..... (Original Signature of Member)

115th CONGRESS 2d Session



To direct that certain assessments with respect to toxicity of chemicals be carried out by the program offices of the Environmental Protection Agency, and for other purposes.

### IN THE HOUSE OF REPRESENTATIVES

M\_\_\_\_ introduced the following bill; which was referred to the Committee on

## A BILL

- To direct that certain assessments with respect to toxicity of chemicals be carried out by the program offices of the Environmental Protection Agency, 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 "Improving Science in
- 5 Chemical Assessments Act".

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# 1SEC. 2. RESEARCH NEEDS AND PRIORITIES OF EPA PRO-2GRAM OFFICES.

3 The Environmental Research, Development, and
4 Demonstration Authorization Act is amended by striking
5 section 7 (42 U.S.C. 4364) and inserting the following:
6 "SEC. 7. RESEARCH NEEDS AND PRIORITIES OF EPA PRO7 GRAM OFFICES.

8 "(a) IN GENERAL.—The Administrator of the Envi-9 ronmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or 10 any other provision of law for environmental research and 11 development related to regulatory program activities shall 12 13 be coordinated with and reflect the research needs and priorities of the relevant program offices, as well as the over-14 15 all research needs and priorities of the Agency, including 16 those defined in the five-year research plan.

17 "(b) HAZARD IDENTIFICATION AND DOSE RESPONSE 18 ASSESSMENTS.—Beginning on the date of the enactment 19 of the Improving Science in Chemical Assessments Act, 20any covered assessments carried out with respect to a 21 chemical substance through the Integrated Risk Informa-22 tion System program of the Environmental Protection 23 Agency as of the day before such date of enactment shall, 24 in lieu of being carried out through such program, be carried out by the relevant program office of the Environ-25 mental Protection Agency, so long as the relevant program 26

office determines there is a need for such an assessment.
 Such an assessment shall be carried out using the sci entific standards specified in section 7B and be based on
 the weight of the scientific evidence.

5 "(c) TOXICITY VALUES.—In carrying out a covered 6 assessment with respect to a chemical substance under 7 subsection (a), the relevant program office shall assign a 8 toxicity value or values, when scientifically supported by 9 the available data, for such chemical substance. With re-10 spect to that assignment, the following shall apply:

"(1) When supported by the available data, the
toxicity value or values shall include a range of point
estimates of risk as well as sources and magnitudes
of uncertainty associated with the estimates.

15 "(2) When multiple point estimates can be de16 veloped, the relevant program office shall—

17 "(A) consider all datasets; and

18 "(B) make a determination about how best
19 to represent the human health risk posed by the
20 chemical substance involved.

21 "(d) Chemical Assessment Database.—

"(1) IN GENERAL.—A toxicity value or values
assigned to a chemical substance under subsection
(c) shall be included in a chemical assessment database to be maintained by the Office of Research and

- Development of the Environmental Protection Agen cy.
- 3 "(2) COMPLETED ASSESSMENTS.—All covered
  4 assessments stored, as of the date of the enactment
  5 of this Act, in the IRIS database of the Environ6 mental Protection Agency shall be retained in the
  7 chemical assessment database established pursuant
  8 to paragraph (1).
- 9 "(3) UPDATES.—Such database shall be up-10 dated pursuant to a covered assessment performed 11 by a relevant program office, including to make a 12 change in the existing toxicity value or values for a 13 chemical substance included in such database.
- 14 "(e) CERTIFICATION.—Beginning 2 years after the 15 date of the enactment of the Improving Science in Chemical Assessments Act and every 2 years thereafter, the Of-16 17 fice of Research and Development of the Environmental Protection Agency shall submit to the Committee on 18 19 Science, Space, and Technology and the Committee on 20Energy and Commerce of the House of Representatives 21 and the Committee on Environment and Public Works of 22 the Senate, a report containing a certification that each 23 covered assessment completed during the period covered 24 by the report was conducted using the scientific standards specified in section 7B. 25

1	"(f) DEFINITIONS.—In this section:
2	"(1) The term 'covered assessment' means, with
3	respect to the evaluation of the human health effects
4	resulting from chronic exposure to a chemical sub-
5	stance, a chemical hazard identification and dose re-
6	sponse assessment (as such terms are defined by the
7	Environmental Protection Agency on the day before
8	the date of the enactment of this Act).
9	"(2) The term 'relevant program office' in-
10	cludes the following offices of the Environmental
11	Protection Agency:
12	"(A) The Office of Water.
13	"(B) The Office of Air and Radiation.
14	"(C) The Office of Land and Emergency
15	Management.
16	"(D) The Office of Chemical Safety and
17	Pollution Prevention.
18	"(E) Any successor to an office specified in
19	subparagraphs (A) through (D) and any other
20	office determined to be relevant by the Adminis-
21	trator of the Environmental Protection Agency.
22	"SEC. 7A. HAZARD IDENTIFICATION AND DOSE RESPONSE
23	STEERING COMMITTEE.
24	"(a) ESTABLISHMENT.—Not later than 30 days after
25	the date of the enactment of this Act, the Administrator

of the Environmental Protection Agency shall establish a
 chemical hazard identification and dose response steering
 committee (referred to in this Act as the 'steering com mittee') to coordinate the conduct of covered assessments
 by relevant program offices for purposes of ensuring that,
 with respect to such assessments, there is no duplication
 of effort by such offices.

8 "(b) DUTY.—The duties of the steering committee9 are the following:

10 "(1) If the steering committee learns that more 11 than one relevant program office intends to conduct 12 covered assessments with respect to the same chem-13 ical substance, the steering committee shall deter-14 mine the most effective means of carrying out a sin-15 gle covered assessment to prevent duplication of ef-16 fort by such offices.

17 "(2) For purposes of supplementing a covered 18 assessment, the steering committee shall consider 19 any third-party assessment of a chemical substance 20 generated by another Federal, State, or inter-21 national agency or agencies or members of the sci-22 entific community that meets the requirements spec-23 ified in subsection (e).

24 "(c) CHAIR; COMPOSITION.—

"(1) CHAIR.—The steering committee shall be
 chaired by the Assistant Administrator of the Office
 of Research and Development of the Environmental
 Protection Agency.

5 "(2) COMPOSITION.—The steering committee shall be composed of 15 members, all of whom shall 6 7 be active, full-time employees of the Environmental 8 Protection Agency, with at least one member rep-9 resenting each relevant program office and each re-10 gional office of the Environmental Protection Agen-11 cy. The members of the steering committee shall be 12 appointed by the Administrator of the Environ-13 mental Protection Agency. Any vacancy shall be 14 filled in the same manner as the initial appointment. 15 "(d) MEETINGS.—The steering committee shall meet at least once each calendar year. 16

17 "(e) THIRD PARTY ASSESSMENT REQUIREMENTS.—
18 The requirements specified in this subsection with respect
19 to a third-party assessment of a chemical substance are
20 that the assessment —

21 "(1) is conducted using scientific standards
22 specified in section 7B;

23 "(2) has undergone independent scientific re24 view for transparency, completeness, and quality;
25 and

"(3) reflects the best available science and the
 weight of the available scientific evidence.

#### 3 "SEC. 7B. SCIENTIFIC STANDARDS.

4 "Covered assessments carried out under section 7 5 and discussion of such assessments and review of third 6 party assessments carried out under section 7A, shall be 7 conducted using scientific information, technical proce-8 dures, measures, methods, protocols, methodologies, or 9 models in a manner consistent with the best available 10 science. In carrying out such an assessment, the relevant 11 program office shall integrate all lines of scientific evi-12 dence and consider, as applicable—

13 "(1) the extent to which the scientific informa-14 tion, technical procedures, measures, methods, proto-15 cols, methodologies, or models employed to generate 16 the scientific information are reasonable for and con-17 sistent with the intended use of the scientific infor-18 mation;

19 "(2) the extent to which the scientific informa20 tion is relevant for the relevant program office's use
21 in making a decision about a chemical substance;

"(3) the degree of clarity and completeness with
which the data, assumptions, methods, quality assurance, analyses employed to generate the scientific information are documented and publicly available in

a manner that honors legal and ethical obligations to
 reduce the risks of unauthorized disclosure and re identification;

4 "(4) the extent to which the variability and un5 certainty in the scientific information, or in the pro6 cedures, measures, methods, protocols, methodolo7 gies, or models, are evaluated and characterized;

8 "(5) the extent of independent verification or 9 peer review of the scientific information or of the 10 procedures, measures, methods, protocols, meth-11 odologies, or models;

12 "(6) the ability of the scientific findings and re-13 search to be replicated or reproduced; and

14 "(7) the extent to which the available scientific
15 information supports dose-response modeling, using
16 non-linear approaches.".