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Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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May 10, 2016

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Dear Administrator McCarthy:

The Committee on Science, Space, and Technology is continuing its longstanding oversight of the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS).[1] As you know, the IRIS program supports the mission of EPA to protect human health and the environment by providing EPA's scientific position on the potential human health effects from exposure to chemicals in the environment.[2] Unfortunately, the IRIS program appears to suffer from a lack of transparency and an inability to produce work in a timely manner. For years, the National Academy of Science (NAS), the Government Accountability Office (GAO), and this Committee, as recent as 2014, have raised concerns that the IRIS program suffers from mismanagement.[3] To assist in the Committee's oversight of this matter, the Committee requests documents and information related to the IRIS program.

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[1] *See, e.g.*, H. Comm. on Science, Space, & Tech., *EPA's IRIS Program: Evaluating the Science & Process Behind Chemical Risk Assessment*, 112th Cong. (Jul. 14, 2011); H. Comm. on Science, Space, & Tech., Subcomm. on Investigations & Oversight, *Toxic Communities: How EPA's IRIS Program Fails the Public*, 110th Cong. (Jun. 12, 2008); H. Comm. on Science, Space, & Tech., Subcomm. on Investigations & Oversight, *EPA's Restructured IRIS System: Have Polluters & Politics Overwhelmed Science?*, 110th Cong. (May 21, 2008).

[2] Gov't Accountability Office, Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program (December 2011) (GAO-12-42) [hereinafter GAO Dec. 2011].

[3] GAO Dec. 2011; Gov't Accountability Office, Chemical Assessments: An Agency wide Strategy May Help Address Unmet Needs for Integrated Risk Information System Assessments (May 2013) (GAO-13-369) [hereinafter GAO May. 2013]; Gov't Accountability Office, Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System (March 2008) (GAO-08-440) [hereinafter GAO Mar. 2008]; Gov't Accountability Office, Report to the Cong.: High-Risk Series An Update (Jan. 2009) (GAO-09-271); Gov't Accountability Office, Report to the Cong.: High-Risk Series An Update (Feb. 2011) (GAO-11-278); Gov't Accountability Office, Report to the Cong.: High-Risk Series An Update (Feb. 2013) (GAO-13-283); Gov't Accountability Office, Report to the Cong.: High-Risk Series An Update (Feb. 2015) (GAO-15-290); H. Comm. on Science, Space, & Tech., *EPA's Status of Reforms to EPA's Integrated Risk Information System*, 113th Cong. (Jul. 16, 2014).

Since 2008, GAO has included the IRIS program on the High Risk List and has published three additional reports highlighting concerns with the IRIS program, issuing 17 recommendations; of those, 12 remain open today.[4] GAO feared that the IRIS program was in jeopardy of becoming obsolete in 2008 due to its inability to issue sound risk assessments in a timely manner.[5] GAO also found that risk assessments were taking up to a decade to complete because of internal controls deficiencies and IRIS managements decisions.[6] Ongoing assessments were delayed waiting for research to become available before moving forward with assessments. This caused a domino effect and ultimately resulted in the assessment process being repeated.[7] GAO highlighted a number of concerns with each step of the IRIS program's assessment process. These concerns include the fact that IRIS has not conducted an evaluation of demand for IRIS assessments since 2003.[8] GAO could not find sufficient evidence to support the 2003 estimate finding that 50 assessments would meet the then-demand.[9] According to GAO, IRIS does not plan to conduct additional demand evaluations despite only issuing 12 assessments since 2011.[10] GAO also found that the IRIS program does not clearly articulate how chemicals are prioritized or selected for assessments, among other concerns.[11]

NAS also made recommendations for the IRIS program in 2011 "on the basis of 'lessons learned' from the formaldehyde assessment..."[12] When reviewing the draft IRIS formaldehyde assessment – an independent scientific review requested by EPA –NAS took it upon themselves to include a number of recommendations. Specifically, NAS stated "IRIS assessment methods and reports is of concern, particularly in light of the continued evolution of risk-assessment methods and the growing societal and legislative pressure to evaluate many more chemicals in an expedient manner."[13] Despite NAS reiterating many of the same concerns in a 2014 report, IRIS has yet to implement all of those recommendations made by the NAS.[14]

On April 27, 2016, Committee staff received an IRIS briefing from EPA staff to better understand the current state of the program and hear firsthand the methodologies used throughout the assessment process. The briefing provided by EPA, while helpful and appreciated, has not provided answers to all of the Committee's questions, including details relating to some basic operating methods of the program. For example, EPA staff could not identify policies and procedures used to identify and determine which substance would receive an assessment. Similarly, EPA staff was unable to confirm which agency official, if any, holds the final decision making power to determine whether an assessment is necessary.

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[4] *Id.*
[5] GAO Mar. 2008, *supra* note 3.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] GAO May 2013, *supra* note 3.
[10] Environmental Protection Agency, Integrated Risk Information System, *IRIS Recent Additions*, *available at* https://www.epa.gov/iris/iris-recent-additions.
[11] GAO May 2013, *supra* note 3.
[12] National Academies of Sciences, Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde (2011).
[13] *Id.*
[14] National Academies of Sciences, Review of the EPA's Integrated Risk Information System (IRIS) Process: Committee to Review the IRIS Process Board on Environmental Studies and Toxicology Division on Earth and Life Studies (2014).

According to a 2011 *New York Times* report, IRIS Director Vincent Cogliano "wants to take a proactive approach to identifying new substances that should be evaluated. The goal, he said, is to identify problem chemicals and substances before it is too late."[15] Regrettably, it appears that Mr. Cogliano has failed to implement a proactive approach since IRIS has only completed one risk assessment since fiscal year 2014, and there is no apparent policy or procedure for identifying new substances.

To add to the litany of reviews conducted on this failing program, in 2012, congressional appropriators directed NAS to conduct another review of the IRIS program. NAS's resulting 2014 report again recommended that IRIS develop a "handbook" to "provide a quality-management plan that includes clear methods for continuing assessments" and "to develop clear and transparent processes that allow external stakeholder input early in the IRIS process."[16] However, during its recent briefing with Committee staff, EPA was unable to provide any clarity on the status or development of the "handbook". More concerning, despite NAS calls for more transparency, it was recently announced that "EPA will no longer announce the availability of draft IRIS assessments for public comment in the Federal Register."[17] This action appears to directly contradict specific recommendations for more transparency.

According to the *New York Times*, Director Cogliano characterized IRIS as "kind of the center of everything EPA does scientifically."[18] The program, however, has proven unable to produce risk assessments in a timely and transparent manner. The Committee is concerned that EPA is not taking the recommendations of GAO and NAS seriously.

The Committee is committed to ensuring that EPA is efficiently and transparently basic its decisions on sound science. To better understand the current state of the IRIS program, please provide the following documents and information as soon as possible, but no later than noon on May 24, 2016:

1. All documents and communications related to the development of "the handbook" as outlined in the National Academy of Sciences 2014 report entitled a "Review of the EPA's Integrated Risk Information System (IRIS) Process."

2. All documents and communications related to the budgeting and filling of new positions within the IRIS program, including the number of new positions, associated funds allocated to each position, position descriptions, duty locations, and responsibilities from January 1, 2008 to the present.

3. All documents and communications related to the involvement of the Office of the Secretary related to IRIS risk assessments from January 1, 2008, to the present.

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[15] Jeremy P. Jacobs, *New Director at EPA Plans Shakeup of Laggard Chemical-Risk System*, THE NEW YORK TIMES, Mar. 30, 2011, *Available at: http://www.nytimes.com/gwire/2011/03/30/30greenwire-new-director-at-epa-plans-shakeup-of-laggard-c-94659.html?pagewanted=all* [here in after Jacobs, *EPA Plans Shakeup*].
[16] *Id.*
[17] 81 C.F.R. § 18625 (Mar. 31, 2016).
[18] Jacobs, *EPA Plans Shakeup, Supra* note 15.

4. All documents and communications related to the 2003 IRIS demand evaluation, and any additional demand analyses conducted.

5. All documents and communications related to the prioritization of chemicals in the IRIS assessment queue, including meeting notes, methodologies, data, policies and procedures used in the process of prioritizing chemicals from January 1, 2008, to the present.

6. All documents and communications related to the consideration, evaluation and discussion of the linear no-threshold dose-response theory, along with other competing scientific models and theories, when assessing chemicals in the IRIS program from January 1, 2008 to the present.

7. All documents and communications related to the "stopping rules" from January 1, 2008, to the present.

8. All documents and communications related to the policies and procedures regarding the "HERO database" from January 1, 2008, to the present.

9. All documents and communications related to the implementation of the Government Accountability Office's recommendations made to IRIS from January 1, 2008, to the present.

10. All documents and communications related to the implementation of National Academy of Sciences' recommendations made to IRIS from January 1, 2008, to the present.

11. All documents and communications related to the implementation of the "IRIS Program Multi Year Agenda" issued in December 2015.

12. All documents and communications related to the status of the redesign of "IRIS Track."

The Committee has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 394 of the Ford House Office Building. The Committee prefers, if possible, to receive all documents in electronic format. An attachment to this letter provides additional information regarding producing documents to the Committee.

If you have any questions about this request, please contact Drew Colliatie or Lamar Echols of the Science, Space, and Technology Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

Lamar Smith

Lamar Smith
Chairman

cc: The Honorable Eddie Bernice Johnson, Ranking Minority Member, House Committee on Science, Space and Technology

Enclosure

Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents, in unredacted form, that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.

2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.

3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.

4. Documents produced in electronic format should also be organized, identified, and indexed electronically.

5. Electronic document productions should be prepared according to the following standards:

   (a) The production should consist of single page Tagged Image File ("TIF"), or PDF files.

   (b) Document numbers in the load file should match document Bates numbers and TIF or PDF file names.

   (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.

8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.

9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.

10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.

11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.

13. In complying with this request, be apprised that the U.S. House of Representatives and the Committee on Science, Space, and Technology do not recognize: any of the purported non-disclosure privileges associated with the common law including, but not limited to, the deliberative process privilege, the attorney-client privilege, and attorney work product protections; any purported privileges or protections from disclosure under the Freedom of Information Act; or any purported contractual privileges, such as non-disclosure agreements.

14. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.

15. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.

16. Unless otherwise specified, the time period covered by this request is from January 1, 2008 to the present.

17. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.

18. All documents shall be Bates-stamped sequentially and produced sequentially.

19. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 324 of the Ford House Office Building.

20. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive

documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Schedule Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.

3. The terms "and" and "or" shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

4. The terms "person" or "persons" mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term "identify," when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.

6. The term "referring or relating," with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.