

IMPROVING SCIENCE IN CHEMICAL ASSESSMENTS ACT

DECEMBER 21, 2018.—Ordered to be printed

Mr. SMITH of Texas, from the Committee on Science, Space, and Technology, submitted the following

R E P O R T

[To accompany H.R. 6468]

The Committee on Science, Space, and Technology, to whom was referred the bill (H.R. 6468) 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, having considered the same, report favorably thereon without amendment and recommend that the bill do pass.

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COMMITTEE STATEMENT AND VIEWS

PURPOSE AND SUMMARY

The purpose of H.R. 6468, the “Improving Science in Chemical Assessments Act,” is to give the relevant program offices within the Environmental Protection Agency (EPA) the primary authority to carry out hazard identification and dose response assessments on

chemical substances. The effect would be to make these assessments more efficient and responsive to the regulatory need of the program offices. The legislation also prescribes scientific standards for the assessments to ensure transparency and accuracy.

BACKGROUND AND NEED FOR LEGISLATION

H.R. 6468 remedies deficiencies in the Integrated Risk Information System (IRIS) program at EPA. Since 2009, the Government Accountability Office and the National Academy of Sciences have issued multiple reports criticizing the IRIS program. The most common criticisms involve a lack of transparency, procedural flaws, and improper science. IRIS assessments can take up to ten years or more to complete and are often not needed or irrelevant by the time they are finished. Therefore, this legislation is necessary to continue the program's core functionality at the agency and make the products of these assessments more relevant to current regulatory activity.

LEGISLATIVE HISTORY

On September 6, 2017, the Subcommittee on Environment and the Subcommittee on Oversight of the Committee on Science, Space, and Technology held a hearing entitled, "Examining the Scientific and Operational Integrity of EPA's IRIS Program." The purpose of this hearing was to examine the EPA's IRIS program. The hearing focused on scientific and operational integrity issues related to the functionality and goals of the IRIS program. Witnesses were: Dr. Kenneth Mundt, Principal, Ramboll Environ; Dr. James Bus, Senior Managing Scientist, Exponent; and Dr. Thomas Burke, Professor, Bloomberg School of Public Health, Johns Hopkins University.

On July 23, 2018, H.R. 6468, the "Improving Science in Chemical Assessments Act," was introduced by Environment Subcommittee Chairman Andy Biggs.

On July 24, 2018, the Committee on Science, Space, and Technology met to consider H.R. 6468, the "Improving Science in Chemical Assessments Act." The Committee ordered the bill to be reported to the House by a recorded vote of 17–13.

COMMITTEE VIEWS

The Committee recognizes the importance and continued need for hazard identification and dose response assessments carried out by EPA. This legislation decentralizes the function within the agency for purposes of making the assessments more relevant to the regulatory needs of the program offices. To maintain consistency and prevent duplication in this new construction, the legislation creates a steering committee housed in the Office of Research and Development (ORD). Lastly, the legislation codifies scientific standards for carcinogen risk assessment. These standards are derived from those existing in current law under the Toxic Substances Control Act as well as EPA's own Guidelines for Carcinogen Risk Assessment.

SECTION-BY-SECTION

Section 1. Short title

This section establishes the short title of the bill as the “Improving Science in Chemical Assessments Act.”

Section 2. Research needs and priorities of EPA program offices

This section amends section 7 of the Environmental Research, Development, and Demonstration Authorization Act, and adds new sections 7A and 7B.

Section 7, as amended by H.R. 6468, ensures that covered assessments conducted by the EPA are responsive to the needs of the program offices by directing chemical assessments previously conducted by the IRIS Program to be carried out by the relevant program office within EPA. It also promotes reliability and completeness by ensuring that covered assessments will be carried out using the best available science and based on the weight of the scientific evidence. Program offices are directed to assign a toxicity value or values to the chemical substance when supported by the available data.

Section 7A creates a steering committee led by the ORD to coordinate the chemical assessments to promote consistency and prevent duplication of assessments. The steering committee has the authority to consider third party assessments as supplements to the covered assessments being carried out by the program offices provided they reflect the best available science and the weight of the available scientific evidence.

Section 7B ensures the science is complete and accurate, requiring EPA to consider the relevance and completeness of the data, as well as whether the findings are reproducible as a factor in determining its influence in generating the toxicity values.

EXPLANATION OF AMENDMENTS

There were no amendments to this bill.

COMMITTEE CONSIDERATION

On July 24, 2018, the Committee met in open session and ordered reported favorably the bill, H.R. 6468, by roll call vote, a quorum being present.

ROLL CALL VOTES

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY - 115th

Full Committee Roll Call

Working Quorum: 13

Reporting Quorum: 20

DATE: July 24, 2018

Bill: H.R. 6468
ROLL CALL NO. 2

FINAL PASSAGE

PASSED

MEMBER	AYE	NO	PRESENT	NOT VOTING
1 Mr. SMITH, <i>Chair</i> - TX	X			
2 Mr. LUCAS - OK **				
3 Mr. ROHRBACHER - CA	X			
4 Mr. BROOKS - AL	X			
5 Mr. HULTGREN - IL				
6 Mr. POSEY - FL				
7 Mr. MASSIE - KY	X			
8 Mr. WEBER - TX				
9 Mr. KNIGHT - CA	X			
10 Mr. BABIN - TX	X			
11 Mrs. COMSTOCK - VA	X			
12 Mr. LOUDERMILK - GA				
13 Mr. ABRAHAM - LA	X			
14 Mr. PALMER - AL	X			
15 Mr. WEBSTER - FL	X			
16 Mr. BIGGS - AZ	X			
17 Mr. MARSHALL - KS	X			
18 Mr. DUNN - FL	X			
19 Mr. HIGGINS - LA	X			
20 Mr. NORMAN - SC	X			
21 Mrs. LESKO - AZ	X			
22 Mr. CLOUD - TX	X			
1 Ms. JOHNSON, <i>Ranking</i> - TX		X		
2 Ms. LOFGREN - CA		X		
3 Mr. LIPINSKI - IL		X		
4 Ms. BONAMICI - OR		X		
5 Mr. BERA - CA		X		
6 Ms. ESTY - CT		X		
7 Mr. VEASEY - TX		X		
8 Mr. BEYER - VA		X		
9 Ms. ROSEN - NV		X		
10 Mr. LAMB - PA		X		
11 Mr. MCNERNEY - CA		X		
12 Mr. PERLMUTTER - CO				
13 Mr. TONKO - NY		X		
14 Mr. FOSTER - IL				
15 Mr. TAKANO - CA		X		
16 Ms. HANABUSA - HI				
17 Mr. CRIST - FL				
TOTALS	17	13		

** Vice Chair

APPLICATION OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1 requires a description of the application of this bill to the legislative branch where the bill relates to the terms and conditions of employment or access to public services and accommodations. This bill gives the relevant program offices within EPA the primary authority to carry out hazard identification and dose response assessments on chemical substances. As such this bill does not relate to employment or access to public services and accommodations.

Legislative branch employees and their families, to the extent that they are otherwise eligible for the benefits provided by this legislation, have equal access to its benefits.

STATEMENT OF OVERSIGHT FINDINGS AND RECOMMENDATIONS OF THE COMMITTEE

In compliance with clause 3(c)(1) of rule XIII and clause (2)(b)(1) of rule X of the Rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the descriptive portions of this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

H.R. 6468, the "Improving Science in Chemical Assessments Act," will give the relevant program offices within the Environmental Protection Agency (EPA) the primary authority to carry out hazard identification and dose response assessments on chemical substances.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 6468 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111–139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 6468 does not direct the completion of any specific rule makings within the meaning of 5 U.S.C. 551.

FEDERAL ADVISORY COMMITTEE ACT

The Committee finds that the legislation does not establish or authorize the establishment of an advisory committee within the definition of 5 U.S.C. App., Section 5(b).

UNFUNDED MANDATE STATEMENT

Section 423 of the Congressional Budget and Impoundment Control Act (as amended by Section 101(a)(2) of the Unfunded Mandates Reform Act, P.L. 104–4) requires a statement as to whether the provisions of the reported include unfunded mandates. The Committee estimates that H.R. 6468 contains no intergovernmental

or private-sector mandates as defined in the Unfunded Mandates Reform Act.

EARMARK IDENTIFICATION

H.R. 6468 does not include any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI.

COMMITTEE ESTIMATE

The Committee estimates that implementing H.R. 6468 would have no effect on direct spending or revenue.

BUDGET AUTHORITY AND CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

The Committee advises that a Congressional Budget Office cost estimate was not available at the time this report was printed.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

ENVIRONMENTAL RESEARCH, DEVELOPMENT, AND DEMONSTRATION AUTHORIZATION ACT

* * * * *

【SEC. 7. (a) The Administrator of the Environmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or any other provision of law for environmental research and development related to regulatory program activities shall be coordinated with and reflect the research needs and priorities of the program offices, as well as the overall research needs and priorities of the Agency, including those defined in the five-year research plan.

【(b) For purposes of subsection (a), the appropriate program offices are—

【(1) the Office of Air and Waste Management, for air quality activities;

【(2) the Office of Water and Hazardous Materials, for water quality activities and water supply activities;

【(3) the Office of Pesticides, for environmental effects of pesticides;

【(4) the Office of Solid Waste, for solid waste activities;

【(5) the Office of Toxic Substances, for toxic substance activities;

【(6) the Office of Radiation Programs, for radiation activities; and

【(7) the Office of Noise Abatement and Control, for noise activities.

【(c) The Administrator shall submit to the President and the Congress a report concerning the most appropriate means of assur-

ing, on a continuing basis, that the research efforts of the Agency reflect the needs and priorities of the regulatory program offices, while maintaining a high level of scientific quality. Such report shall be submitted on or before March 31, 1978.】

SEC. 7. RESEARCH NEEDS AND PRIORITIES OF EPA PROGRAM OFFICES.

(a) *IN GENERAL.*—The Administrator of the Environmental Protection Agency shall assure that the expenditure of any funds appropriated pursuant to this Act or any other provision of law for environmental research and development related to regulatory program activities shall be coordinated with and reflect the research needs and priorities of the relevant program offices, as well as the overall research needs and priorities of the Agency, including those defined in the five-year research plan.

(b) *HAZARD IDENTIFICATION AND DOSE-RESPONSE ASSESSMENTS.*—Beginning on the date of the enactment of the Improving Science in Chemical Assessments Act, any covered assessments carried out with respect to a chemical substance through the Integrated Risk Information System program of the Environmental Protection Agency as of the day before such date of enactment shall, in lieu of being carried out through such program, be carried out by the relevant program office of the Environmental Protection Agency, so long as the relevant program office determines there is a need for such an assessment. Such an assessment shall be carried out using the scientific standards specified in section 7B and be based on the weight of the scientific evidence.

(c) *TOXICITY VALUES.*—In carrying out a covered assessment with respect to a chemical substance under subsection (a), the relevant program office shall assign a toxicity value or values, when scientifically supported by the available data, for such chemical substance. With respect 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.

(2) When multiple point estimates can be developed, the relevant program office shall—

(A) consider all datasets; and

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

(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 Agency.

(2) *COMPLETED ASSESSMENTS.*—All covered assessments stored, as of the date of the enactment of this Act, in the IRIS database of the Environmental Protection Agency shall be retained in the chemical assessment database established pursuant to paragraph (1).

(3) *UPDATES.*—Such database shall be updated pursuant to a covered assessment performed by a relevant program office, in-

cluding to make a change in the existing toxicity value or values for a chemical substance included in such database.

(e) **CERTIFICATION.**—Beginning 2 years after the date of the enactment of the Improving Science in Chemical Assessments Act and every 2 years thereafter, the Office of Research and Development of the Environmental Protection Agency shall submit to the Committee on Science, Space, and Technology and the Committee on Energy and Commerce of the House of Representatives and the Committee on Environment and Public Works of the Senate, a report containing a certification that each covered assessment completed during the period covered by the report was conducted using the scientific standards specified in section 7B.

(f) **DEFINITIONS.**—In this section:

(1) The term “covered assessment” means, with respect to the evaluation of the human health effects resulting from chronic exposure to a chemical substance, a chemical hazard identification and dose-response assessment (as such terms are defined by the Environmental Protection Agency on the day before the date of the enactment of this Act).

(2) The term “relevant program office” includes the following offices of the Environmental Protection Agency:

(A) The Office of Water.

(B) The Office of Air and Radiation.

(C) The Office of Land and Emergency Management.

(D) The Office of Chemical Safety and Pollution Prevention.

(E) Any successor to an office specified in subparagraphs (A) through (D) and any other office determined to be relevant by the Administrator of the Environmental Protection Agency.

SEC. 7A. HAZARD IDENTIFICATION AND DOSE-RESPONSE STEERING COMMITTEE.

(a) **ESTABLISHMENT.**—Not later than 30 days after 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 committee”) 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.

(b) **DUTY.**—The duties of the steering committee are the following:

(1) If the steering committee learns that more than one relevant program office intends to conduct covered assessments with respect to the same chemical substance, the steering committee shall determine the most effective means of carrying out a single covered assessment to prevent duplication of effort by such offices.

(2) For purposes of supplementing a covered assessment, the steering committee shall consider any third-party assessment of a chemical substance generated by another Federal, State, or international agency or agencies or members of the scientific community that meets the requirements specified in subsection (e).

(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.

(2) *COMPOSITION.*—The steering committee shall be composed of 15 members, all of whom shall be active, full-time employees of the Environmental Protection Agency, with at least one member representing each relevant program office and each regional office of the Environmental Protection Agency. The members of the steering committee shall be appointed by the Administrator of the Environmental Protection Agency. Any vacancy shall be filled in the same manner as the initial appointment.

(d) *MEETINGS.*—The steering committee shall meet at least once each calendar year.

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

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

(2) has undergone independent scientific review for transparency, completeness, and quality; and

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

SEC. 7B. SCIENTIFIC STANDARDS.

Covered assessments carried out under section 7 and discussion of such assessments and review of third-party assessments carried out under section 7A, shall be conducted using scientific information, technical procedures, measures, methods, protocols, methodologies, or models in a manner consistent with the best available science. In carrying out such an assessment, the relevant program office shall integrate all lines of scientific evidence and consider, as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the scientific information are reasonable for and consistent with the intended use of the scientific information;

(2) the extent to which the scientific information is relevant for the relevant program office's use 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) the extent to which the variability and uncertainty in the scientific information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized;

(5) the extent of independent verification or peer review of the scientific information or of the procedures, measures, methods, protocols, methodologies, or models;

- (6) the ability of the scientific findings and research to be replicated or reproduced; and*
- (7) the extent to which the available scientific information supports dose-response modeling, using non-linear approaches.*

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