term ''Endocrine Disruption Expert Panel'', ''Expert Panel'', or ''Panel'' means 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 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) establish (subject to subsection (b)(1)) an Endocrine Disruption Expert Panel and direct the Panel to consider and report to the Director on issues related to identification, classification, or eval-

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

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

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

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

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

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

(A) an up-to-date list specifying each chemical identified by the Director to be a potential or actual endocrine-disrupting chemical and identifying the level of evidence that the chemical disrupts the human endocrine system, the level of concern that the chemical disrupts the human endocrine system, and the pathways

of exposure to the chemical for humans and animals; and

(B) a report on—

(i) the National Toxicology Program's activities 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 (established under subsection (a)(2)) from among individuals who—

(A) have established expertise in the field of endocrine disruption research by publishing research in peer-reviewed literature and have received Federal endocrine-research-related funding within the 2 years preceding appointment under this subsection;

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

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

(C) 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.—During each of the 10 years following the date of the enactment of this Act, the Expert Panel shall—

(A) consider, and report to the Director on, issues related to 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 identify future research priorities as appropriate; and

(C) maintain a list that identifies chemicals of concern for endocrine disruption effects

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

(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 chemical's potential to disrupt the human endocrine system.

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

(c) PETITIONS.—

(1) IN GENERAL.—Any State, Tribe, local government, Federal agency, 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 upon new information.

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

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

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

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

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. 2851 et seq.) is amended by adding at the end the following:

"SEC. 463C. ENDOCRINE DISRUPTION RESEARCH PROGRAM.

''(a) PROGRAM.—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 how chemicals can disrupt the human endocrine system. Such program shall—

''(1) be designed—

''(A) 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;

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

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

''(2) include research to design, develop, and validate appropriately sensitive tests to screen and

identify chemicals capable of disrupting the human endocrine system;

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

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

''(B) brain and neurobehavioral disorders;

''(C) metabolic syndrome, prediabetes, diabetes, improper glucose and fat metabolism, obesity, and cardiovascular disorders;

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

''(E) hormonally driven cancer; and

''(F) other related effects;

''(4) consider the potential for additive and synergistic effects;

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

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

''(7) 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

''(8) 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.

''(b) WORKSHOPS AND FORA.—The Director of the Institute may conduct workshops and fora and provide information on the health effects associated with chemicals that may disrupt the endocrine system in order to—

''(1) identify chemicals for research under subsection (a);

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

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

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

''(c) DEFINITIONS.—In this section:

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

''(2) 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.''.

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, a Federal agency's response 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 agency's regulatory authority; and

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

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

(ii) the level of concern associated with any such chemical's potential 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—

(1) each Federal agency with regulatory authority over the chemical shall—

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

(B) make the strategy publicly available not later than 180 days after the agency receives the Director's finding; and

(C) include in the strategy methods to promote voluntary actions by industry for reducing human exposure to the chemical; and

(2) each Federal agency with regulatory authority over the chemical shall take action under such authority, such as 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 24 months after 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 a manner in or affecting interstate commerce unless the pathway to human exposure is mitigated before or in conjunction with such use.

(2) FEDERAL AGENCY ACTION.—Not later than 24 months after the Director makes publicly available such a finding under section 101(a)(3)(B), each Federal agency with regulatory authority over the chemical subject to the finding shall establish regulations or take other actions to implement the prohi-

bition in paragraph (1) with respect to such 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, Tribe, local government, or 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 courts of appeal shall have exclusive original jurisdiction over such action.

TITLE III—TRAINING

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

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

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

TITLE IV—MISCELLANEOUS

SEC. 401. AUTHORIZATION OF APPROPRIATIONS.

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