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FIXING EPA'S BROKEN INTEGRATED RISK INFORMATION SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

JUNE 11, 2009

Serial No. 111–33

Printed for the use of the Committee on Science and Technology

Available via the World Wide Web: http://www.science.house.gov

U.S. GOVERNMENT PRINTING OFFICE

49–964PDF WASHINGTON : 2009

For sale by the Superintendent of Documents, U.S. Government Printing Office
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FIXING EPA'S BROKEN INTEGRATED RISK INFORMATION SYSTEM

THURSDAY, JUNE 11, 2009

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC.

The Subcommittee met, pursuant to call, at 1:11 p.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chair of the Subcommittee] presiding.

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Subcommittee on Investigations and Oversight

Hearing on

Fixing EPA's Broken Integrated Risk Information System

Thursday, June 11, 2009
1:00 p.m. – 3:00 p.m.
2318 Rayburn House Office Building

Witness List

Dr. Kevin Teichman
Deputy Assistant Administrator for Science
Office of Research and Development
Environmental Protection Agency

Mr. John Stephenson
Director, Natural Resources and Environment,
Government Accountability Office

HEARING CHARTER

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT
COMMITTEE ON SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

Fixing EPA's Broken Integrated Risk Information System

THURSDAY, JUNE 11, 2009
1:00 P.M.—3:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

Purpose

On Thursday, June 11, 2009, the Subcommittee on Investigations and Oversight of the House Committee on Science and Technology will hold a hearing entitled *"Fixing EPA's Broken Integrated Risk Information System."* We will receive testimony from two witnesses at this hearing: Mr. John Stephenson, Director, Natural Resources and Environment, U.S. Government Accountability Office, and Dr. Kevin Teichman, the Deputy Assistant Administrator for Science, Office of Research and Development, the Environmental Protection Agency. They will testify about the new Integrated Risk Information System (IRIS) process announced by EPA Administrator Lisa Jackson on May 21, 2009.

Background

By the end of the Bush Administration, the Environmental Protection Agency's (EPA) IRIS process was broken. What began two decades ago as an initiative at EPA to establish a reliable database on what science said about the risks of particular chemicals devolved by the end of the Bush Administration into a tortured round of interagency bickering, mediated by the Office of Information and Regulatory Affairs (OIRA). As a result of the IRIS process breaking down, public health offices across the country and around the world, as well as concerned citizens, were left without the reliable, expanding, up-to-date database of chemical risks that they had come to count on.[1]

A chemical's entry in the IRIS database is nothing more than a science-based assessment of risks associated with a particular chemical. IRIS entries are produced in the Office of Research and Development (ORD) of EPA, and those entries are not an expression of regulatory intent or advice. The entries are not even all that is required of a complete risk assessment as defined in the seminal National Academies of Science report, *Risk Assessment in the Federal Government: Managing the Process*

[1] The Subcommittee has carried out extensive work on OIRA's role in relationship to IRIS. In 2008, the Subcommittee held two hearings on this subject. The first of these hearings was on May 21, 2008, when the Subcommittee took testimony from Dr. George Gray, the then-Assistant Administrator for Research and Development at EPA, and Ms. Susan Dudley, the then-Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. Additionally, Mr. John Stephenson of GAO testified on findings regarding the lack of productivity in the IRIS process. In the second hearing, on June 12, 2008, the Subcommittee received testimony from Mr. Jerry Ensminger (U.S.M.C., retired), Mr. Lenny Seigel (Executive Director, Center for Public Environmental Oversight), and Dr. Linda Greer (Director of the Health Program at the Natural Resources Defense Council). On June 11, 2008 Chair Miller sent a document request to OMB asking for all materials relating to OIRA's involvement in the proposed IRIS entry for trichloroethylene (TCE). In response, the Committee received a few boxes of materials. The great majority of those materials were either peer reviewed articles, articles done by EPA staff, or research reports done under contract to industry or polluting agencies. Subcommittee staff were obliged to visit OMB's office to review thousands of pages of documents and take notes because the office refused to provide copies. A clear picture of OIRA's almost daily involvement on TCE emerged from that review. However, OIRA refused to provide access to most documents regarding interagency communications or internal communications surrounding TCE. Because the 110th Congress was drawing to a close, it was not practical to push for a subpoena for these records. We were never shown any document that could have been construed as having Executive Privilege attached to it. OIRA's entire approach appeared to amount to little more than obstruction of the work of the Subcommittee; in a sense, OIRA did to the Subcommittee's investigation what they have perfected in terms of slow-rolling IRIS proposals.

(1983).[2] And risk assessment is a long step away from a regulatory effort, which is described in the terminology of the panel as "risk management." However, the absence of IRIS entries for widely used, toxic chemicals leaves State and local regulators, first responders, and citizens without crucial information that can guide their response to an emergency or an emerging health or environmental threat.

OIRA has been involved in the IRIS process since the closing years of the Clinton Administration. Initially OIRA was pulled into the process to facilitate interagency discussions about particular chemicals proposed for IRIS listings. Agencies that had a record of pollution with certain chemicals were concerned that new IRIS standards would trigger the long march to new regulations and the end result would be that the polluting agencies would have to change their practices and clean up legacy wastes. Those who polluted saw that disputing what scientific research had found about the risks of a particular chemical could become the first line of defense against the distant possibility of regulation.[3] By the late 1990s, OIRA was playing a role as facilitator for contentious interagency discussions for some particular proposed IRIS listings.[4]

Suppressing IRIS entries essentially shuts down the flow of coherent, reliable information about what chemicals pose what kinds of risks. Testimony received by the Subcommittee at the second day of hearings on this subject in 2008 emphasized the important role of IRIS as a public health and safety resource. That hearing, entitled "*Toxic Communities: How EPA's IRIS Program Fails the Public,*" took testimony from U.S.M.C. (retired) Master Sergeant Jerry Ensminger, the Executive Director of the Center for Public Environmental Oversight, Mr. Lenny Siegel, and Dr. Linda E. Greer, Director for Health Programs at the Natural Resources Defense Council. Mr. Ensminger was particularly compelling in making a case for why polluting agencies such as DOD should not be allowed privileged access to discussions about the science of potential pollutants.

> It is a known fact that the United States Department of Defense is our nation's largest polluter. It is beyond my comprehension why an entity with that type of reputation and who has a vested interest in seeing little to no environmental oversight would be included in the scientific process. Not only are they obstructing science, they are also jeopardizing the public health for millions of people all around the world . . . and yet this Administration and past Congresses have allowed DOD's tentacles to infiltrate the realm of science.[5]

Mr. Ensminger was stationed at Camp LeJeune. His daughter, Janey, died of acute lymposytic leukemia. Water at the Camp was contaminated with trichloroethylene (TCE) and perchlorate (perc) and these chemicals, as well as other volatile organic compounds in the water system at the Camp, may have caused Janey's condition. DOD has been working for many years to block new IRIS standards on TCE and perc.

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[2] In that 1983 report, "*Risk Assessment in the Federal Government: Managing the Process,*" the National Research Council panel identified four components of a complete risk assessment: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. IRIS reflects science that addresses the first two conditions. In discussing the difference between risk assessment and risk management, the Academy panel wrote: "Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision." See the discussion on page 3 of the 1983 report.

[3] This effort by polluters, or those who fear regulation of whatever stripe, of pushing the struggle back to what the science says about a particular risk rather than arguing over how to structure a regulation has been described as "paralysis by analysis." Science lends itself to endless study because there is never an absolute, final answer to any question, but always another layer of research that could add to the body of accumulated knowledge. If those who want to avoid regulation can shift the terms of discussion from the risk management end of the spectrum to the science and what uncertainties remain, a regulatory struggle need never begin. For analysis of how this process has unfolded among regulated industries, see David Michaels, *Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health,* Oxford University Press, New York, 2008.

[4] The Subcommittee was also able to review records from 1998 when OIRA first began to push into the interagency struggles over characterizing risks to former marines and their families from TCE and other chemicals at Camp LeJeune. At that time, OIRA's interest was more in the costs of the studies and making sure the then-proposed survey study met OIRA quality standards. OIRA reviews all survey instruments as part of its authority under the *Paperwork Reduction Act of 1980.*

[5] "*Toxic Communities: How EPA's IRIS Program Fails the Public,*" Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, June 12, 2008, p. 132.

During the Bush Administration, OIRA's involvement changed in scope and kind from what it had been in the Clinton Administration. John Graham, the first Director of OIRA in the Bush Administration, brought in technical specialists—including toxicologists—to tend to science-based discussions of proposed environmental regulations, guidance and IRIS entries. Graham also oversaw a complete overhaul—some might describe it as an endless evolution—of the review and approval process for IRIS proposals.

IRIS Process Reforms Past and Present

On April 10, 2008, EPA announced a new IRIS review process for future entries into the IRIS database. In testimony before the Subcommittee, the then Assistant Administrator for Research and Development at EPA, Dr. George Gray, described this new process as "streamlined." Comparing the process as it existed before 2004 and the process announced on April 10, 2008, it is hard to understand in what sense the process could be described as "streamlined" (see Attachments 1 and 2). The fruits of this new process were exactly four new IRIS entries in the years since that process was announced (actually, they had gone through as a single proposal as they were four variants on one chemical compound so this could be counted as "one" new entry and not distort the record). In the two years prior to announcing this new process, EPA had been allowed to post four new entries (two each year).

GAO issued a very strong report concerning mismanagement of the IRIS program in a March, 2008 report (*"Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System,"* GAO–08–440). In addition, GAO added the IRIS program to its *"High Risk"* report in January of 2009—placing additional pressure on EPA and the new Administration to take steps to fix this broken process.

On May 21, EPA Administrator Lisa Jackson announced a new IRIS process that appears to be much improved over the system she inherited (see Attachment 3). It imposes transparency on interagency comments concerning proposed IRIS entries; it eliminates the ability of polluting agencies (such as the Department of Energy, NASA, or the Department of Defense) to further drag out assessments by declaring particular chemicals as "mission critical"; it puts EPA solidly in charge of the entire process with a timeline for each step in the process.

All of these steps away from an OIRA-dominated system are positive. However, questions still remain about how this process will perform in actual practice.

1. Control: Will EPA really have the muscle to stand up to pressure from more powerful agencies that have historically obstructed IRIS entries as a way of strangling potential regulation? Will EPA be able to withstand pressure from offices inside the White House should those offices mobilize to block or significantly redo a proposed IRIS listing? EPA faired badly during the prior Administration in struggles over science and regulation. Some of those problems reflected the political preferences of the Bush Administration, but some of those problems reflect the ingrained institutional interests of other agencies who do not want to be regulated and White House offices that want to have a great measure of control over what EPA (among many agencies) can and cannot do. Institutional interests do not change with elections, and EPA will still face some pressure on that front. The Chair's position has been that EPA scientists should be in charge of EPA science products.
2. What role will OIRA play? This is really a more specific observation related to control, but the new plan announced by Administrator Jackson is ambiguous about what White House offices will be involved in reviews of EPA IRIS proposals. Because discussion of proposed listings is supposed to be limited solely to "science" matters, it is hard to imagine any White House office actually having the time or resources to appropriately weigh in on science matters—even the Office of Science and Technology Policy. There is no office in the White House that does "science" per se. OIRA is really designed to weigh in on the "risk management" side of the regulatory equation, not the "risk assessment" or science side which comes well before any regulatory proposal is even contemplated. No office in the White House is more influential with agencies than is the Office of Management and Budget (OMB) precisely because OMB controls every agency's budget request. OIRA is housed at OMB and that location gives them a very powerful voice, when they raise it, in the work of the line agencies. Is it appropriate to let OIRA play any role at all in science matters?
3. Productivity: While the newly announced process does eliminate some steps in the IRIS approval process, it remains to be seen whether it will allow for a substantial increase in IRIS entries being finalized by EPA. With 700 new

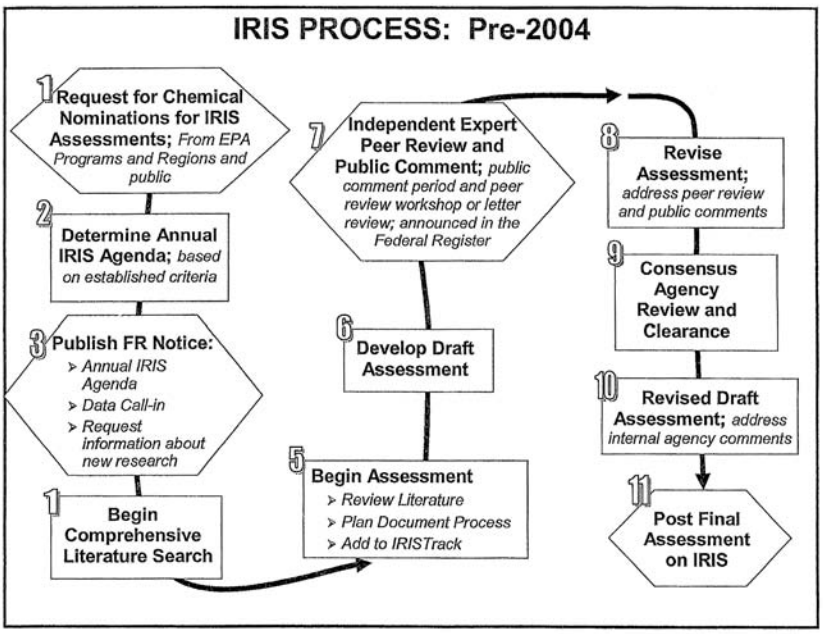
chemicals entering the marketplace each year, and a backlog of needed updates and new entries, the bare minimum standard for success of IRIS is probably 20 entries a year—which is what the new process promises to deliver.

The Subcommittee will pursue these matters, and others, during the hearing. If IRIS is unable to function effectively, public health and safety will ultimately suffer. Getting this program right is a high priority for the Subcommittee and the country. The Subcommittee Chair expects to send a request letter to the Government Accountability Office to have them continue to monitor the new IRIS process.

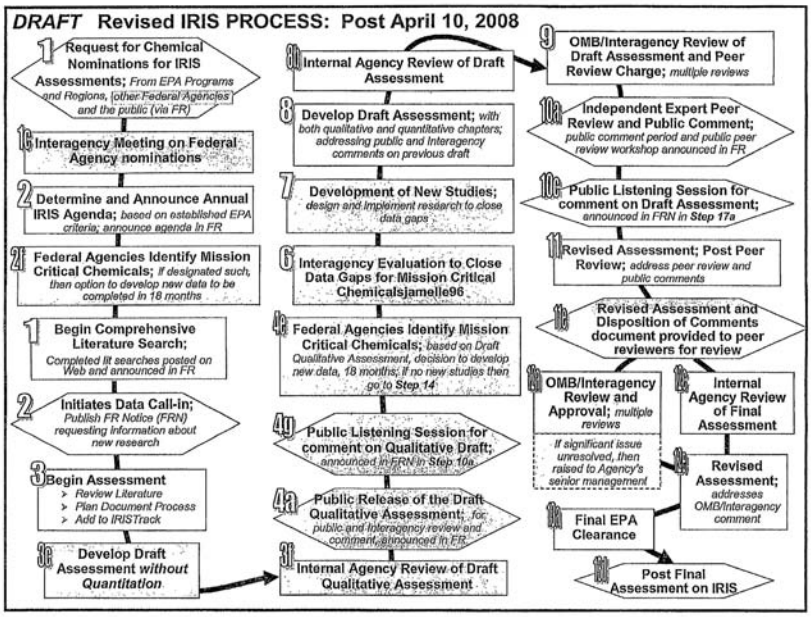
Chair MILLER. Good afternoon. The hearing will now come to order. Welcome to today's hearing entitled *"Fixing EPA's Broken Integrated Risk Information System."*

A little more than a year ago Susan Dudley, then the head of the Office of Information Regulatory Affairs at OMB, OIRA, and Dr. George Gray, then the head of the Office of Research and Development at EPA, testified before this subcommittee. The hearing was to examine the stunning lack of productivity in a—in new and revised risk assessments for chemicals in the EPA's Integrated Risk Information System, IRIS.

Dudley and Gray testified that the productivity was a complicated approval process for assessments which this flowchart produced by EPA, Mr. Whittaker, illustrated. This is the complicated process that they needed to fix.



So they testified that they had solved the problem by developing a streamlined approval process which this flowchart, also produced by EPA, illustrates.



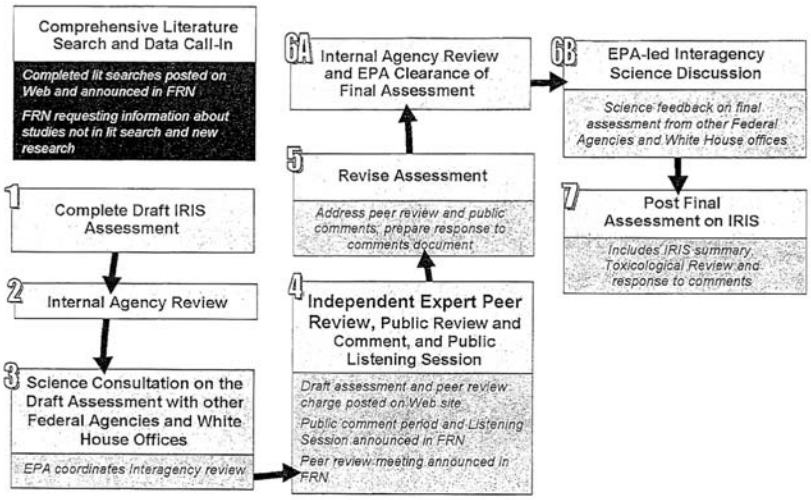
Again, Mr. Whittaker, if you could show the complicated system, chart one, okay, and then the simplified system, chart two.

Gray's and Dudley's testimony reminded me of a famous quotation from Marx—not Karl, Chico. "Well, who are you going to believe? Me or your own eyes?" Gray's and Dudley's testimony strained credulity in other ways. Dudley explicitly denied in her testimony that OIRA, the office that she headed, ever challenged scientific assessments by EPA scientists. Scientific assessment of a toxic effect of chemical exposure would not even remotely be OIRA's job. Our staff today released a report on IRIS that shows that OIRA did just that on several occasions, enough to conclude that intruding on scientific assessments was routine for OIRA. Dudley testified that the streamlined process, that was chart two, for approving IRIS listings was entirely EPA's handiwork. Our staff's report shows that the process was a result of a multi-year, interagency process that was driven by OIRA, not by EPA.

OIRA's conduct in requiring a perpetual paralysis in approval procedures and intruding on the independence of EPA's scientists appears to have been intended to keep IRIS from doing its job and to keep us all in the dark about the public health consequences of chemical exposures. It certainly had that effect. While 70 chemicals were in some stage of review by EPA, EPA averages three new and revised IRIS entries a year.

The new EPA Administrator, Lisa Jackson, announced a new process on May 21, 2009. This chart illustrates the new process.

Assessment Development Process for New IRIS



May 20, 2009

EPA's Integrated Risk Information System

Assessment Development Process

Introduction:

The Integrated Risk Information System (IRIS) is an U. S. Environmental Protection Agency (EPA) database that contains quantitative and qualitative risk information on human health effects that may result from exposure to environmental contaminants.

Through IRIS, EPA provides the highest quality science-based human health assessments to support Agency regulatory activities. IRIS is a key program in EPA's Office of Research and Development (ORD).

The Assessment Development Process:

Prior to the start of the development of the draft IRIS assessment, EPA conducts a scientific literature search and initiates a data call-in:

- Scientific Literature Search
  - ORD appoints a chemical manager for each chemical on the proposed Agenda.
  - The chemical manager(s) direct an EPA contractor to conduct and complete a comprehensive search of the scientific literature for the chemical.
  - Completed literature searches are posted on the EPA's Web site
- Data Call-In
  - After the literature search has been completed for each chemical, EPA publishes a Federal Register Notice (FRN) that notifies the public that completed literature searches for a set of chemicals are available on the IRIS Internet site.
  - FRN invites the public and other agencies to submit additional scientific information (peer reviewed studies, reports, other assessments, etc.) on the chemical.
  - FRN requests information on new research that may be planned, underway, or in press.
  - FRN includes information on how and where to submit scientific information.

After the literature search and data call-in are complete, EPA begins development of the IRIS human health assessment.

All draft human health assessments developed in the IRIS Program are subjected to rigorous, open, independent external peer review. Selected IRIS assessments considered being of major importance or high profile may be peer reviewed by panels of experts convened by EPA's Science Advisory Board or by the National Academy of Sciences. In addition, IRIS assessments developed under the seven step process outlined below, are expected to be completed within approximately two years from the Step 1 start date. Some IRIS assessments, however, because of their complexity, large scientific literature base, or high profile may take longer.

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May 20, 2009

1. EPA Develops and Completes a Draft IRIS Toxicological Review (Duration 345 days)

A. ORD assembles an IRIS assessment team.

B. ORD assesses the data in the scientific literature and any information submitted as a result of the data call-in and develops a draft assessment for the chemical being assessed, including:

   a. summary of potentially important health effects;

   b. summary of information on potential mode(s) of action;

   c. summary of information about potentially susceptible populations;

   d. a quantitative assessment, including application of uncertainty factors, default approaches, mode of action information, and dose-response modeling; and

   e. identification of potential uncertainties that impact the qualitative and quantitative aspects of the assessment.

C. ORD completes the draft IRIS Toxicological Review.

2. Internal EPA Review (Duration 60 days)

A. ORD submits the draft IRIS Toxicological Review for internal Agency review.

B. Internal Agency review includes scientists from EPA programs and regions.

C. Internal agency review identifies any scientific issues to determine the level of peer review, needed panel member disciplines, and the scope of the review.

3. EPA Initiates Interagency Science Consultation on Draft IRIS Toxicological Review (Duration 45 days)

A. EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other Federal agencies and White House offices for a science consultation.

B. The science consultation step is managed and coordinated by EPA

   a. EPA provides a specified date for receipt of written comments.

   b. EPA hosts meeting of other agencies and White House offices to discuss issues raised by comments.

C. All written comments received during Interagency Science Consultation become part of the public record

D. ORD revises the draft assessment documents, as appropriate.

E. If EPA considers appropriate, science questions that arise during science consultation may be included as part of a charge question to the peer review panel.

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May 20, 2009

4. EPA Initiates Independent External Peer Review of Draft IRIS Toxicological Review, Public Review and Comment on Draft IRIS Toxicological Review, and Holds a Public Listening Session (Duration 105 days)

A. External Peer Review

a. EPA provides the draft IRIS Toxicological Review and peer review charge questions for independent external peer review.

b. EPA publishes an FRN at least 30 days prior to the peer review meeting notifying the public about the time and place of the meeting.

c. Peer reviews are public meetings, generally through a face-to-face meeting of panelists, though some may be held via public teleconference.

d. The report of the external peer review panel becomes part of the official public record for the IRIS assessment

B. Public Review and Comment

a. EPA releases the draft IRIS Toxicological Review for public review and comment.

b. ORD prepares an FRN announcing a public comment period of 60 days.

i. The draft IRIS Toxicological Review is released on EPA's Web site on the day that the FRN is published.

ii. The FRN includes detailed instruction for submitting public comments.

iii. The public comment period is open to all stakeholders, including other Federal Agencies and White House offices.

c. Public comments are submitted to ORD

i. All comments received during the official public comment period will be submitted through E-Gov (www.regulations.gov).

ii. All public comments will be part of the official public record.

iii. Public comments submitted by the close of the comment period will be provided to the peer reviewers at least 10 working days prior to the peer review meeting.

iv. Only those comments received by the close of the public comment period are guaranteed of being provided to the external peer review panel in advance of the peer review meeting.

v. If an extension of a comment period is requested and granted, and a second FRN is published, the comments submitted during the extension may not be able to be provided to the peer reviewers before the meeting.

C. Public Listening Session

a. EPA holds a Public Listening Session after the public release of the draft assessment and before the peer review meeting.

b. The Listening Session provides an opportunity for interested parties to present scientific and technical comments on the draft IRIS health assessment to EPA and other interested parties.

c. An FRN announcing the Listening Session is generally published as least 30 days prior to the Listening Session meeting.

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May 20, 2009

d. FRN includes all logistical information regarding the meeting.

e. All Listening Sessions are held in the Washington, DC metropolitan area.

5. EPA Revises IRIS Toxicological Review and Develops IRIS Summary (Duration 60 days)

A. ORD evaluates the external peer review panel report and all public comments.

B. ORD revises the draft IRIS Toxicological Review, as appropriate, and develops the IRIS Summary.

C. Length of revision process may depend on the complexity of the IRIS Toxicological Review and complexity and number of peer reviewer and public comments.

D. ORD develops a disposition of peer reviewer and public comments and provides these as an appendix to the IRIS Toxicological Review.

6A.Internal EPA Review of Final IRIS Toxicological Review and IRIS Summary (Duration 45 days)

A. ORD sends the IRIS Toxicological Review and IRIS Summary for final internal Agency review.

B. This review is intended as a final check-in with Agency program and regions.

6B. EPA-led Interagency Science Discussion (Duration 45 days – concurrent with Step 6A.)

A. EPA provides other agencies and White House offices with the final draft of the IRIS Summary and Toxicological Review and appendix describing disposition of peer review and public comments.

B. Other agency and White House Office scientists have opportunity to provide written scientific feedback.

C. EPA hosts meeting with White House offices and other agencies to discuss any scientific issues related to the final draft of the IRIS Summary and Toxicological Review and appendix.

D. All written comments by other agencies and White House offices documented in the record.

7. EPA Completion of IRIS Toxicological Review and IRIS Summary (Duration 30 days)

A. ORD completes the IRIS Toxicological Review and IRIS Summary.

B. ORD prepares the final assessment for Agency's Web site posting.

C. ORD insures 508 Compliance and EPA Web site compliance.

D. ORD posts the assessment to the IRIS data base.

E. ORD completes and maintains the public record.

TOTAL: 23 Months

4 of 4

If we are to believe our own eyes, the new process is substantially streamlined.

Just as important, discussions between Federal Government agencies about IRIS listings will be transparent. There is no excuse for keeping interagency discussions secret from Congress and from the American people. We are entitled—I am speaking as a Member of Congress and as one of the American people, we are entitled to know the potential health effects of chemical exposures even if various government agencies find the chemicals very useful.

And no agency can trigger an even more tortured approval process by declaring that a chemical is "mission critical." Under strict rules of grammar the word "perpetual" is like the word "naked" or "nude." Neither allows for degrees, but the IRIS approval process devised by Dudley's OIRA was perpetual for all chemicals and more perpetual for "mission critical" chemicals.

We are interested in hearing today about EPA's new procedures, and there should be little doubt that the procedures are an improvement, but we need to see how the procedures work in practice to know whether the procedures are enough of an improvement. The institutional interests and ambitions of federal agencies survive presidential transitions. There will still be agencies that want to use chemicals without annoying restrictions and may try to avoid risk management issues by obstructing the risk assessment of an IRIS listing. And it is human nature to forsake power reluctantly, even the unwholesome, even sinister power that OIRA exercised over EPA's scientific assessments.

The American people need and deserve credible, scientifically-sound assessments of the health effects of chemical exposures. That means EPA must be in charge, not OIRA.

The Subcommittee will continue to work to follow the work of IRIS, and I have written the GAO to ask that they closely monitor the new IRIS process as well. And I have now included both our staff report on IRIS as well as a new report from the Center for Progressive Reform with my statement for the record. [*See Appendix: Additional Material for the Record*.]

I now recognize my distinguished colleague, Dr. Broun, for his opening statement.

[The prepared statement of Chair Miller follows:]

PREPARED STATEMENT OF CHAIR BRAD MILLER

A little more than a year ago, Susan Dudley, then the head of the Office of Information and Regulatory Affairs in OMB, and Dr. George Gray, then the head of the Office of Research and Development at EPA, testified before this subcommittee.

The hearing was to examine the stunning lack of productivity in new and revised risk assessments for chemicals in the EPA's Integrated Risk Information System (IRIS).

Dudley and Gray testified that the productivity problem was a complicated approval process for assessments, which this flow chart produced by EPA illustrated.

But Gray and Dudley said they had solved the problem by developing a streamlined approval process, which this flow chart, also produced by EPA, illustrated.

Gray's and Dudley's testimony reminded me of a famous quotation from Marx—not Karl, but Chico: "Well, who you gonna believe, me or your own eyes?"

Gray's and Dudley's testimony strained credulity in other ways.

Dudley explicitly denied in her testimony that OIRA, the office that she headed, ever challenged scientific assessments by EPA's scientists. Scientific assessment of the toxic effect of chemical exposure would not even remotely be OIRA's job. Our staff today released a report on IRIS that shows that OIRA did just that on several occasions, enough to conclude that intruding on scientific assessments was routine for OIRA. Dudley testified that the "streamlined" process for approving IRIS listings was entirely EPA's handiwork. Our staff's report shows that the process was the result of a multi-year, interagency process driven by OIRA, not EPA.

OIRA's conduct in requiring a perpetual paralysis in approval procedures and intruding on the independence of EPA's scientists appears to have been intended to keep IRIS from doing its job, and to keep us all in the dark about the public health consequences of chemical exposures. It certainly had that effect. While 70 chemicals were in some stage of review by EPA, EPA averaged three new and revised IRIS entries a year.

The new EPA Administrator, Lisa Jackson, announced a new process on May 21, 2009. This chart illustrates the new process. If we are to believe our own eyes, the new process is substantially streamlined.

Just as important, discussions between Federal Government agencies about IRIS listings will be transparent. There is no excuse for keeping interagency discussions secret from Congress and the American people. We are entitled to know the potential health effects of chemical exposures, even if various government agencies find the chemicals very useful.

And no agency can trigger an even more tortured approval process by declaring that a chemical is "mission critical." Under strict rules of grammar, the word "perpetual" is like the word "naked": neither allows for degrees. But the IRIS approval process devised by Dudley's OIRA was perpetual for all chemicals, and more perpetual for mission critical chemicals.

We are interested in hearing today about EPA's new procedures, and there should be little doubt that the procedures are an improvement. But we will need to see how the procedures work in practice to know whether the procedures are enough of an improvement. The institutional interests and ambitions of federal agencies survive presidential transitions. There will still be agencies that want to use chemicals without annoying restrictions, and may try to avoid risk management issues by obstructing the risk assessment of an IRIS listing. And it is human nature to forsake power reluctantly, even the unwholesome, even sinister power that OIRA exercised over EPA's scientific assessments.

The American people need and deserve credible, scientifically sound assessments of the health effect of chemical exposures. That means the EPA must be in charge, not OIRA.

This subcommittee will continue to follow the work of IRIS, and I have written the GAO to ask that they closely monitor the new IRIS process as well.

Mr. BROUN. Thank you, Mr. Chair.

The Integrated Risk Information System (IRIS) process was originally developed in the mid 1980's for a specific task. Different offices throughout the EPA were relying on different assessments of the health effects of exposure to chemicals.

IRIS was intended to establish a uniform database within EPA to—that represented a consensus determination. Over time, however, IRIS became an authoritative resource on chemical toxicity. As a credit to the agency's diligence, other agencies, states, and the international community and industries increasingly began to rely on IRIS, and assessments took on increased importance. These outside groups have sought to impact a process that was not initially designed to handle external pressures. The result has been an IRIS process that has effectively broken down.

As we learned from GAO last year, EPA had a backlog of 70 ongoing assessments and managed to complete only two assessments in each of the last two years. Even when EPA managed to produce assessments, the National Academy of Sciences has roundly criticized their work. The competing priorities of issuing assessments in a timely manner and producing assessments that are scientifically credible are central to the problems we face today.

The completely unsatisfactory timeframes for these assessments are the results of several factors. Reviews are becoming more complex as attention increases for high-profile chemicals. EPA management and program decisions are delaying completion. Outside stakeholder reviews are becoming more detailed, and Congressional action is becoming more prevalent.

All of these delays have compounded effects and create a domino effect on schedules as Mr. Stephenson pointed out in previous testimony. Until recently the IRIS process was an opaque process that had no schedule deadlines and limited outside review. While the previous Administration's proposed process wasn't perfect, it was

the first time that the process was formalized, thoroughly examined, and given strict timelines. If nothing else, the previous Administration recognized the untenable nature of the existing IRIS process and presented a proposal to fix the problem.

While the previous process wasn't perfect, neither is this new process. Previous processes required EPA to develop a consensus assessment, the original purpose of the IRIS process. The newly-proposed process does not require each EPA office to concur on assessments but rather to simply consult.

Furthermore, these internal agency consultations are not required to be available to the public, which ultimately limits transparency. EPA's failure to develop consistent assessments raises the questions of how authoritative and useful IRIS will be in the future.

One of the assessed arguments for the new proposal is its new streamlined process. As I mentioned earlier, the natural tension between fairness and timeliness begs the question of whether a streamlined process will ultimately sacrifice scientific credibility, especially considering recent negative reviews from the National Academy of Sciences. In order to streamline the process, the new Administration has cut out quality control measures such as visibility and the adjudication of peer review comments, the requirement for a qualitative assessment review, the public review of that qualitative assessment, the evaluation of agency interest in closing data gaps for mission-critical chemicals, design and implementation of new studies for mission-critical chemicals, and the development of short-term research projects that may aid in filling data gaps.

More importantly, this new streamlined process uses a bit of slight of hand to take the scientific literature review and data culling periods off the schedule entirely. This work will still be done, but EPA doesn't account for this time in its schedule, allowing them to create the appearance of a speedier process.

One of the largest criticisms of the previous proposal was the role played by the White House and more importantly OMB and Office of Regulatory Information and Affairs. Despite these previous criticisms, the new process states that White House offices will continue to be involved in the interagency consultation process.

Apparently this was only a concern when it was politically fashionable. If anyone had a problem with the previous Administration's meddling, you can probably expect more of the same since OIRA is staffed almost exclusively by career civil servants.

Somebody tried to dismiss this concern by noting that EPA is not ultimately responsible for the process but they always had final authority. Even under the previous process it could be claimed that even with that previous authority, EPA was still subordinate to the influence of OMB.

Similarly, one could argue that EPA will truly have final authority under the new process, but ultimately the EPA Administrator still works for the President. The only difference is that now maybe the Administrator also works for the new environment czar, Carol Browner. We aren't really sure about this since she is removed from any type of Congressional oversight, transparency or accountability.

I hope that science's rightful place doesn't turn out to be behind the cloak of deliberative process and executive communication.

Despite concerns about White House meddling, OMB has provided useful input into EPA assessments according to GAO's 2008 report. While OMB should certainly not use this review process to obstruct or prevent assessments, EPA also shouldn't be afraid to address valid scientific inquiries.

Additionally, OMB plays an important role in shepherding the interagency process. Without OMB taking the lead in this process, it remains to be seen if EPA will have enough clout to force or compel other agencies to comply with its timelines and directions.

This also raises another question relating to who will ultimately be the adjudicator of conflicts, an arbiter of scientific disputes. In an ideal world neither the White House nor EPA would be involved in this as it is truly a discussion meant for the scientific community.

Unfortunately, in the real world there needs to be a bureaucratic referee. Is EPA truly an unbiased partner when they are the agency that drafts the assessments? What incentive does EPA have to incorporate peer review as comments that may contradict their opinions? Are we setting up a system when EPA will be responsible for monitoring its own work?

Even if EPA is unbiased or the Office of Research and Development's staff tasks to conduct these assessment experts on every chemical are aware of all the science? If the answer is no, then aren't we essentially making pure but poorly informed assessments? If none of these questions matter because assessments go through peer review, why would it matter if other agencies, industry or the White House, were involved since the final product will be peer reviewed?

As you can tell, I remain very skeptical of the new process, but I do see some commendable aspects. New transparency measures for the interagency review process are promising, even though they don't extend into internal communication between EPA line offices, which could prove to be just as informative and important.

Despite this potential bright spot, several other questions remain.

With that, Mr. Chair, I am attaching a letter from Toxicology Excellence for Risk Assessment to my statement that I will enter in the record, and I appreciate your indulgence and look forward to the witnesses' testimony.

[The prepared statement of Mr. Broun follows:]

PREPARED STATEMENT OF REPRESENTATIVE PAUL C. BROUN

The Integrated Risk Information System (IRIS) process was originally developed in the mid-1980's for a specific task. Different offices throughout the Environmental Protection Agency (EPA) were relying on different assessments of the health effects of exposure to chemicals. IRIS was intended to establish a uniform database within EPA that represented consensus determinations.

Over time, however, IRIS became an authoritative resource on chemical toxicity. As a credit to the agency's diligence, other agencies, states, the international community, and industries increasingly began to rely on IRIS, and the assessments took on increased importance. These outside groups have sought to impact a process that was not initially designed to handle external pressures. The result has been an IRIS process that has effectively broken down.

As we learned from GAO last year, EPA had a backlog of 70 ongoing assessments and managed to complete only two assessments in each of the last two years. Even

when EPA managed to produce assessments, the National Academy of Sciences has roundly criticized their work. The competing priorities of issuing assessments in a timely manner and producing assessments that are scientifically credible are central to the problems we face today.

The completely unsatisfactory timeframes for these assessments are the result of several factors. Reviews are becoming more complex as attention increases for high profile chemicals, EPA management and program decisions are delaying completion, outside stakeholder reviews are becoming more detailed, and Congressional action is becoming more prevalent. All of these delays have compounding effects and create a "domino effect" on schedules as Mr. Stephenson pointed out in previous testimony.

Until recently, the IRIS process was an opaque process that had no schedule deadlines and limited outside review. While the previous Administration's proposed process wasn't perfect, it was the first time that the process was formalized, thoroughly explained, and given strict timelines. If nothing else, the previous Administration recognized the untenable nature of the existing IRIS process and presented a proposal to fix the problem.

While the previous process wasn't perfect, neither is this the new process. Previous processes required EPA to develop a consensus assessment - the original purpose of the IRIS process. The newly proposed process does not require each EPA office to concur on assessments. but rather to simply consult. Furthermore, these internal agency consultations are not required to be available to the public, which ultimately limits transparency. EPA's failure to develop consensus assessments raises the question of how ?authoritative and useful IRIS will be in the future.

One of the arguments for the new proposal is its new streamlined process. As I mentioned earlier, the natural tension between thoroughness and timeliness begs the question of whether a streamlined process will ultimately sacrifice scientific credibility. especially considering recent negative reviews from the National Academy of Sciences. In order to streamline the process, the new Administration has cut out quality control measures such as visibility into the adjudication of peer review comments; the requirement for a qualitative assessment review: the public review of that qualitative assessment: the evaluation of agency interests in closing data gaps for mission critical chemicals. the design and implementation of new studies for mission critical chemicals, and the development of short-term research projects that may aid in filling data gaps. More importantly, this new streamlined process uses a bit of slight-of-hand to take the scientific literature review and data call-in periods off the schedule entirely. This work will still be done, but EPA doesn't account for this time in its schedule, allowing them to create the appearance of a speedier process.

One of the largest criticisms of the previous proposal was the role played by the White House, and more importantly the Office of Management and Budget (OMB) and the Office of Regulatory Information and Affairs (OIRA). Despite these previous criticisms, the new process states that White House offices will continue to be involved in the interagency consultation process. Apparently this was only a concern when it was politically fashionable. If anyone had a problem with the previous Administration's "meddling," you can probably expect more of the same since OIRA is staffed almost exclusively by career civil servants.

Some may try to dismiss this concern by noting that EPA is now ultimately responsible for the process, but they always had final authority, even under the previous process. It could be claimed that even with that previous authority, EPA was still subordinate to the influence of OMB. Similarly, one could argue that EPA will truly have final authority under the new process, but the ultimately the EPA Administrator still worked for the President. The only difference is that now maybe the Administrator also works for the new Environment Czar Carol Browner. We aren't really sure about this since she is removed from any type of Congressional oversight, transparency, or accountability. I hope that science's "rightful place" doesn't turn out to be behind the cloak of deliberative process and executive communication.

Despite concerns about White House meddling, OMB has provided useful input into EPA assessments according to GAO's 2008 report. While OMB should certainly not use this review process to obstruct or prevent assessments, EPA also shouldn't be afraid to address valid scientific inquiries. Additionally, OMB plays an important role in shepherding the interagency process. Without OMB taking the lead in this process, it remains to be seen if EPA will have enough clout to force or compel other agencies to comply with its timelines and directions.

This also raises another question relating to who will ultimately be the adjudicator of conflicts and arbiter of scientific disputes. In an ideal world, neither the White House nor EPA would be involved in this, as it truly is a discussion meant for the scientific community. Unfortunately in the real world there needs to be a

bureaucratic referee. Is EPA truly an unbiased partner when they are the agency that drafts the assessments? What incentive does EPA have to incorporate peer reviewer's comments that may contradict their opinions? Are we setting up a system where EPA will be responsible for monitoring its own work? Even if EPA is unbiased, are the Office of Research and Development (ORD) staff tasked to conduct these assessments experts on every chemical and aware of all the science? If the answer is no, then aren't we essentially making pure, but poorly informed assessments? If none of these questions matter because assessments go through peer review, why would it matter if other agencies, industry, or the White House were involved since the final product will be peer reviewed?

As you can tell, I remain very skeptical of the new process but I do see some commendable aspects. New transparency measures for the interagency review process are promising even though they don't extend to internal communications between EPA line offices which could prove to be just as informative and important. Despite this potential bright-spot, several other questions remain.

With that, Mr. Chairman, I am attaching a letter from Toxicology Excellence for Risk Assessment (TERA) to my statement that I will enter into the record. I appreciate your indulgence and look forward to the witnesses' testimony.

[The information follows:]

Toxicology Excellence for Risk Assessment

TERA *a nonprofit corporation dedicated to the best use of toxicity data for risk values*

June 10, 2009

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Representative Paul Broun, M.D.
Subcommittee on Investigations and Oversight
Committee on Science and Technology
U.S. House of Representatives
394 Ford House Office Building
Washington, DC 20515

Dear: Dr. Broun

I strongly encourage, without reservation, broad scientific collaboration in order for EPA's IRIS process to meet the needs of the 21st century. Specifically, based on my experience,[1] training, and discussions with EPA staff, as well as scientists from many interested groups, I highly recommend that EPA:

- Clarify the process of involvement with the scientific community; the process for resolving scientific disagreements among interested parties needs to be explicit.
- Work with outside groups with appropriate conflict restrictions to bring in data, opinions, and solutions to complex problems. EPA does not have all the answers. Balancing our individual and group biases will yield better science.
- Allow sufficient time and opportunities for discussion of scientific issues, for example, a 60-day comment period (as in rulemaking) for all parties; EPA should recognize that resolution of scientific issues will take longer.
- Enhance training of EPA staff in dose response assessment techniques, and mentors its younger staff to the artisan and expert levels; many EPA staff do not know basic dose response assessment information.
- Develop safe dose values by scientific consensus among EPA offices and fellow federal agencies, and outside experts as appropriate.

[1] Prior to working at Toxicology Excellence for Risk Assessment (*TERA*) for 15 years, I worked for 15 years at the U.S. Environmental Protection Agency (EPA), holding several leadership roles on specific key projects, including the creation of EPA's IRIS.

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A Brief History of IRIS

IRIS is a national treasure, held in trust by the EPA for all of us.[2]

It has not always been this way, however.

IRIS first started in 1986, as a mechanism to harmonize "safe" dose values[3] among EPA program offices, after it was found that 39 of 40 values for chemicals derived by separate program offices were different from each other. Only one chemical had similar values developed by different program offices; however, this single instance of congruence happened by luck, not by scientific reasoning. This dismal record of 0 for 40 was due in part to the enormous workload of staff and the general lack of communication among EPA offices doing safe dose assessment work.

Within 5 years, EPA had created IRIS to house unanimous consensus information for 500 chemicals. This remarkable turnaround came about through collaborative work among senior EPA scientific staff on two agency peer review work groups,[4] and the commitment of EPA management. Different EPA offices proposed risk values, which were reviewed in monthly internal meetings; values with which everyone agreed were loaded on IRIS. Senior scientific staff among EPA offices interacted on numerous safe dose deliberations prior to work group review and younger staffers had training in preparation for agency work group meetings.

During the early 1990s the influence of IRIS grew and the risk values were being used in many regulatory and enforcement situations; states, industries, and other interested parties petitioned EPA to reconsider many values based on newer data and analysis. Unfortunately, EPA had few dedicated resources for such reconsiderations,[5] and as a result, EPA's polite letters of reply were often followed by years of EPA inactivity.

Due to this intense scrutiny and the receipt of resources in the latter 1990s, EPA management began a process of IRIS consolidation. One of the casualties of this consolidation was the abandonment of the successful work groups, and the dwindling of collaborative spirit among agency offices soon followed. Several reorganizations of the IRIS process have been proposed since the late 1990s, the latest is under discussion today.

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[2] Dourson M. and J. Patterson. 2004. The Integrated Risk Information System: Challenges and Opportunities. Risk Policy Report. 11(5): 29-31.

[3] "Safe" doses within EPA go by the name of Reference Dose or (RfD) for noncancer toxicity oral exposures, Reference Concentration (RfC) for noncancer toxicity inhalation exposures, or Oral Slope Factors (OSF) for cancer toxicity oral exposures or Inhalation Unit Risk for cancer inhalation exposures.

[4] The RfD/RfC work group for noncancer toxicity, and the Carcinogen Risk Assessment Verification Endeavor (CRAVE) work group for cancer toxicity.

[5] In the early 1990s, 75 requests for reconsideration were pending. Each request was estimated to require the use an average of $10,000 in extramural funds and 0.1 FTE, or total funds of $750,000 and 7.5 FTE. In contrast, EPA had a total of 0.3 FTE in dedicated resources and no extramural funds (M. Dourson, personal recollections).

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But IRIS as a repository representing the best Agency safe doses has been lost.

Fully one quarter of all IRIS values do not reflect the latest EPA safe doses.[6] In particular, the Office of Pesticide Programs (OPP) of EPA has developed or revised risk values based on the most recent available data for numerous substances, yet these newer values are not available on IRIS. Developing a process that provides for timely development of risk values, while allowing for full engagement by representatives from the relevant program offices, will allow IRIS to resume its former place as the comprehensive site for EPA risk values.

2009 IRIS Process

The 2009 IRIS process has the advantages of a tightened time frame and clearer entry points for deliberations, and will serve well for many of the chemicals assessed within the program that have limited scientific issues and environmental impact (e.g., a chemical is found at only a few Superfund sites). However, the proposed 2009 process will not work for chemicals with major scientific issues and environmental impact (e.g., dioxin) without a significant increase in the timeline, as EPA acknowledges. In such cases, EPA's process must:

- Allow time in the schedule when key studies are ongoing, planned, or, under development; for example, we now have much better knowledge of perchlorate's toxicity due to over 5 million dollars of research since 1997; this knowledge has lead to a more credible safe dose.
- Ensure that the public listening session is directly tied to the external peer review, and that peer reviewers are present or aware of the points raised.
- Define criteria for use of EPA's Science Advisory Board or the NAS reviews; also, these panels need to include a sufficient number of erudite risk assessment scientists, and preferably be chaired by one of them.

More importantly, EPA's IRIS staff needs to listen.

The single, most intense frustration on the IRIS process, made by many erudite scientists, both inside and outside EPA, is that EPA's IRIS staff will not listen to, or is not capable of understanding, their scientific comments. Several of these folks have told me that they see no point in further research on mode of action (MOA) because it will not be fully, or even partially, considered by EPA IRIS staff. This is particularly worrisome, since EPA's well-written cancer risk assessment guidelines[7] emphasizes MOA understanding in cancer assessments.

The process for resolving scientific disagreements within the agency and between EPA and other agencies is not clear in the current reorganized process. Are key decisions made by consensus, or will one scientist have the final say? Most scientists have a bias one way or

[6] See EPA IRIS list of substances and focus on files with OPP Reregistration documentation at www.epa.gov/iris.

[7] U.S. Environmental Protection Agency. 2005. Guidelines for carcinogen risk assessment. Washington D.C. EPA/630/P-03/001B.

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another (for example, as a toxicologist, I am biased when reviewing epidemiology studies in one direction). Thus, if a decision is made only by one scientist then it will likely be bias in one direction. It is only in the collective balancing of biases that the best science can be brought forward, much like the intersection of multiple events in a Venn diagram.

In contrast, the resolution of disagreements in the EPA 2008 IRIS reorganization seemed more clear with a very deliberative process for chemicals of high impact to environmental protection. For example, the safe dose for perchlorate was eventually determined by a panel of scientists from the National Academy of Sciences to be 25 times higher than what EPA proposed. But this panel only came about after a more deliberative process involving several federal agencies, and several years of intense work, including numerous research studies, similar to what the 2008 IRIS reorganization suggested.

Do reorganizations matter?

Perhaps more important than any reorganization, however, is the incorporation of flexibility in the overall process based on the determination of working relationships among all participants. In the early days of IRIS, the EPA program and research offices communicated poorly. Forcing discussions among EPA offices soon fostered a scientific, collaborative spirit, which not only built IRIS to 500 chemicals in 5 years but also trained younger staff to be better risk assessment scientists. A key aspect of this process was that the scientists from different offices discussed the assessments and reached resolution on key recurring issues. This collaboration also assisted the development of EPA-wide risk assessment guidelines and research to improve the basis of risk assessments.

While the 2009 process, suitably amended, will provide opportunities for EPA and other scientific agencies and outside parties to discuss scientific issues, it does not appear to provide similar opportunities for discussion within the EPA among different offices. Direct communication and collaboration amongst EPA staff is also essential to insure that the best science is incorporated into the IRIS assessments. The fact that the current IRIS process is not looked upon favorably by many EPA staff attests to this failure within EPA to communicate.

Scientific collaboration with all interested parties, could propel EPA's IRIS process, and the science and practice of risk assessment, forward to meet the needs of the 21st century. I strongly encourage, without reservation, such a collaborative spirit; for it is only in our collective efforts that we will best protect the public's health.

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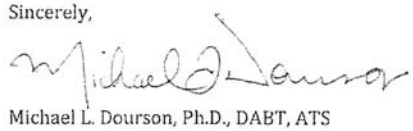
Nothing less should be expected of us.

Sincerely,



Michael L. Dourson, Ph.D., DABT, ATS
President
Toxicology Excellence for Risk Assessment (*TERA*)[8]

[8] Toxicology Excellence for Risk Assessment (*TERA*) is a non-profit, 501(c)(3) corporation that develops partnerships among government, industry and other interested groups to address risk assessments of high visibility (such as formaldehyde, perchlorate, and soluble nickel) and cooperative ventures such as the Voluntary Children's Chemical Exposure Program (VCCEP), the International Toxicity Estimates for Risk (*ITER*) database, the Risk Information Exchange (RiskIE) database, and the Alliance for Risk Assessment (*ARA*). *TERA's* funding sources are primarily government agencies (such as EPA, NIOSH, FDA, Health Canada, and U.S. States---at 67% in 2008). *TERA* also accepts funding from DoD and industry, if the sponsors accept its conditions of publication.

See also http://toxnet.nlm.nih.gov/ for *ITER*, and http://www.allianceforrisk.org/ for RiskIE and the *ARA*.

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TERA Statement of Purpose

Toxicology Excellence for Risk Assessment (*TERA*) is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes. Our mission is to protect public health by developing and communicating risk assessment information, improving risk methods through research, and educating the public on risk assessment issues. Some specific activities of *TERA* are listed below.

- Establish high-quality risk assessment values based on the latest scientific data and methods through the **Verifiable Estimates for Risk Assessment** (*VERA*) program
- Provide a unique side-by-side comparison of hazard values, information and dose response from organizations and independent parties worldwide through the **International Toxicity Estimates for Risk** (*ITER*) Database
- Conduct research to improve the underlying methods for human and ecological risk assessment
- **Peer Review and Consultation** of risk information, methods and study designs through an independent and public process
- Educate diverse groups on risk assessment issues, through training courses, scientific support and the State Hazard Evaluation Lending Program (**State HELP**)
- Improve the practice of risk assessment through independent and objective guidance and advice

TERA is a non-profit corporation organized under section 1702.01 of the Ohio Revised Code, and is classified as a **501(c)(3) organization** under the Internal Revenue Service Code. Corporations, companies, associations, individuals and foundations may support the work of *TERA* through tax-deductible contributions.

6

Chair MILLER. Thank you, Dr. Broun.

I ask unanimous consent that all additional opening statements submitted by Members be included in the record. Without objection, so ordered.

It is my pleasure now to introduce our witnesses. Dr. Kevin Teichman is the Deputy Assistant Administrator for Science in the Office of Research and Development at EPA, and Mr. John Stephenson is back. He is the Director of Natural Resources and Environment at the Government Accountability Office.

As our witnesses should know, you will each have five minutes for your spoken testimony. Your written testimony will be included

in the record. When you all have completed your spoken testimony, we will begin with questions. Each Member will have five minutes to question the panel.

It is the practice of this subcommittee to receive testimony under oath, although we have not made it our habit to refer cases for perjury prosecution, which I am sure is a great relief to Dr. Gray and Ms. Dudley. You also have the right to be represented by counsel. Do any of you have any objection to taking an oath?

Both witnesses indicated that they did not. You also have the right to be represented by counsel. Do either of you have a counsel here? Counsel with you?

Also, I understand that you may have—although both of you, I know, have encyclopedic knowledge of this topic, you may have other staff with you who may need to—who might need to help with an answer. Would it be helpful if anybody else from your staffs who might need to help you with an answer also take the oath at the same time?

Okay. All right. Please stand and raise your right hand. Do you swear to tell the truth and nothing but the truth?

The record will show that both witnesses have taken the oath.

We will now begin with Dr. Kevin Teichman. Dr. Teichman, please begin.

STATEMENT OF DR. KEVIN TEICHMAN, DEPUTY ASSISTANT ADMINISTRATOR FOR SCIENCE, OFFICE OF RESEARCH AND DEVELOPMENT (ORD), U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)

Dr. TEICHMAN. Good afternoon, Mr. Chair and Members of the Subcommittee. I am Dr. Kevin Teichman, the Deputy Assistant Administrator for Science in EPA's Office of Research and Development. I am also the Acting EPA Science Advisor, and in this role I serve as a member of the Office of Science and Technology Policy's Task Force on Scientific Integrity. I appreciate this opportunity to discuss with you EPA's Integrated Risk Information System, IRIS.

Before I begin I would like to thank Congressman Miller and the Subcommittee for your support of the IRIS Program. The importance of a successful IRIS Program to the health of the American people was acknowledged by this subcommittee in two past hearings and by Chair Miller's previous introduction of legislation on this topic. Your continued interest in the future of the IRIS Program is greatly appreciated.

IRIS is one of EPA's most important and most public products. IRIS has been a highly-regarded resource for providing information on the potential human health risks from long-term exposures to contaminants. IRIS assessments are used by EPA programs and regions as the scientific foundation for Agency actions to protect human health.

IRIS assessments are also used by environmental and health professionals and State and local governments, as well as internationally. Because of the widespread use of IRIS risk information, it is of utmost importance that the process used to develop this information, and the resulting assessments posted on IRIS, reflect

the highest possible standards for scientific quality, scientific integrity, transparency, and timeliness.

Administrator Jackson, coming from careers at both EPA and the New Jersey Department of Environmental Protection, recognizes the critical role that EPA plays in disseminating timely, high quality, and accessible human risk information on environmental contaminants. Just four months after coming to EPA she announced a new IRIS process that is more responsive to the needs of the Agency and its work to effectively and efficiently protect the health of all Americans.

The new IRIS process is more timely, transparent, and will ensure the highest level of scientific integrity. It will rely on an opportunity for public review and comment followed by a rigorous, open, and independent external peer review process to guarantee the scientific quality of the IRIS assessments.

There are several aspects of the new process that I would like to highlight. First, the new IRIS process will be entirely managed by EPA. Second, there is no longer an opportunity for another federal agency to prolong the process by asking that additional research be conducted before an assessment can be produced.

Instead, EPA will announce the chemicals that will be assessed far enough in advance so that any interested party could conduct short-term studies that could add to the peer-reviewed scientific literature.

Third, all written comments from other federal agencies and White House offices will become part of the public record. Opportunities for scientific comment by other federal agencies and White House offices was maintained in the new process, because EPA welcomes input from interested experts that may add to the scientific quality of the draft or final assessment.

Also, the assessment process has been streamlined to ensure that more new and updated assessments are included on IRIS. While still robust, the assessment development process for most chemicals will be shortened to 23 months, speeding the availability of IRIS assessments.

There are two steps introduced in the previous process that were retained in the new process. First, the opportunity for any interested party to provide information to EPA prior to the external peer review meeting. These listening sessions allow interested parties to present scientific comments on draft IRIS assessments during the public comment period and before the external peer review period. EPA has found the listening sessions to be a valuable step in public outreach and participation.

Second, changes in EPA's scientific judgments from public comments and peer review will be clearly documented and explained, maximizing the transparency of the final product.

Finally, to give this new process an added boost, the Administrator has directed that for fiscal year 2010, resources for the IRIS program should be increased, and the President's budget request includes an additional $5 million and ten FTEs full-time equivalents, for the IRIS program.

In conclusion, EPA remains dedicated to listening and being responsive to the public, to independent experts, and to scientists and other federal science agencies as it develops IRIS human health as-

sessments. The ability of EPA's program to succeed has been significantly improved now that some steps have been removed or revised. EPA is confident that we can continue to provide the critical human health risk information to EPA's programs and regions that ensure the Agency's actions protect the public health.

Thank you very much, and I am happy to answer any questions that you may have.

[The prepared statement of Dr. Teichman follows:]

PREPARED STATEMENT OF KEVIN TEICHMAN

Good afternoon, Mr. Chairman and Members of the Subcommittee. I am Dr. Kevin Teichman, the Deputy Assistant Administrator for Science in EPA's Office of Research and Development. I am also the Acting EPA Science Adviser, and in this role I serve as a member of the Office of Science and Technology Policy's (OSTP's) Task Force on Scientific Integrity. I appreciate this opportunity to appear at this hearing and discuss with you EPA's Integrated Risk Information System (IRIS). In this written testimony, I will include a brief description of the recent history of the IRIS program as well as discuss some of the highlights of the new IRIS process that was announced by EPA Administrator Lisa P. Jackson on May 21, 2009.

Before I begin, I would like to thank Congressman Miller and this Subcommittee on behalf of EPA, and personally, for support of the IRIS program. The importance of a functioning and successful IRIS program to the health of the American people was acknowledged by this subcommittee in two past hearings and by Chairman Miller's introduction of H.R. 7234, the *Integrated Risk Information System Authorization Act*. Since the purpose of IRIS is to provide timely, high quality, and accessible human health risk information on environmental contaminants that may endanger the health of the American public, your continued interest in the future of the IRIS program is greatly appreciated.

IRIS is one of EPA's most successful and most public products. IRIS has been a highly regarded resource for providing information on the potential human health risks from long-term exposure to various contaminants. The IRIS assessments used by EPA's Program Offices and Regions are the science foundation for Agency actions to protect human health. IRIS assessments are also used by risk assessors and environmental and health professionals in State and local governments, as well as internationally. Because of the widespread recognition and use of IRIS risk information, it is of utmost importance that the process used to develop this information, and the resulting assessments posted on IRIS, reflect the highest possible standards for scientific quality and integrity, transparency, and timeliness.

On April 10, 2008, a new IRIS process was created via a memorandum from former Deputy Administrator Marcus Peacock that codified the IRIS process. This process introduced additional, time-consuming steps, some of which were not transparent to the public.

On January 26, 2009, Lisa P. Jackson was sworn in as EPA's 11th Administrator. On January 23, 2009, Administrator-Designee Jackson wrote to all EPA staff that, "*As Administrator, I will ensure EPA's efforts to address the environmental crises of today are rooted in three fundamental values: science-based policies and programs, adherence to the rule of law, and overwhelming transparency. By keeping faith with these values and unleashing innovative, forward-thinking approaches—we can further protect neighborhoods and communities throughout the country.*" Coming from careers at both EPA and the New Jersey Department of Environmental Protection, Administrator Jackson recognized the critical role that EPA plays in disseminating timely, high quality, and accessible human health risk information on environmental contaminants. Thus, one of her highest priorities was to take the necessary steps to strengthen and revitalize the process by which EPA develops and disseminates human health risk information.

On May 21, 2009, just four months after coming to EPA, Administrator Jackson announced a new IRIS process that is more responsive to the needs of the Agency in its work to effectively and efficiently protect the health of all Americans. The new IRIS assessment development process, which was implemented immediately, is more streamlined, transparent, and timely, and will ensure the highest level of scientific integrity. It will rely primarily on an opportunity for public review and comment followed by a rigorous, open, and independent external peer review process to guarantee the scientific quality of the IRIS assessments.

There are several aspects of the new process that I would like to highlight. The first is that the new IRIS process will be entirely managed by EPA. Second, there

is no longer an opportunity for another federal agency to prolong the assessment process by asking that additional research be conducted before an assessment can proceed. Instead, EPA will announce the chemicals that will be assessed far enough in advance so that any interested party could conduct short-term studies that could add to the peer-reviewed scientific literature for that chemical. Third, all scientific comments from other federal agencies and White House offices will become part of the public record for that chemical assessment. Opportunities for scientific comment by other federal agencies and White House offices was maintained in the new process, because EPA welcomes input from interested experts that may add to the science quality of the draft or final assessment.

Finally, the assessment process has been streamlined to ensure that more new and updated assessments are included on IRIS. While still robust, the assessment development process for most chemicals will be shortened to 23 months, speeding the availability of IRIS assessments to the human health risk assessor community and the public.

There are two aspects that were retained in the new process. First, is the opportunity for any interested party to provide information to EPA prior to the external peer review meeting. These listening sessions, announced in the *Federal Register*, allow all interested parties to present scientific and technical comments on draft IRIS health assessments to EPA and other interested parties during the public comment period and before the external peer review meeting. EPA has found the listening sessions to be a valuable step in public outreach and participation. The listening session comments are considered by the Agency as it revises the draft assessment in response to the independent external peer review and public comments. As with scientific comments from other federal agencies, listening session comments become part of the public record. Second, changes in EPA's scientific judgments from public comments and peer review will be clearly documented and explained, maximizing the transparency of the final product.

Finally, to give this new process an added boost, the Administrator has directed that for fiscal year 2010, resources for the IRIS program should be increased, and the President's budget request includes an additional $5 million and 10 FTEs for the IRIS program.

EPA remains dedicated to listening and being responsive to the public, to independent experts, and to scientists in other federal science agencies as it develops IRIS human health assessments. The ability of EPA's IRIS program to succeed has been significantly improved now that some steps have been removed or revised. EPA is confident that we can continue to provide the critical human health risk information to EPA's Programs and Regions that ensure the Agency's actions protect the public health.

Thank you for the opportunity to discuss with you EPA's new and improved IRIS program. I am happy to answer any questions that you may have.

BIOGRAPHY FOR KEVIN TEICHMAN

Dr. Kevin Teichman is the Deputy Assistant Administrator for Science in the Office of Research and Development (ORD); he is also the Acting Science Advisor for the Agency. He previously served as the Director of the Office of Science Policy (OSP) within ORD. In this capacity, he coordinated ORD participation in EPA's policy-making in all media (air, water, waste, pesticides and toxic substances) to ensure these policies reflected sound science. In addition, he helped lead the planning of EPA's research program, striving to ensure the research program responded to the needs of EPA's Program and Regional Offices and maintained its leadership role in the environmental research community.

During the enactment of the *Clean Air Act Amendments of 1990*, Dr. Teichman served as the Associate Director of Science in OSP, and OSP Staff Director of the Air Staff prior to that, with similar responsibilities to those above but limited to air pollution. In addition, he managed EPA's indoor air quality research program, including research devoted to characterizing indoor pollutants sources, assessing indoor exposures, studying associated health effects, assessing potential risks, and developing prevention/mitigation approaches to indoor air pollution.

Dr. Teichman has B.S. and M.S. degrees from the Massachusetts Institute of Technology and a Ph.D. degree from the University of California at Berkeley, all in Mechanical Engineering. He lives in Derwood, Maryland where he and his wife Marsha are proud "empty nesters."

Chair MILLER. Thank you, Dr. Teichman.

Mr. Stephenson is recognized for five minutes.

STATEMENT OF MR. JOHN B. STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEPHENSON. Thank you, Mr. Chair. I am pleased to be here today to discuss our prior findings and recommendations on EPA's IRIS program as well as the results of our preliminary review of EPA's most recently announced IRIS reforms announced on May 21, 2009.

As you know, the IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals in the environment. It is the critical component of EPA's capacity to support scientifically-sound risk management decisions, policies, and regulations.

In March 2008, we reported that the IRIS program was at serious risk of becoming obsolete because the Agency had not been able to complete timely, credible chemical assessments or decrease its backlog of 70 ongoing assessments. EPA completed only five assessments last year and has only completed one assessment so far this year.

We also found that the timeframes for completing assessments were unacceptably long, often taking over a decade. In many cases assessments became obsolete before they could be finalized and were stuck in an endless loop of assessment and reassessment.

In April 2008, EPA unveiled a revised process, and we were disappointed to find out that it was not responsive to our recommendations and was actually worse than the process that it replaced, institutionalizing a process that would take six to eight years at best to complete, enabling federal agencies to delay ongoing assessments by requesting additional research and declaring comments from other agencies deliberative and excluded from the public record.

As we testified before this subcommittee last year, we were extremely concerned about the consequences of these problems because IRIS assessments are, after all, the cornerstone of scientific integrity at the Agency. In fact, we added EPA's toxic chemical assessment and control processes to our January 2009 report on government-wide, high-risk areas in need of increased attention by executive agencies and the Congress, a GAO designation reserved for only the most serious Federal Government problems.

Today I am pleased to report that while it is too soon to offer a blanket endorsement, the new IRIS process introduced by EPA on May 21 of this year appears to be a giant step in the right direction. In particular we believe that the new IRIS process, if managed effectively, will be largely responsive to the recommendations we made in our March 2008 report.

First the process will be managed by EPA rather than OMB as the former process was. Second, it addresses key transparency concerns by expressly requiring that all written comments provided by other federal agencies on draft IRIS assessments be part of the public record. Third, the new process streamlines the previous one by consolidating and eliminating some steps and committing to a two-year completion timeframe. Importantly, it eliminates the step under which other federal agencies could have IRIS assessments suspended indefinitely to conduct additional research. We also be-

lieve that the requested increase of $5 million and ten additional staff positions will help ensure that more resources are allocated to the IRIS program to meet user needs.

While these changes reflect a significant improvement that can help EPA restore the integrity and productivity of the program, we offer the following observations for EPA to consider as it implements the new process.

First, there are no timeframes stated for the literature search and data call in kind of the pre-Step 1. This tends to understate the 23-month timeframe for completing assessments.

Second, it is not clear what purpose—what the purpose of the interagency consultation meetings is, which is Step 3 and Step 6B on the new process, what the role of OMB and other White House offices are exactly, and whether decisions will be documented in the public from decisions coming out of those steps.

Third, it seems to us that comments from the federal agencies, which is Step 3, could be solicited at the same time draft assessments are sent to independent peer reviewers and the public, which is Step 4, and saving additional time in the process.

Fourth, it is not clear how EPA plans to respond to our March 2008 report recommendation to provide at least a two-year notice of planned assessments. The new process does not specifically address such important planning steps as the call for nominations of chemicals to be assessed and the establishment of an IRIS agenda.

We believe that giving agencies and the public more advanced notice to plan assessments would enable external parties with an interest in a given chemical to complete relevant research before the start of an IRIS assessment, and thus, make the assessment even more efficient.

Finally, unlike a number of other EPA programs with statutory deadlines for completing various activities, no enforceable deadlines apply to the IRIS program. We believe that legislating statutory deadlines could help EPA better ensure the viability of this critical program.

Mr. Chair, that concludes the summary of my statement, and I will be happy to answer questions.

[The prepared statement of Mr. Stephenson follows:]

PREPARED STATEMENT OF JOHN B. STEPHENSON

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss our prior findings and recommendations on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program as well as the results of our preliminary review of EPA's most recent IRIS reforms, announced on May 21, 2009. As you know, IRIS is one of the most significant tools that EPA has developed to effectively support its mission to protect people and the environment from harmful chemical exposures. The IRIS database contains EPA's scientific position on the potential human health effects of exposure to more than 540 chemicals in the environment and is, therefore, a critical component of EPA's capacity to support scientifically sound risk management decisions, policies, and regulations.

In a March 2008 report, we identified significant deficiencies in EPA's IRIS assessment process that threatened the viability of the program, and we made a num-

ber of recommendations to correct them.[1] In response, EPA issued a revised assessment process in April 2008 that did not respond to our recommendations but rather made changes likely to further exacerbate the problems we had identified. Largely as a result of the agency's lack of responsiveness, we added transforming EPA's processes for assessing and controlling toxic chemicals as a high-risk area in our January 2009 biennial status report on government-wide high-risk areas requiring increased attention by executive agencies and Congress.[2] In announcing new reforms to the IRIS assessment process on May 21, 2009, EPA echoed our findings—that the April 2008 assessment changes reduced the transparency, timeliness, and scientific integrity of the IRIS process—and highlighted both our high-risk designation of this important EPA program and the President's recent emphasis on the importance of transparency and scientific integrity in government decision-making.

In this context, my testimony today discusses (1) the findings from our 2008 report and testimonies on the prior IRIS assessment processes[3] and (2) our preliminary evaluation of EPA's May 2009 process reforms. For this statement, we have supplemented our prior work with a preliminary review of the EPA process reforms and some IRIS productivity data. We conducted our work from May 28 to June 11, 2009, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform our work to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

The Viability of the IRIS Program Is at Risk

In March 2008, we reported that the IRIS program is at serious risk of becoming obsolete because the agency has not been able to complete timely, credible chemical assessments or decrease its backlog of 70 ongoing assessments. In addition, assessment process changes EPA had recently made, as well as other changes EPA was considering at the time of our review, would have further reduced the timeliness, credibility, and transparency of IRIS assessments. Among other things, we concluded the following:

- EPA was unable to routinely complete IRIS assessments in a timely manner. From 2000 to 2007, EPA completed on average about five IRIS assessments a year. The more recent trend has been a decline in productivity: In fiscal years 2006 and 2007, EPA completed two assessments each year; in 2008, EPA completed five assessments—four of which were related chemicals assessed and peer reviewed together but finalized individually; and thus far in fiscal year 2009, EPA has finalized one assessment.
- Further, as we reported in 2008, because EPA staff time was dedicated to completing assessments in the backlog, EPA's ability to both keep the more than 540 existing assessments up to date and initiate new assessments was limited. We found that 48 of the 70 assessments being conducted as of December 2007 had been in process for more than five years—and 12 of those, for more than nine years. These time frames have lengthened. Currently, of those 70 assessments, 58 have now been ongoing for more than five years—and 31 of those for more than nine years.
- We also found that EPA's efforts to finalize IRIS assessments have been thwarted by a combination of factors. These factors include (1) the Office of Management and Budget's (OMB) requiring two additional reviews of IRIS assessments by OMB and other federal agencies with an interest in the assessments, such as the Department of Defense, and (2) EPA management decisions, such as delaying some assessments to await the results of new research.
- The two new OMB/interagency reviews of draft assessments involve other federal agencies in EPA's IRIS assessment process in a manner that limits the credibility and transparency of, and hinders EPA's ability to manage, IRIS assessments. For example, some of these agencies' review comments could be influenced by the potential for increased environmental cleanup costs and other legal liabilities if EPA issued an IRIS assessment for a chemical that resulted in a decision to regulate the chemical to protect the public. Moreover,

[1] GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, GAO–08–440 (Washington, D.C.: Mar. 7, 2008).

[2] GAO, *High-Risk Series: An Update*, GAO–09–271 (Washington, D.C.: January 2009).

[3] See the Related GAO Products section later in this statement.

the input these agencies provide to EPA is treated as "deliberative" and is not released to the public. Regarding EPA's ability to manage its IRIS assessments, in 2007 OMB required EPA to terminate five assessments that for the first time addressed acute, rather than chronic, exposure—even though EPA had initiated this type of assessment to help it implement the *Clean Air Act*.

- The changes to the IRIS assessment process that EPA was considering but had not yet issued at the time of our 2008 review would have added to the already unacceptable level of delays in completing IRIS assessments and further limited the credibility of the assessments. For example, the changes would have allowed potentially affected federal agencies to have assessments suspended for up to 18 months to conduct additional research. As we reported in 2008, even one delay can have a domino effect, requiring the assessment process to essentially be repeated to incorporate changing science.

In April 2008, EPA issued a revised IRIS assessment process. As we testified before this subcommittee in May 2008, the new process was largely the same as the draft we had evaluated during our review and did not respond to the recommendations in our March 2008 report. Moreover, some key changes were likely to further exacerbate the credibility and productivity concerns we had identified. For example, EPA's revised process formally defined comments on IRIS assessments from OMB and other federal agencies as "deliberative" and excluded them from the public record. As we have stated, it is critical that input from all parties—particularly agencies that may be directly affected by the outcome of IRIS assessments—be publicly available. In addition, the estimated time frames under the revised process, especially for chemicals of key concern, would have likely perpetuated the cycle of delays to which the majority of ongoing assessments have been subject. Instead of streamlining the process, as we had recommended, EPA institutionalized a process that from the outset was estimated to take six to eight years for some chemicals of key concern that are both widespread and likely to cause cancer or other serious health effects. This was particularly problematic because of the substantial rework often required to take into account changing science and methodologies.

EPA's Latest IRIS Process Reforms Appear Largely Responsive to Our Recommendations, But Their Success Will Depend on Effective Management

Overall, EPA's May 2009 IRIS assessment process reforms represent significant improvements and, if implemented effectively, would be largely responsive to the recommendations made in our March 2008 report.

- First, the new process and the memorandum announcing it indicate that the IRIS assessment process will be entirely managed by EPA, including the interagency consultations (formerly called OMB/interagency reviews). Under EPA's prior process, these two interagency reviews were required and managed by OMB—and EPA was not allowed to proceed with assessments at various stages until OMB notified EPA that it had sufficiently responded to comments from OMB and other agencies. The independence restored to EPA under the new process is critical in ensuring that EPA has the ability to develop transparent, credible IRIS chemical assessments that the agency and other IRIS users, such as State and local environmental agencies, need to develop adequate protections for human health and the environment.
- Second, the new process addresses a key transparency concern highlighted in our 2008 report and testimonies. As we recommended, it expressly requires that all written comments on draft IRIS assessments provided during the interagency consultation process by other federal agencies and White House offices be part of the public record.
- Third, the new process streamlines the previous one by consolidating and eliminating some steps. Importantly, EPA eliminated the step under which other federal agencies could have IRIS assessments suspended in order to conduct additional research, thus returning to EPA's practice in the 1990s of developing assessments on the basis of the best available science. As we highlighted in our report, as a general rule, requiring that IRIS assessments be based on the best science available at the time of the assessment is a stand-

ard that best supports the goal of completing assessments within reasonable time periods and minimizing the need to conduct significant levels of rework.[4]

- Fourth, as outlined in the EPA Administrator's memorandum announcing the new IRIS process, the President's budget request for fiscal year 2010 includes an additional $5 million and 10 full-time-equivalent staff positions for the IRIS program, which is responsive to our recommendation to assess the level of resources that should be dedicated to the IRIS program in order to meet user needs and maintain a viable IRIS database.

We are encouraged by the efforts EPA has made to adopt most of our recommendations, including those addressing EPA's ability to manage its IRIS assessment process, transparency practices, and streamlining the lengthy IRIS assessment process. The changes outlined above reflect a significant redirection of the IRIS process that, if implemented effectively, can help EPA restore the credibility and increase the productivity of this important program. While these broad reforms provide a sound general framework for conducting IRIS assessments, the manner in which EPA implements the new process will determine whether the agency will be able to overcome its long-standing productivity problems and complete credible and transparent assessments. Specifically, management attention is warranted on certain aspects of the new process that are incomplete or lack clarity.

- EPA's estimated time frames of about two years for standard IRIS assessments—those that are not particularly complex or controversial—do not include the time required to complete two steps that are nonetheless included in the assessment process. As a result, EPA has likely understated the time required to complete an assessment. The steps lacking timeframes—the scientific literature review and the request to the public and other agencies to submit relevant research (the data call-in)—are integral to developing an assessment. In prior IRIS assessment processes, EPA provided timeframes for these steps. Importantly, including the time frames for these steps would likely bring the estimated overall time for completing standard assessments closer to three years. We note that this more realistic timeframe may be problematic because when assessments take longer than two years, they can become subject to substantial delays stemming from the need to redo key analyses to take into account changing science and assessment methodologies.
- While EPA states that some IRIS assessments may take longer because of their complexity, large scientific literature base, or high profile, the agency does not provide any guidance on likely or expected time frames for assessments of these chemicals. This is noteworthy because we found that EPA has not been able to complete assessments of the most important chemicals of concern, such as those likely to cause cancer or other significant health effects. For example, EPA's assessment of dioxin has been ongoing for 18 years. It is critical that EPA establish timeframes to enable the agency to manage complex assessments.
- EPA's new process does not include a discussion of key planning steps. Specifically, it omits important pre-assessment steps included in prior processes—such as a call for nominations of chemicals to be assessed and the establishment of the IRIS agenda, which is list of chemicals that EPA plans to assess. Accordingly, it is not clear whether or when EPA will implement our recommendation that it provide at least two years' notice of planned assessments. Among other things, doing so would give agencies and the public more advance notice of planned assessments and enable external parties with an interest in a given chemical to, for example, complete relevant research before the start of an IRIS assessment.
- Particularly in light of the fact that EPA's estimates for completing assessments are likely understated, we believe that the agency should continue to look for additional opportunities to streamline its process. For example, it is not clear why EPA could not solicit comments from other federal agencies at the same time it sends the initial draft assessment to independent peer reviewers and publishes it in the *Federal Register* for public comment. In addition to reducing overall assessment time frames, this change could enhance transparency. Specifically, by obtaining the first draft of the assessment at the same time as the other federal agencies, the public and peer reviewers could have greater assurance that the draft had not been inappropriately bi-

[4] As also stated in our report, we understand that under exceptional circumstances, it may be appropriate to wait for the results of an important ongoing study, such as a major epidemiological study that will provide new, critical data for an assessment.

ased by policy considerations of these agencies, including ones that may be affected by the assessment's outcome, such as the Departments of Defense and Energy. Some of these agencies and their contractors could, for example, face increased cleanup costs and other legal liabilities if EPA issued an IRIS assessment for a chemical that resulted in a decision to regulate the chemical to protect the public.

- The new assessment process states that "White House offices" will be involved in the interagency consultation process but does not indicate which offices. Given that (1) EPA will be performing the coordinating role that OMB exercised under the prior process and (2) the purpose of these consultations is to obtain scientific feedback, it is unclear whether OMB will continue to be involved in the interagency consultation process.
- EPA has specified in its new assessment process that written comments provided by other federal agencies will become part of the public record. However, it is silent as to the purpose of the consultation meetings and, if applicable, whether EPA plans to document for the public record any significant oral agreements or decisions made at the consultation meetings. In order to ensure transparency and alleviate any concerns of potential bias in the assessments, it will be important for EPA to be clear on these matters.

In addition to addressing these issues, the viability of the IRIS program will depend on effective and sustained management and oversight. Collectively, a number of factors that can impede the progress of IRIS assessments present significant management challenges. These include the following:

- Unlike a number of other EPA programs with statutory deadlines for completing various activities, no enforceable deadlines apply to the IRIS program. We have stated in previous testimonies on the IRIS program that if EPA is not able to effectively maintain this critical program, other approaches, including statutory requirements, may need to be explored. We believe the absence of statutory deadlines may contribute to EPA's failure to complete timely IRIS assessments. For example, assessment schedules can easily be extended—and consistently are. These chronic delays in completing IRIS assessments have detrimental consequences for EPA's ability to develop timely and scientifically sound decisions, policies, and regulations.
- Science and methodologies are constantly changing. Thus, there will always be a tension between assessing the best available science and waiting for more information. IRIS will remain viable only if it returns to its model of using the best science available at the time of its assessments and plans for periodic updates of assessments to identify the need for revisions.
- An overarching factor that affects EPA's ability to complete IRIS assessments in a timely manner is the compounding effect of delays—even one delay can have a domino effect, requiring the process to essentially be repeated to incorporate changing science. For example, delays often require repeating reviews of the scientific literature on a chemical to take into account the time that has passed since the literature review was completed; this, in turn, may require detailed analyses of any new studies found to be relevant.
- Long-standing difficulties in completing assessments of chemicals of key concern—those that are both widespread and likely to cause significant health issues—stem in part from challenges by external parties, including those that may be impacted by EPA regulation of chemicals should an assessment lead to such action. Such challenges are to be expected and can be best addressed by EPA's focusing on the best available science, credible expert review, and completing the assessments.
- The IRIS assessment process has been frequently changed in recent years; IRIS process reforms, such as those recently issued, are not established in a regulation or statute and thus can easily be altered. As we have reported, EPA's continual changes present a challenge to the chemical managers who are undertaking the assessments, particularly in the absence of current operating procedures to guide chemical managers on basic procedures and program management responsibilities for the development, review, and finalization of IRIS assessments.

In conclusion, EPA's most recent changes to the IRIS assessment process appear to represent a significant improvement over the process put in place in 2008. That is, if implemented effectively, the changes may appropriately restore to EPA its control of the IRIS process, increase the transparency of the process, and streamline aspects of the process, among other things. We believe that the agency's ability to

produce timely, credible, and transparent assessments will also depend in large measure on clear implementation procedures and rigorous management oversight, given the numerous factors that can impede EPA's ability to complete timely IRIS assessments and the lack of clarity on some aspects of the new process. Perhaps most importantly, EPA needs to hold itself more accountable to the public and Congress for carrying out this important component of its mission, especially since the IRIS program is discretionary.

Mr. Chairman, this concludes my prepared statement. I would be happy to respond to any questions that you or other Members of the Subcommittee may have at this time.

GAO Staff Acknowledgments

Contributors to this testimony include Christine Fishkin (Assistant Director), Laura Gatz, Richard P. Johnson, Summer Lingard, Nancy Crothers, Antoinette Capaccio, and Carol Kolarik.

Related GAO Products

Scientific Integrity: EPA's Efforts to Enhance the Credibility and Transparency of Its Scientific Processes. GAO–09–773T. Washington, D.C.: June 9, 2009.

High-Risk Series, An Update. GAO–09–271. Washington, D.C.: January 2009.

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BIOGRAPHY FOR JOHN B. STEPHENSON

Mr. Stephenson is currently the Director of Natural Resource and Environment issues for the U.S. Government Accountability Office—the independent investigative arm of the Congress. In that capacity, he has for the past nine years directed numerous studies and research projects, issued hundreds of reports, and testified on many occasions before several Senate and House Committees. His work has provided invaluable assistance to the Congress in its oversight and legislative role on diverse environmental protection issues such as clean air, clean water, safe drinking water, chemical controls, toxic substances, climate change, superfund, and hazardous materials spill prevention and cleanup, as well as critical infrastructure protection.

Prior to his current position, he led numerous GAO studies and investigation in the information technology and federal acquisition and federal grant areas. He has extensive experience in dealing with Congressional Committees and Members, federal agencies, trade associations, special interest groups, and State and local governments. From April 1998–February 2000, he was Deputy Staff Director for the Senate Special Committee on the Year 2000 Technology Problem for the Chairman (Senator Robert Bennett, R–UT), and Vice Chairman (Senator Christopher Dodd, D–CT). In that capacity, he ran the day-to-day operations of the Committee including orchestrating over 35 hearings, preparing legislation, organizing briefings and Floor activities for the Full Senate, working with the White House's Year 2000 Director and staff, and organizing numerous press and public events. He returned to GAO in March 2000 where he was Executive Assistant to the U.S. Comptroller General (the head of GAO) until entering the Senior Executive Service in October 2000.

Mr. Stephenson holds a BS degree in Industrial Management from Purdue University, an MBA from Xavier University, and is a graduate of the Harvard Kennedy School of Government's Senior Executive Fellows program. He lives in Fairfax Station, Virginia with his wife, 11-year-old daughter, and 9-year-old son. He also has two grown sons who reside in Cincinnati, Ohio.

DISCUSSION

Chair MILLER. Thank you, Mr. Stephenson.

We will now begin our first round of questions, and I now recognize myself for five minutes.

ENSURING EPA'S PROGRAM CONTROL

Mr. Stephenson, I want to talk about control of IRIS by EPA. IRIS, as Dr. Broun pointed out in his opening statement, has always provided for control, at least according to the statute, stated control by EPA. But in the last eight years certainly EPA's control was very much eroded by pressures from other agencies, that although the IRIS listing has no regulatory affect, it is a precursor to regulation. And there were agencies that liked using chemicals without restrictions and didn't want to have to mess with the risk management issues. So it was easy to stymie a risk assessment through IRIS and not have to worry about it.

And there were officials at OMB who seemed to be more than happy to help them in that effort at OIRA. Whether it was the other agencies or the manufacturers of the chemicals or simply an anti-regulatory zeal, OIRA was more than happy to block it.

Mr. Stephenson, in light of all that history, how can we be sure? Should we continue to worry that EPA will not, in effect, be in control, even though it may, according to the stated procedures, be in control?

Mr. STEPHENSON. A multi-faceted question. OMB does serve a purpose in facilitating interagency comments. There is no question. The problem with the old process was that all of those comments were declared delivered evidence, so there was no honest broker, if you will, as to what comments were being provided and when. So we think the fact that this process allows for complete transparency and all of those comments, which are supposed to be comments on the scientific integrity of the assessment, be made public. So that is huge.

Having said that, you know, EPA like every other agency works for the White House, and OMB is an office of the White House, and so the proof is going to be in the pudding as to how much influence OMB may or may not have in this current process. And now with you asking us to do so, we are going to be watching that closely.

Chair MILLER. Are there things for us to watch for? Are there going to be early indicators that will tell us that EPA is truly in charge or only nominally in charge, and it is still being run out of OIRA or by the White House?

Mr. STEPHENSON. Well, the only thing you can really do is track individual assessments through the process, and see what kind of comments are made and by whom and what the reaction is to those comments. Interestingly, in the old OMB, while it is true they said that EPA was in charge, if you talked to OIRA, if you talked to the other part of OMB, they would—who did the part reviews if you are familiar with those, they clearly said that OMB was in charge. So even within OMB it was unclear who was in charge of that IRIS process.

THE EFFECT OF AN IRIS LISTING

Chair MILLER. Mr. Stephenson, the opening statements kind of raised the question of whether there should be more process, more procedures, more of a chance to challenge EPA, that EPA should not be the final decider, should not make the final decision on IRIS listings. But do IRIS listings have any regulatory effect? Is there anything that anybody cannot do or has to do because of the way a chemical is listed in IRIS?

Mr. STEPHENSON. No. You correctly mentioned that it is a precursor to deciding how to control dangerous chemicals, if you need to at all, and so we view it as a purely scientific process that shouldn't be meddled—you shouldn't be mixed with science policy, which also has a legitimate role.

Chair MILLER. Well, if there is a regulatory effort after the—after an IRIS listing to manage the—a risk that IRIS, an IRIS listing identifies, does—how is the science treated there? Are all the same issues revisited in the regulatory process?

Mr. STEPHENSON. Well, sure. I mean, you have an opportunity to question the relevance of the science for a given regulation, but each one is a case-by-case issue. The beauty of IRIS is that it is the official agency position on a given chemical, and therefore, the starting point to decide where you want to go from there. It doesn't mean anything about regulation purely.

Chair MILLER. But if the formaldehyde industry, for instance, wanted to argue that formaldehyde is actually good for you, they could do that in the regulatory process for risk management regulations. Is that correct?

Mr. STEPHENSON. Well, I would think they would do it in both places; in the IRIS process as well as the regulatory process.

Chair MILLER. My time has expired.

I now recognize Dr. Broun for five minutes.

Mr. BROUN. Thank you, Mr. Chair.

HOW IRIS ASSESSMENTS ARE USED

Just to go along with what Chair Miller was just talking about, Mr. Stephenson, it is my understanding that a lot of private sector stakeholders are basically using IRIS assessments as a de facto regulatory statement. Is this true?

Mr. STEPHENSON. I have no way of knowing that.

Mr. BROUN. Okay. What part in IRIS's process should outside stakeholders play?

Mr. STEPHENSON. If they have—remember, IRIS is supposed to be a collection and a synthesis of existing research that is available at the time the assessment is—begins, essentially, and so there are good researchers and scientists throughout industry, throughout the other federal agencies, throughout academia. All of those people are allowed to contribute to an individual assessment once they see the draft assessment and it goes out for public comment. And all of those comments can be seen by the public and vetted by other scientists, and everyone in this process seemingly can see how EPA dispenses with each of those comments.

TRANSPARENCY PROCESS

Mr. BROUN. Chair Miller referred to me as Dr. Broun. I am a physician. There are some on this whole committee that would argue that I am not a scientist, but I am. There are some research scientists that would argue that, but I am an applied scientist, and I believe in the scientific process and believe in peer review and lots of it. The more peer review that enters into the process, the greater I think we have in scientific integrity.

When I graduated from medical school, the things I was being taught at that time, to be absolutely factual, have subsequently been shown to not be factual, and I think we have a lot of things going on in public policy today such as climate change caused by human effects on the climate are part of that, but it is kind of—I don't want to go off on that tangent, but to get back to IRIS, so is—I am just real concerned that there is not enough transparency, Mr. Stephenson.

You talked about the transparency, but is all the discussion within the agency or within anybody who has comments on the assessments being done, is all of that available for public peer review?

Mr. STEPHENSON. It is supposed to be.

Mr. BROUN. Everything?

Mr. STEPHENSON. We hope so. Like you say, it is a scientific process, and we would hope all of that is very public and vetted in the public.

Mr. BROUN. How about the oral arguments, interagency oral arguments, any consultation meetings, things like that? Will all of those things be available for public peer review?

Mr. STEPHENSON. We don't know, but that is why we say more clarification is needed in those consultation steps within the process, and if there are any decisions made, our recommendation would be that they be made public. But EPA may have a better clarification on that.

Mr. BROUN. Doctor?

Dr. TEICHMAN. It is certainly our intention to make sure that all the written comments are put in the public docket, but we also know that there is sometimes discussions that go on orally. We would hope in those discussions, and what we have tried to do since we will be controlling the process, is to encourage people to provide the important points even in those oral discussions in writing so they are made open and transparent to the public. And that is just within the interagency discussion steps at 3, Step 3 and Step 6A in your chart number three, Mr. Chair, if I remember correctly.

I think it is also important to note that when there are disagreements potentially between agencies, which can occur, that that is when it is a good time, in fact, to turn to peer review, Mr. Broun, just as you have identified. And so it is the consultations both inside of the Agency where we may have some scientific disagreements on a draft assessment, as well as when we had the interagency discussions, that those become, in fact, very good charge questions to the peer review panel for them to opine on to inform us in the federal system.

Mr. BROUN. Well, I hope that you can assure this committee that all opinions, particularly dissentive views, within any oral discussion, consultation is available for public preview, because I think it is absolutely critical for scientific integrity, first thing. Secondly is to guarantee that there is a correct peer review process and that there is not a quashing of opposing views by any entity, whether it is an agency or an individual scientist, what have you. I think it is absolutely critical for the health of this country and its science that those things—so please assure this committee that that is going to be the policy at EPA.

Dr. TEICHMAN. It is certainly something as I think Mr. Stephenson has mentioned that is a bit vague in the process as identified and something that requires further discussion and clarification to be more precise. So I would prefer to have that discussion before I assure this committee at this particular time. But it is something we will certainly have discussion about.

If I may for just a brief moment, however, I want to make sure we are distinguishing sometimes between those comments that are scientific in nature and those that may be policy in nature, because it is, indeed, we hope with our IRIS process to really focus on the scientific comments, because, indeed, our IRIS assessments are not regulatory.

And if I may draw attention actually to a report by the bipartisan policy center that you may be familiar with since it is co-chaired by Sherwood Boehlert, a friend, I believe, of this committee in the past, okay, and has esteemed Members on it such as Lynn Goldman and John Graham from, therefore, across the political spectrum.

Chair MILLER. I think the screen is actually obscuring the portrait of Mr. Boehlert.

Dr. TEICHMAN. That I can't see. I apologize. But, anyway, I did want to make it clear that, indeed, your—the comments about scientific disagreements we certainly want to make sure are aired, but we want to distinguish those from policy ramifications. These are the recommendations, in fact, from Sherwood Boehlert's bipartisan committee:

> "Distinguishing between science and policy is not always easy or straightforward, and scientists must make choices based on values in the course of their work. Nonetheless, policy debate would be clarified and enhanced if a systematic effort were made to distinguish between questions that can be resolved through scientific judgments and those involved judgments about values and other matters of policy."

So what we are trying to do here is to keep the focus on the scientific arguments that are the basis for the conclusions drawn in our IRIS assessments, and it is later in subsequent steps when regulations occur that the policy ramifications can be debated as well.

Mr. BROUN. Well, thank you, Doctor. My time is long up, and the Chair——

Dr. TEICHMAN. I apologize.

Mr. BROUN.—has been very long suffering, but I just want to make one statement from a—Mr. Chair. Policy makes a difference, too, and it needs to be transparent, and we need to make abso-

lutely certain that any discussion, policy or scientific, I think is available for the public.

Thank you, Mr. Chair.

Chair MILLER. Thank you, Mr.—Dr. Broun.

I now recognize Ms. Dahlkemper for five minutes.

Ms. DAHLKEMPER. Thank you, Mr. Chair, and I want to thank you and the Ranking Member for bringing forward this important hearing and thank the witnesses for joining us today.

PROGRAM SCHEDULE AND PRODUCTIVITY

I want to talk a little bit about the productivity side of things, and as we are looking at your new process here, you have certain durations, Dr. Teichman, on there, and I want to ask you about how EPA will guarantee that these dates are met. Obviously, it is a good, aggressive schedule, I believe, but how are you going to make sure that these dates are met with the different processes?

Dr. TEICHMAN. We are going to do our absolute best. In terms of a guarantee, I cannot promise that every assessment will last only 23 months. There will, indeed, be situations, and we hope they are few and far between, and indeed, this is stated in the Administrator's testimony as well that she gave two days ago on the other side of the Hill, if you will, that most assessments we expect to try and stick to the 23 months.

I have worked for the Administrator now for five months. I can tell you she is a very intelligent, very aggressive individual who keeps us on our toes and does everything she can to support our efforts.

In that regard you also should hopefully take some solace in the fact that the policy was discussed. I was certainly not in the room, as it was, but among the Administrator and her staff and officials within OMB, and I don't know, other agencies, perhaps, too, and it was agreement across the board on this particular process. So I believe there will be other agencies who will be held to task as we try and hold to the schedule to commitments that they made to the Administrator in those initial negotiations.

Ms. DAHLKEMPER. Mr. Stephenson, do you have any comments on this in terms of how you think this could be achieved?

Mr. STEPHENSON. We have already mentioned that some of the early steps are missing, so you are already behind the eight ball on the 23 months. Most importantly it is mentioned on the chart here that you are going to do a comprehensive literature search and data call, which will be in the notice, so there is a process that has to be followed to do that, which will take some time.

In addition, our recommendation from 2008, about the importance of a two-year planning window is critical here so that the whole research community, well in advance, will know which chemicals are going to be assessed two years down the road and can put together any research they deem appropriate before the process actually starts. That will completely avoid, you know, the development of research as the particular chemical is being assessed and make the whole process more efficient.

We think this is really ambitious, but we are going to be watching.

POTENTIAL IMPROVEMENTS

Ms. DAHLKEMPER. Also, as you were speaking, Mr. Stephenson, you were mentioning different—about five or six different improvements that you would like to see, and I guess I want to ask you, Dr. Teichman, about that, you know, about his, Mr. Stephenson's testimony on that.

Mr. STEPHENSON. Well, some of them were just clarifications but yes.

Dr. TEICHMAN. Well, some were clarifications and some I have written down. I am not sure I have got them all correctly written, but I will state that as, hopefully, and I think I can—if I parrot back correctly, the statement of my co-witness here, that if managed effectively, the new EPA process for IRIS would be considered very responsive to the GAO recommendations of the past.

Therefore, we are trying to demonstrate a commitment to seriously consider what GAO tells, and we will consider the recommendations that the co-witness has asked. We would like to have a chance to try the process as it has been agreed to, and I think Mr. Stephenson has said it is worth a try, but we need to take a look and see how we progress. I know the Chair has asked GAO in a year to report back, and I think we are anxious to follow that particular path. But we will still, nonetheless, consider certainly for clarification, the recommendations from GAO and even some of the potential changes if, indeed, they enhance the process in our estimation as well.

Ms. DAHLKEMPER. I thank you, and I yield back.

Chair MILLER. Thank you, and I now recognize myself for a second round of questions.

My—we will be called for votes in maybe 20 minutes, half an hour, and my intention will be just to have questions probably until that time and then that will be the end of our hearing when we get called for votes.

DELIBERATIVE PROCESS

Dr. Teichman, there were questions about written, everything written is going to be available. There is no assertion that it is deliberative. We all get to see it. Congress sees it, the American people sees it. It is public.

Dr. Broun asked questions about oral discussions, telephone conversations, conversations at a water cooler, whatever, meetings. And to the extent that they produce in writing, that will then—the writing will be available. There is—it is probably not reasonable to expect that everything will be transcribed, but in the past when we have asked, specifically Ms. Dudley, about who was involved in what conversations and what conversations there were and what was said, she asserted a deliberative process privilege, which I read the cases that discuss deliberative process privilege, it is a very light privilege. It is basically—it protects anything—discussions—if the only reason that Congress or a court is asking for it is out of idle curiosity, but if there is any real need for it at all, that it should be available.

It—my understanding is the Administration does not—EPA now does not assert a deliberative process privilege for any oral con-

versations. So if Congress calls upon people involved in the decision to tell us who was in the discussion, what they had to say, that that would be—those would be questions that you would answer as well as you could remember them. Is that correct?

Dr. TEICHMAN. I am not a lawyer, but that is certainly my interpretation as well.

THE GAO HIGH-RISK LIST

Chair MILLER. Okay. All right. I think Ms. Dahlkemper asked around the high-risk list or came close to it. Mr. Stephenson, I assume that being on the GAO's high-risk list is something that a Federal Government agency would regard about the same way a bank would regard being on the FDIC's watch list. It is not a favorite place to be.

How long do you expect it would take IRIS to kind of earn their way off that list?

Mr. STEPHENSON. The high-risk designation is not only designated to IRIS, it has to do with TOSCA reform as well.

Chair MILLER. Uh-huh.

Mr. STEPHENSON. So we need to wait and see proof that the problems that we have observed have been addressed, and there is no, you know, it is not—it is fairly subjective. It is up to GAO when we decide to add or remove things from that risk. It doesn't carry any designation other than the fact that we hope that the Agency and the Administration will devote greater attention to it, and the Congress for that matter. That is why we do it.

So to get on that list we are very, very, very concerned. We are a conservative agency, and it doesn't get put on that list lightly. There were only three new additions to the list this year, and this was one of them.

Chair MILLER. Dr. Teichman, I assume it is a high priority to get off that list?

Dr. TEICHMAN. Most certainly, sir.

ROYAL DEMOLITION EXPLOSIVE

Chair MILLER. Okay. Thank you. Mr. Stephenson, you examined in the GAO report last year the IRIS process specifically for a chemical called Royal Demolition Explosive or RDX. What is the status of that?

Mr. STEPHENSON. We haven't done any specific work on that. It was one of the chemicals we highlighted to illustrate how broken the process was and how long it was taking. I believe it had been in assessment over a decade. In updating for this hearing we noticed that it had been removed from EPA's list of chemicals undergoing assessment, and we haven't been able to follow up onto exactly why that happened. It was on there a month ago and removed as of a day ago.

Chair MILLER. Dr. Teichman, do you know why RDX has gone missing?

Dr. TEICHMAN. I can tell you what response I got when I posed that same question to the staff. Nonetheless, I would prefer to give a full response to a question for the record on where the chemical managers involved would be able to comment on the decision proc-

ess that is involved with that particular chemical. But it was, indeed, listed for possible assessment under the IRIS Program, but we have identified 48 assessments that we think are priority chemicals, and in the second batch an additional 48. RDX is in the second batch, so I would prefer, again, for a question for the record to give the decision process as to why it is in the second batch.

Chair MILLER. If you would submit it on the record.

Mr. Whittaker, in a show of bipartisanship would you like to—would you raise the screen so we can all see the portrait of Mr. Boehlert?

I now yield back the remaining 10 seconds of my time and recognize Dr. Broun for another round of questions.

ASSESSMENT TIMELINESS

Mr. BROUN. Thank you, Mr. Chair. I understand there is a natural tension between fairness and timeliness with assessments. The question is, will this streamlined process ultimately sacrifice scientific credibility, especially considering the recent negative reviews of the assessments by the National Academy of Science? And the question I have really for both of you is, if EPA can't get the assessment right in 10 years, what makes you think, each one of you, that you can produce better results in 23 months?

Mr. STEPHENSON. I mean, we are going to—we think 23 months is optimistic. We are going to be looking, but the problem is it is like a domino effect. If the assessment takes too long, there is new research that becomes available. You have to reconsider, and it goes back to square one again. That is what I meant about the endless assessment and reassessment. This is supposed to be a process that synthesizes existing research that is available at the time and should be able to be done fairly quickly and vetted. These assessments are supposed to be updated routinely, you know, every 10 years. So with 540 chemicals on the list, if you are not doing at least 54 a year, you are not even keeping up.

So we think this is very ambitious. We are not sure there is enough resources devoted to this yet, but that is a very good question.

Dr. TEICHMAN. It is a very ambitious goal.

Mr. STEPHENSON. It is an ambitious goal. I don't disagree, and we have certainly asked for additional resources to help us meet that goal in the President's budget request. There are a couple of things I think, though, that are different than perhaps the past as we look at the new process.

The first is this new process as I mentioned earlier was developed in consultation with other federal agencies, and therefore, I believe there is a mutual commitment to try and meet the schedule that has been identified. This does not mean that it isn't aggressive and that we shouldn't take a look and see in a year's time if we have been able to stick to it. We welcome that type of a review and hope to be able to successfully demonstrate we were able to meet that goal of 23 months.

Second is the listening sessions that I referred to earlier are still maintained in this process. This is a chance where the external peer review meeting that—where there used to be an opportunity for somebody to speak for two or three minutes or perhaps as many

as five or seven minutes, no longer than I was able to testify today, I would add, most likely, that that was perhaps insufficient time for real discussion and exchange. The listening sessions actually now are for much longer periods of time, more interchanged with those who have any opinions they wish about our draft assessments, and that listening session is, indeed, also shared with the external peer review panel and their assessment.

So I believe that is a very positive step that will hopefully enable us to air for greater, longer periods of time potential disagreements in the scientific facts and let the external peer review panel tell us their position on those arguments.

Mr. BROUN. Has the timeframe for peer review changed at all?

Dr. TEICHMAN. I believe the time period is 60 days at this point. I think it might have been a little longer. I have to check. I apologize.

Mr. STEPHENSON. I got it at 105 days.

Mr. BROUN. Mr. Chair, I am not real interested in a lot of conversations that go around the water fountain, but those conversations that do have to do with scientific integrity as well as the scientific process I think are very important, and I hope that we can, as a committee be reassured that those conversations will be reported and will be open and for public view. And it is just something that I think is absolutely critical for scientific integrity, and I just want—I just throw that out as a comment to both of you all.

And with that I will yield back to the Chair for the next round, if we have one.

Chair MILLER. Thank you. Just one more brief round.

I do want to point out that when we raised the screen to reveal the portrait of Mr. Boehlert, we also revealed the portrait of a substantially slimmer Chair Sensenbrenner, which is perhaps more bipartisan than I really intended to be.

PEER REVIEWS

Dr. Teichman, Step 4 of the new process is an independent expert peer review, which Dr. Broun has been asking about already, and our staff understands that that will usually be done on a face-to-face basis, meetings, and perhaps that could be transcribed or—but in some cases it will also be done by the National Academy of Sciences. We understand that peer review can be done by mail, it can be done through the Internet, it can be done face to face, it can be done through an Academy of Sciences study.

Can you give us a sense of what each of those different methods for peer review will cost and how you will decide which method?

Dr. TEICHMAN. First of all, let me since I was under oath correct the statement I said before about 60 days indeed as my co-witness has said it. Now that I have it in front of me, it is 105. I was confusing with a different step.

In terms of the cost for each of the individual types of peer reviews, I would like to provide that as information for the record. However, it is important to state that we very carefully consider the complexity of a given assessment as to which form of peer review that we would use. To use a letter if you want an IRIS assessment would be very rare. At the other end of the spectrum to go the National Academy of Sciences, which we have done, one of the

most controversial chemicals, is hopefully equally rare. More times than not we will convene a peer review panel, which would have a face-to-face meeting that might be the contractor choosing the panelists, or it might be our own science advisory board.

And the cost for those four different options we will be glad to provide, but certainly they vary as from the letter review to the NAS, based on the complexity of the assessment.

Chair MILLER. Can you, Dr. Teichman, can you tell us who some of the contractors are who have been contracted with—that EPA contracted with to conduct the peer review?

Dr. TEICHMAN. I am only familiar with one and any mention is not considered an endorsement, but nonetheless, I think the Eastern Research Group has been one of the organizations that our National Center for Environmental Assessment has used to locate peer reviewers and pull together such panels.

Chair MILLER. What procedures do you have in place to make sure that there are no conflicts of interest with forums conducting the peer review process?

Dr. TEICHMAN. The firms themselves, again, I would prefer to have a better chance to put this in the record than I will be able to convey right now, but if you are talking about the choice of the firms, those are competed, and I don't know what confidentiality or impartiality statements they may have to be to be a successful bidder on the contract.

However, the people who they hire as subcontractors, as panelists there, there are, indeed, statements that have to be provided where people state what their potential associations are, and they demonstrate that they are impartial.

Chair MILLER. Mr. Stephenson, are you familiar with any work that the GAO has done on outside contractors for peer reviews?

Mr. STEPHENSON. Not specifically contractors but there are two different brands of scientific advisory committees the EPA uses. There is 24 of them in total, and we noted in the testimony in the Senate that seven of those have specific conflict of interest procedures for their membership, but the others do not. And they are—that may not be inappropriate because you are trying to seek points of view on a given chemical or giving a scientific assessment or a given regulation. So we just observe that EPA should not confuse the purpose of both of those two different kinds of scientific advisory committees.

Chair MILLER. Dr. Teichman, it seems that some of the most widely-used chemicals with perhaps the most troubling health consequences are the ones that are tied up for the longest time in—or have been in the past in IRIS: formaldehyde, TCE, Perk, Dioxin. How are you going to set priorities for completing assessments?

Dr. TEICHMAN. Well, indeed, we wish to tackle those chemicals that we think pose the greatest risk to the American public, and those become our priorities. It is not an issue of any particular stakeholder group interest one way or the other, anybody influencing our decision other than we believe it poses a high risk, and those become the chemicals that we go after.

And we believe we do it in a rigorous fashion that everybody has an opportunity to comment and to tell us if we have gotten it right

in our draft and hopefully we have done it correctly by the time we have the final assessment.

Chair MILLER. Okay. Are you going to include others, both interagency suggestions or outside——

Dr. TEICHMAN. We take suggestions from everybody as we publish our list of potential chemicals we could be working on and others that people wish to recommend, and that includes other federal agencies, it includes State and health organizations. It is a *FR*—a *Federal Register* notice asking for people's thoughts on what our agenda should be.

Chair MILLER. I yield back the remaining three seconds of my time.

Dr. Broun, do you have any more questions?

FAIRNESS AND TIME CONSTRAINTS

Mr. BROUN. Going back to peer review process, Doctor, I am looking at the document actually here, and you were correct the first time, that you are supposed to announce a public comment period of 60 days for peer review, and again, as a physician I am concerned that 60 days, 105 days may or may not be enough, and 23 months may not be enough time to adequately evaluate each of these chemicals.

How can you guarantee—but in the review process how can you guarantee fairness in that IRIS process if you give the public only 60 days to review?

Dr. TEICHMAN. We believe 60 days will be adequate to give the public fair opportunity to comment. We believe the combination of the listening sessions gives them even a chance to interact with us on the draft assessment prior to the external peer review panel coming together. If indeed somebody in a rare instance asks for an extension and indeed the material in front of you discusses that potentiality, we do, indeed, offer such an extension, but we can't promise, in fact, that their comments will be before the peer review committee. And we believe it is best for as many public comments to be shared with the peer review committee as they make their deliberations.

Mr. BROUN. Was the 60-day number just picked somewhat arbitrarily? Did you all just think that that is a good period of time, or was there a particular thought in giving enough time but not too much?

Dr. TEICHMAN. I think that is a fair way of putting it. It was not arbitrary in terms of we plucked it randomly, we plucked it out of midair. We think this is an appropriate amount of time. If it turns out as we have explored this that people feel they must have 90 days, for example, it is something to consider down the road.

MORE ON THE TRANSPARENCY PROCESS

Mr. BROUN. All right. Thank you, sir. Back to the transparency, will you commit to truly making the IRIS process transparent by creating a public docket for all materials received at EPA related to each IRIS assessment, including materials that EPA has received but which it decides will not, it will not allow them to make its assessment decisions?

Dr. TEICHMAN. Yes, indeed. All comments that we receive in the written form as we have discussed will be in the public docket. We always include all the information that has been given to us, whether or not it is what we use in our final assessment, so that people see the total record, and they can choose from among it as to what they think should be influencing our final word.

Mr. BROUN. So that it is a promise to us that that will be done, and I hope you can promise us at some point that all those oral discussions and those conversations and consultations that do occur orally will be provided for the public also.

With that, Mr. Chair, I yield back.

Dr. TEICHMAN. May I just comment for a moment, Mr. Chair, if I can?

Chair MILLER. Dr. Teichman.

Dr. TEICHMAN. Again, we will be—the oral comments I wish to come back to the Agency and have further discussion on. On the written, I am not aware that we have never or that we have ever not put every written comment that we got from the public or as part of the peer review in the docket. What is interesting and new in this process is, in fact, now the written comments we get from other agencies will also be in the public docket.

CLOSING

Chair MILLER. I think we are now done with our questions.

There is a phrase I have heard all my life, which I suspect is a southern phrase. I am sure Dr. Broun has heard it as well then. When we want to disassociate ourselves from someone else, not take full responsibility for the conduct and other, we say, "I didn't take him to raise."

But it appears that I have taken IRIS to raise, this subcommittee has taken IRIS to raise, GAO has taken IRIS to raise. So we will continue to close—to watch IRIS closely. We think it is important that IRIS perform its mission and produce the right number of very sound, credible, scientifically-sound, credible assessments.

Mr. BROUN. Mr. Chair, would you yield?

Chair MILLER. Mr.—Dr. Broun.

Mr. BROUN. Thank you for yielding, sir. I am very happy you have taken IRIS to raise and that we are having this hearing and that you are continuing this process because I think it is absolutely critical for the public to have total confidence in what assessments are made by IRIS and by the government across the board.

I think there are many things that are being put out by the government that are declared scientific that aren't, and it does not—things in the way of determinations that aren't accepted by the public, and I think rightfully so. And so I am glad you have taken IRIS to raise, sir, and I am eager to continue in this process with you, so I thank you very much, and I congratulate you on taking IRIS to raise.

Chair MILLER. Thank you, Dr. Broun. We may not think alike, but we do talk alike.

Before we bring the hearing to a close I want to thank our witnesses today for testifying before the Committee. We may see you again.

Under the rules of the Committee the record will remain open for two weeks for additional statements from the Members and for any answers to any follow-up questions the Committee may have for the witnesses. Dr. Teichman, you had said you wanted to provide additional information.

And with that the witnesses are excused, and the hearing is now adjourned.

[Whereupon, at 2:15 p.m., the Subcommittee was adjourned.]

Appendix 1:

Answers to Post-Hearing Questions

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ANSWERS TO POST-HEARING QUESTIONS

Responses by Kevin Teichman, Deputy Assistant Administrator for Science, Office of Research and Development (ORD), U.S. Environmental Protection Agency (EPA)

Questions submitted by Chairman Brad Miller

Q1. During the hearing, we discussed the status of the chemical called Royal Demolition Explosive (RDX), in the IRIS process. Please explain the decision process and process for removal of RDX from EPA's list of chemicals undergoing IRIS assessment.

A1. There are over 80 assessments in progress in the IRIS program, all at various stages of development.

EPA made a decision to focus its resources on those assessments that were farthest along in the process and work as quickly as possible to finish up that first set and then turn its attention to the second set of chemicals/substances. The first set consisted of 48 assessments. Each of those 48 was at the internal Agency review step or further in the process. As assessments are completed and staff are available to work on the next set of assessments, focus will shift to the approximately 40 other assessments on the IRIS agenda, which will become the priority list for 2010–2011. RDX was one of the assessments where development of the IRIS toxicological review report had not progressed to the point where a draft assessment was in, or ready, for internal Agency review. Thus, RDX will be on the second set of IRIS chemical assessments.

Q2. We also discussed the independent expert peer review step of the new IRIS process. Please clarify the timeframes provided for peer review and the anticipated costs for each method of peer review. Moreover, please explain EPA's plan for mitigating conflicts of interest during the peer review process.

A2. Part 1—Types of Reviews:

Timeframes for IRIS Peer Reviews

The timeframe provided in the new IRIS process provides for a 105-day peer review process. We are working on processes to be put into place for peer reviews conducted through a contractor convened peer review panel and the EPA's Science Advisory Board (SAB) peer review panel to meet that timeframe. We will also work with the National Academy of Sciences (NAS) to determine if they would be able to meet the 105-day timeframe. We recognize that, on occasion, there will be particularly complex assessments that may take longer than 105 days.

Costs for IRIS Peer Reviews

Letter Review: All independent external peer reviews for IRIS draft assessments are conducted at public meetings. *Thus, letter reviews are not used for external peer review of draft IRIS human health assessments.*

Contractor-Convened Panel: Extramural cost for these types of peer reviews range from $35,000 to $70,000. Cost depends on the complexity of the assessment, which determines the number of different types of expertise needed, the number reviewers required, the number of days scheduled for the public review meeting, and the cost of the meeting venue. The staff time required is around 80 hours on average. This includes four staff attending the day(s)-long panel meeting and preparing materials for presentation at the meeting. The rest of the staff time is spent by the work assignment manager, project officer, and contracting officer writing and approving Statements of Work, working out the details of the date and location of the meeting, making sure the panel members have the needed range of expertise, etc.

Estimates:

Extramural costs: $35,000 to $70,000

Intramural costs: $5,000 to $7,000

Science Advisory Board (SAB) (chartered under Federal Advisory Committee Act [FACA]): The estimated cost of a standard peer review by the Agency's SAB is $200,000 to $250,000. The cost includes: contractor support, travel, Special Government Employee (SGE) salary, plus EPA FTE cost in the office of the SAB, Designated Federal Official (DFO), management, and personnel staff. This does not, however, include EPA scientist(s) or management staff time in the office requesting SAB's review of the draft assessment. The staff time required is around 80 hours

on average. This includes four staff attending the day(s)-long panel meeting and preparing materials for presentation at the meeting.

Estimates:

SAB's costs: $200,000 to $250,000

Requesting office intramural costs: $5,000 to $7,000

National Academy of Sciences/National Research Council (NAS/NRC): External peer review by the NAS/NRC is estimated to cost $800,000–1,000,000. This does not, however, include EPA scientist(s) or management staff time in the EPA office requesting NAS's review of the draft assessment. The staff time required is difficult to estimate because often times the NAS has multiple meetings; however, an estimate may be 120 hours on average.

Estimates:

Extramural costs: $800,000 to $1,000,000

Intramural costs: $8,000 to $10,000

A2. Part 2: EPA's Plan for Mitigating Conflict of Interest (applies to all types of reviews)

Since the Agency's Peer Review Policy was first affirmed in 1994, EPA has made tremendous strides in building a strong and well recognized peer review program. EPA's Science Policy Council has updated and improved the *EPA Peer Review Handbook* including clarifying conflict of interest and impartiality issues. This *Handbook* is used to guide and implement peer review across the Agency, including IRIS peer reviews. A recent report by the EPA Inspector General provided several suggestions for how we can improve our peer review practices. We welcome the opportunity for continuous improvement. EPA's Science Policy Council is updating the *EPA Peer Review Handbook* to clarify the definition of the "appearance of a lack of impartiality." In addition, our Office of Research and Development is updating some of its procedures to enhance its use of peer review.

Q3. Will EPA place all interagency comments in the public record?

A3. On May 21, 2009, EPA Administrator Lisa Jackson announced a new process for health assessment development and review for the IRIS Program. The new process is summarized as follows:

Step 1—document development,

Step 2—internal EPA review,

Step 3—interagency science consultation,

Step 4—external peer review and public comment,

Step 5—document revision,

Step 6A—final internal EPA review,

Step 6B—interagency science discussion, and

Step 7—posting the final assessment on the IRIS database.

The new process affords federal agencies and White House offices three opportunities to comment on science issues in draft IRIS assessments (Steps 3, 4 and 6B). In Step 3, the Interagency Science Consultation, federal agencies and White House offices will be invited to provide written scientific comments on the draft Toxicological Review and draft charge to external peer reviewers before the assessment is released for public review and comment. Also, in Step 4, the External Peer Review and Public Comment, the federal agencies and White House offices may provide written comments on the draft Toxicological Review during the public comment period. All comments received during the announced public comment period automatically become part of the public docket for the assessment. Finally, in Step 6B, the Interagency Science Discussion, federal agencies and White House offices will be invited to provide written scientific comments specifically on EPA's response to external peer review and public comments before the final assessment is posted on IRIS.

As specified in the new IRIS process, all written comments received during the Interagency Science Consultation (Step 3) and the Interagency Science Discussion (Step 6B) will be documented in the public record. This applies to all comments received on or after May 21, 2009. When the draft assessment is released for external peer review and public comment, the following documents will be posted on the docket at *www.regulations.gov* and on the National Center for Environmental Assessment (NCEA) and IRIS web sites:

- *Interagency Science Consultation draft Toxicological Review*

- *Interagency Science Consultation draft external peer review charge*
- *All written comments as received from agencies as part of the Interagency Science Consultation*
- *External Peer Review draft Toxicological Review*
- *Final Charge to External Peer Reviewers*

When the final assessment is posted on the IRIS database, the following documents will be posted on the NCEA and IRIS web sites:

- *Interagency Science Discussion draft Toxicological Review with summary and disposition of external peer review and public comments*
- *Interagency Science Discussion draft IRIS Summary*
- *All written comments as received from federal agencies and White House offices as part of the Interagency Science Discussion*
- *Final Toxicological Review and IRIS Summary.*

Appendix 2:

Additional Material for the Record

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NIPPING IRIS IN THE BUD: SUPPRESSION OF ENVIRONMENTAL SCIENCE BY THE BUSH ADMINISTRATION'S OFFICE OF MANAGEMENT AND BUDGET

A staff report by the Majority Staff of the Subcommittee on Investigations and Oversight
for Subcommittee Chairman Brad Miller
Committee on Science and Technology
U.S. House of Representatives

June 11, 2009

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NIPPING IRIS IN THE BUD: SUPPRESSION OF ENVIRONMENTAL SCIENCE BY THE BUSH ADMINISTRATION'S OFFICE OF MANAGEMENT AND BUDGET

By the end of the Bush Administration, the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) process was broken. What began two decades ago as an initiative at EPA to establish a reliable database on what science said about the risks of particular chemicals devolved by the end of the Bush Administration into a tortured round of interagency bickering, mediated and even stimulated by the Office of Information and Regulatory Affairs (OIRA). As a result of the IRIS process breaking down, public health offices across the country and around the world, as well as concerned citizens, were left without the reliable, expanding, up-to-date database of chemical risks that they had come to rely upon.

The Bush Administration's OIRA used its position at the top of the Executive branch to force EPA to undergo a multi-year, interagency review ostensibly designed to establish a new process for creating new or updated IRIS database entries. At the same time, OIRA both supplied detailed scientific challenges to proposed IRIS entries and coordinated scientific comment from agencies across the government. OIRA's own scientific comments on proposed listings included detailed editorial comments that would have changed the import and meaning of the scientific findings in EPA's documents. All of this was done in secret, without any acknowledgement to the public or the Congress that OIRA was calling the shots.[1] IRIS was broken, not by accident, but through conscious, sustained effort from officials in OIRA.

1. The Subcommittee has carried out extensive work on OIRA's role in relationship to IRIS. In 2008, the Subcommittee held two hearings on this subject. The first of these hearings was on May 21, 2008, when the Subcommittee took testimony from Dr. George Gray, the then-Assistant Administrator for Research and Development at EPA, and Ms. Susan Dudley, the then-Administrator of the Office of Information and Regulatory Affairs (OIRA) at the Office of Management and Budget. Additionally, Mr. John Stephenson of GAO testified on findings regarding the lack of productivity in the IRIS process. In the second hearing, on June 12, 2008, the Subcommittee received testimony from Mr. Jerry Ensminger (U.S.M.C., retired) , Mr. Lenny Seigel (Executive Director, Center for Public Environmental Oversight), and Dr. Linda Greer (Directer of the Health Program at the Natural Resources Defense Council). On June 11, 2008 Chairman Miller sent a document request to OMB asking for all materials relating to OIRA's involvement in the proposed IRIS entry for trichloroethylene (TCE). In response, the Committee received a few boxes of materials. The great majority of those materials were either peer reviewed articles, articles done by EPA staff, or research reports done under contract to industry or polluting agencies. Subcommittee staff were obliged to visit OMB's office to review thousands of pages of documents and take notes because the office refused to provide copies. A clear picture of OIRA's almost daily involvement on TCE emerged from that review. However, OIRA refused to provide access to most documents regarding interagency communications or internal communications surrounding TCE. Because the 110th Congress was drawing to a close, it was not practical to push for a subpoena for these records. We were never shown any document that could have been construed as having Executive Privilege attached to it. OIRA's entire approach appeared to amount to little more than obstruction of the work of the Subcommittee; in a sense, OIRA did to the Subcommittee's investigation what they have perfected in terms of slow-rolling IRIS proposals.

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BACKGROUND

OIRA is a small office of some 50 career staff housed inside the Office of Management and Budget (OMB). With origins in the Paperwork Reduction Act of 1980, OIRA's role has expanded well beyond simply trying to reduce the paperwork burden on citizens and businesses to being the central White House voice, some would say choke-point, on regulations of all varieties. It has been OIRA that has most passionately and persistently insisted on using cost-benefit analysis in assessing proposed regulations, even in the face of criticism that such calculations tend to understate benefits because many of them are so hard to monetize, like the value of a human life.[2] Historically, it has been staffed by statisticians, economists and lawyers. There are real differences between the way OIRA operated under President Bill Clinton and under President George W. Bush, but there is a consistent theme of OIRA being a watchdog on what regulatory agencies were attempting to do to comply with statutes and, on occasion, court orders.

In the 110th Congress, at the direction of Subcommittee Chairman Brad Miller (D-NC), the Subcommittee on Investigations and Oversight looked very carefully at how OIRA was interfering with the science-based work of regulatory agencies. In addition to two hearings on Executive Order 13422, which the Bush Administration put in place to empower OIRA to control regulatory agendas at agencies across the government—an order the Obama Administration has now withdrawn--the Subcommittee held two hearings on the IRIS at EPA. IRIS provided a perfect example of how OIRA was branching out into challenging the science being done at regulatory agencies.

A chemical's entry in the IRIS database is nothing more than a science-based assessment of risks associated with a particular chemical. IRIS entries are produced in the Office of Research and Development (ORD) of EPA, and those entries are not an expression of regulatory intent or advice. The entries are not even all that is required of a complete risk assessment as defined in the seminal National Academies of Science report, *Risk Assessment in the Federal Government: Managing the Process* (1983).[3] And risk assessment is a long step away from a regulatory effort, which is described in the terminology of the panel as "risk management." However, the absence of IRIS entries for widely used, toxic chemicals leaves state and local regulators, first responders, and citizens without crucial information that can guide their response to an emergency or an emerging health or environmental threat.

OIRA has been involved in the IRIS process since the closing years of the Clinton

2 . "Life's Value Shrinks at EPA," Matthew Madia, OMB Watch, July 22, 2008.
3. In that 1983 report, "Risk Assessment in the Federal Government: Managing the Process," the National Research Council panel identified four components of a complete risk assessment: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. IRIS reflects science that addresses the first two conditions. In discussing the difference between risk assessment and risk management, the Academy panel wrote: "Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision." See the discussion on page 3 of the 1983 report.

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Administration. Initially OIRA was pulled into the process to facilitate interagency discussions about particular chemicals proposed for IRIS listings. Agencies that had a record of pollution with certain chemicals were concerned that new IRIS standards would trigger the long march to new regulations and the end result would be that the polluting agencies would have to change their practices and clean up legacy wastes. Those who polluted saw that disputing what scientific research had found about the risks of a particular chemical could become the first line of defense against the distant possibility of regulation.[4] By the late 1990s, OIRA was playing a role as facilitator for interagency discussions regarding particularly contentious proposed IRIS listings.[5]

Suppressing IRIS entries essentially shuts down the flow of coherent, reliable information about what chemicals pose what kinds of risks. Testimony received by the Subcommittee at the second day of hearings on this subject emphasized the important role of IRIS as a public health and safety resource. That hearing, entitled, "Toxic Communities: How EPA's IRIS Program Fails the Public," took testimony from U.S.M.C. (retired) Master Sergeant Jerry Ensminger, the Executive Director of the Center for Public Environmental Oversight, Mr. Lenny Siegel, and Dr. Linda E. Greer, Director for Health Programs at the Natural Resources Defense Council. Mr. Ensminger was particularly compelling in making a case for why polluting agencies such as DOD should not be allowed privileged access to discussions about the science of potential pollutants.

> It is a known fact that the United States Department of Defense is our nation's largest polluter. It is beyond my comprehension why an entity with that type of reputation and who has a vested interest in seeing little to no environmental oversight would be included in the scientific process. Not only are they obstructing science, they are also jeopardizing the public health for millions of people all around the world... and yet this Administration and past Congresses have allowed DOD's tentacles to infiltrate the realm of science.[6]

Mr. Ensminger was stationed at Camp LeJeune. His daughter, Janey, died of acute

4 . This effort by polluters, or those who fear regulation of whatever stripe, of pushing the struggle back to what the science says about a particular risk rather than arguing over how to structure a regulation has been described as "paralysis by analysis." Science lends itself to endless study because there is never an absolute, final answer to any question, but always another layer of research that could add to the body of accumulated knowledge. If those who want to avoid regulation can shift the terms of discussion from the risk management end of the spectrum to the science and what uncertainties remain, a regulatory struggle need never begin. For analysis of how this process has unfolded among regulated industries, see, David Michaels, Doubt Is Their Product: How Industry's Assault on Science Threatens Your Health, Oxford University Press, New York, 2008.

5 . A new report from the Center for Progressive Reform has some of this history. The Subcommittee was also able to review records from 1998 when OIRA first began to push into the interagency struggles over characterizing risks to former marines and their families from TCE and other chemicals at Camp LeJeune. At that time, OIRA's interest was more in the costs of the studies and making sure the then-proposed survey study met OIRA quality standards. OIRA reviews all survey instruments as part of its authority under the Paperwork Reduction Act of 1980.

6. "Toxic Communities: How EPA's IRIS Program Fails the Public," Hearing before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, June 12, 2008, p. 132.

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lymposytic leukemia. Water at the Camp was contaminated with trichloroethylene (TCE) and perchlorate (perc) and these chemicals, as well as other volatile organic compounds in the water system at the Camp, may have caused Janey's condition. DOD has been working for many years to block new IRIS standards on TCE and perc.

In the Bush Administration, OIRA's involvement changed in scope and kind. John Graham, the first director of OIRA, brought in technical specialists—including toxicologists—to tend to science-based discussions of proposed environmental regulations, guidance and IRIS entries. Graham also oversaw a complete overhaul—some might describe it as an endless evolution—of the review and approval process for IRIS proposals. This report will describe that tumultuous review process, how it impacted EPA's productivity and independence, and the true nature of OIRA's role in the interagency review process.[7]

OIRA DOES SCIENCE

Before turning to how the IRIS process was subjected to ongoing interagency negotiations, it is worth examining the day-to-day reality of working on IRIS entries. OIRA has always claimed to Congress and the public that its sole function was as a facilitator of interagency science discussions. John Graham's successor at OIRA, Susan Dudley, described OIRA's role in language that might have applied during the late-Clinton years. An exchange Ms. Dudley had with Subcommittee Chairman Miller in testimony before the Subcommittee on May 21, 2008 is worth quoting at length:

> Chairman Miller. Ms. Dudley, do you think it is part of the role of OMB... to review scientific assessments prepared by other agencies of government?
>
> Ms. Dudley. OMB serves a coordinating function. We coordinate interagency review of various things, so OMB's role I think is a legitimate role. We have scientists that engage other scientists throughout the Federal Government in reviewing IRIS assessments.
>
> Chairman Miller. Well, I understand that there is one toxicologist that works for OIRA, is that correct?
>
> Ms. Dudley. You know, I am not sure exactly their credentials. We have toxicologists, risk assessors, statisticians.
>
> Chairman Miller. Well, they are remarkably productive, because they respond point by point in great detail at great length to the assessments that come up from the scientific agencies of government. Is that all done in-house or are there others who are invited to participate in OIRA's work or OMB's work?

7 . Rebecca Clarren, "The EPA's Stalin Era," Salon.com, November 11, 2008. This article has a succinct discussion of how IRIS entries, or the lack of them, impacts communities facing pollution problems.

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> Ms. Dudley. No, it is certainly an interagency effort. So OMB doesn't provide the—we don't do the analysis, we coordinate it with other agencies. So we take advantage of the expertise throughout the Federal Government.[8]

Later in that same hearing:

> Ms. Dudley. We talk to other federal scientists. Our role is coordinating the scientific dialogue between scientists within the Federal Government.[9]

George Gray, then the EPA Assistant Administrator for ORD, helpfully confirmed this version of OIRA's actions in answer to a question from Chairman Miller about what happened at the OMB interagency review step in the then-new IRIS process announced on April 10, 2008:

> Dr. Gray. This is when the Office of Management and Budget would coordinate a review of the document by other federal agencies... *[in answer to a follow-on question, he continued]* It is my understanding, and I don't know how OMB does the formal process for reviewing these, but this would go out to all of the federal agencies to have an opportunity to comment.[10]

Dudley represented to the Subcommittee that OIRA had scientists on staff so that they could facilitate interagency science discussions of IRIS entries. Gray confirmed this image of OIRA as a simple coordinator of discussion and materials. However, the Subcommittee has ample documentation showing that OIRA's staff scientists did far more than merely coordinate and facilitate science discussions across agencies. OIRA's staff scientists directly challenged the science put forward by EPA IRIS staff in very detailed peer review-type comments.

For example, on December 22, 2005, John Vandenberg, Associate Director for Health at the National Center for Environmental Assessment, ORD, EPA sent an e-mail to Nancy Beck, an OIRA toxicologist brought on staff by John Graham. It read, in relevant part:

> Attached are Toxicological Reviews for four polybrominated diphenyl ethers. This has gone through the EPA IRIS development and review process and is now ready for submittal to an external peer review panel.... We're providing this to see if you'd like to discuss, and would like to know as soon as possible since we'd like to move this toward external

8 . "EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?," Hearings before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, May 21, 2008, p. 64. The Subcommittee was in possession of some records showing detailed peer review-style OIRA comments at the time of this hearing. Other records came to the Subcommittee in response to the June 11, 2008 document request from Mr. Miller to Ms. Dudley.
9. "EPA's Restructured IRIS System," p. 71.
10 . "EPA's Restructured IRIS System," pp. 68-69.

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> peer review and completion in a timely manner.

Two months later, on February 15, 2006, Nancy Beck sent back an e-mail:

> Hi John-
> Attached are agency comments on the draft. Comments came in only from HHS.... let me know how EPA plans to respond to comments. If a conversation is easiest, we can set that up.

The characterization of comments as being only from HHS is misleading. The CDC/ATSDR provided just a paragraph of text expressing their pleasure in the approach EPA is using. NIEHS provided somewhat more commentary—several brief paragraphs, but also additional science references that EPA could consult.

But these "agency comments" were not the sum of comments to come back from Beck. Beck provided more than 11 pages of OIRA's own, very specific editorial and substantive review comments. For example, in discussing the EPA IRIS draft on polybrominated diphenyl (BDE-209), Beck writes:

- page 4- in the Swedish studies how is EPA sure that internal dose is due to inhalation and not dermal absorption?

- page 7- in the distribution section it would be useful to discuss the age-dependent differences in distribution that are mentioned.

- page 14- says the half live is "short"(sic). What is this relative to? For some chemicals a half life of a week would be considered long.

- page 14- what species are the studies referred to in the last paragraph in the half life section? Are these data from rodents?

- page 31- "Together, these studies suggest that decaBDE has a very limited potential to activate the AhR signal transduction pathway, which **is considered to be a key** ~~is the critical~~ toxicological mechanism for many persistent aromatic hydrocarbons." Please also add a citation for this?" *[emphasis in original]*

These comments were chosen at random from approximately 130 bulleted comments provided by Nancy Beck in the response document (see attachment A).

Of the items quoted above, the last observation in the list is very disturbing because it

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represents a substantive editorial change regarding how to characterize the science. White House staff re-writing the "science" was a recurring problem during the Bush Administration's term in office. The most famous case was probably that of Philip Cooney, chief of staff at the Council of Environmental Quality, editing out climate change science language in an annual report on climate programs to play up uncertainty regarding climate change.[11] In the Beck review of the EPA submission of polybrominated diphenyl there are numerous editorial comments altering language, and some appear to enhance uncertainty or reduce the profile of the effect being discussed. Beck repeatedly strikes "neurobehavioral developmental toxicity" or "neurobehavioral toxicity" to replace it with "changes in spontaneous motor behavior" or similar constructions. At one point, Beck edits a statement on accumulation differing by age in the following way (Beck's edits in bold):

> this may imply that different activities may expose different age groups more than others, or that some PBDE congeners may accumulate differently with age, **however the sample size here is very small and firm conclusions cannot be made.**[12]

You don't have to be a scientist to recognize that many of the comments made by Beck are exactly what one would expect from a scientific peer reviewer. But the role of providing the kind of expert feedback Beck was offering is properly for external peer reviewers; that is why an agency assembles a group of experts to provide their best advice and ask smart questions.

However, Beck took upon herself the role that should be reserved for external peer reviewers. Further, she adopted that role from one of the most powerful perches in the Executive branch: OMB. From that post, her words implicitly had the endorsement of the President and the President's top staff. This gives a weight to her observations that no external peer reviewer—no matter how much more expert than Beck—carries. At a minimum, OIRA's intervention added another layer of review and response that delayed moving an IRIS entry through the process. EPA was not in a position to ignore OIRA's comments, and would end up engaging them before they could move forward to external reviews. Looking over the record of endless process reforms and direct review comments and challenges, one could conclude that the whole point of the exercise was to delay IRIS products.

The Subcommittee has records of exchanges similar to that on polybrominated diphenyl on other chemicals. The Subcommittee received an e-mail record from 2005 between

11. For the original story on this, see Andrew Revkin, "Bush Aide Softened Greenhouse Gas Links to Global Warming," New York Times, June 8, 2005; "Editor of Climate Report Resigns," NYT, June 10, 2005; "Ex-Bush Aide Who Edited Climate Reports to Join ExxonMobil," NYT, June 15, 2005.
12 . This quote and proceeding are from a chain of e-mails and interagency documents that are attachment "A". They begin with an e-mail from John Vandenberg to Amy Mills of EPA and others, dated 02/27/2006, and titled "Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE.

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OMB and EPA of dibutyl phthalate review prior to submitting it for external review.[13] As with the polybrominated diphenyl review, that OIRA/interagency review also took approximately two months between the time EPA sent language to OIRA and the time OIRA provided comments back. The Subcommittee also has two sets of comments on toluene: an OIRA response to a February 2005 EPA draft and an EPA compilation of responses to December 2003 OMB comments regarding an external review draft of a toluene toxicological review. This documentary chain suggests that toluene went through one external review in 2003, the draft revised and then reviewed by OIRA; then the toluene draft entry went through further internal EPA developments followed by another round of OIRA review and response more than a year later.[14]

The extent and detail of OIRA's comments vary from chemical to chemical, and they appear to become more elaborate over time. But each example is a powerful illustration that neither Susan Dudley nor George Gray was candid with the Subcommittee about the role of OIRA or the impact of its interventions on EPA's work. Subcommittee staff has been told by one person on the inside of these reviews that the documents in the possession of the Subcommittee are relatively mild compared to, for example, OIRA's efforts on perchlorate. Of course none of these communications were available to the public. There was no way to know that Dudley and Gray were not telling Congress the unvarnished truth because the entire process was veiled behind "deliberative process" claims of privilege. Transparency was anything but the watchword for what OIRA was doing to IRIS both in substance and process between 2003 and 2008.

THE PROCESS IMPROVEMENT MERRY-GO-ROUND

OIRA intervention in the work of IRIS grew throughout the Bush years. It appears to have been a constantly expanding effort that endlessly tweaked the process for reviewing and discussing IRIS entries, and expanded the scope of OIRA's direct involvement in science discussions. While we do not have OIRA documents on this evolution, the Subcommittee does have some EPA documents that shed light on how EPA IRIS staff viewed the situation.

The earliest process e-mail the Subcommittee has is from John Vandenberg, Associate Director for Health at EPA's National Center for Environmental Assessment (NCEA) to Peter Preuss, Director of the NCEA, and others dated September 13, 2004. Comments by the authors of this report appear in italicized text and brackets.

Vandenberg writes,

> Nancy Beck *[OIRA toxicologist]* called me this morning and conveyed

13. This appears as attachment "B". Documents start with an e-mail from John Vandenberg to Bob Benson of EPA and others, dated 02/07/2006, titled "Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate."
14 . Records appear as attachments "C" and "D". The first has hand-written notation, "Comments from OMB (Margo Schwab) 4-19-05." The second is dated "December 30, 2003" and is titled, "Summary of OMB comments and EPA responses".

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> several things: 1) John Graham wants a briefing *[from IRIS staff]* on the naphthalene assessment, focused on **process** from here (e.g. interagency review, consideration of peer review comments). We should arrange in the next couple of weeks if possible. 2) She (Nancy) considers some of the external peer review comments to be significant." *[emphasis in original]*...
>
> I told her we're evaluating the draft in light of peer review comments, that we've heard DOD plans to comment but we have not received any comments from them and I urged her to get them to share their comments. I sketched out the IRIS process insofar as it would normally proceed, noting that a formal interagency review would change the process (and that we'd share a document that reflects our revisions following external peer review). I mentioned IRIS Track (Paul Gilman had also mentioned it, they're interested in seeing it). I didn't give any specific dates to her (perhaps fortunately IRIS track was offline this morning!)
>
> We should talk through how we want interagency review to occur, including any groundrules we want to get set up front to avoid paralysis (e.g., fixed time for other agencies to provide review comments; final disposition/decisionmaking by EPA/ORD on assessment document completion; criteria or conditions calling for additional external peer review). Especially for "biggies" that have interagency review we need to stake out a process that will lead us to be successful in terms of timeliness, clarity, consistency, etc. [15]

By May of 2005, EPA staff were engaged in a formal IRIS process brought on by OIRA's intervention. Vandenberg writes to Preuss and others, an e-mail entitled "IRIS process comments from OMB, next steps." Vandenberg writes:

> In brief, Nancy Beck (and, she says, Dr. Graham) were expecting more detail than provided in the flow chart and 2-pager to address the 'details'. I pushed back, not wanting to have us wait several months to develop new SOPs [standard operating procedures], as this is premature. Nancy seemed to concur, though she is checking with Dr. Graham.
>
> We ended up agreeing to slightly revise the 2-pager to add a bullet on next steps (i.e., public workshop to discuss process and details/issues) and to emphasize or elaborate on the improvements the process will bring.... Further I agreed that in our Federal Register notice announcing the workshop, we'll identify some of the topics and issues for discussion... OMB wants to review this FR notice.... [16]

15 . E-mail from Vandenberg to Preuss and others, 09/13/2004, titled, "naphthalene – OMB request for briefing." Appears as attachment "E".
16 . E-mail from Vandenberg to Amy Mills and others, 05/24/2005, titled, "IRIS process comments from OMB, next steps." Appears as attachment "F".

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By February of 2006, the process was still under discussion. Preuss receives an e-mail from Shannon Cunniff of the Department of Defense's Material of Evolving Regulatory Interest Team (MERIT) that went to Nancy Beck at OIRA as well as many others in agencies across the government.

> OSD, NASA and DOE Sr. staff have reviewed ORD's proposed IRIS revisions chart and detailed explanation of some of the boxes and attached are our comments and suggestions. DHS and DOT were not on our last calls due to scheduling conflicts, so I can not assert to what degree they support these comments...
>
> What you have attached is a) the flow chart – we added numbers to all boxes but also retained your numbering of the latter 10 boxes that correspond to your detailed explanation – and b) an expanded detailed explanation of the boxes that includes, as we discussed, an [sic] proposed explanation for every step to help us all achieve clarity and eventually agreement.
>
> These inserts and changes were drafted by a committee of federal staff and recorded by Mitretek (so you might see Mitretek identified as a "commentor"(sic). All of our insertions or changes are in color and underlined.
>
> We suggest that after you look this over that we set up another multi-agency meeting to bring all the interested federal agencies together to discuss the process steps and see if together can reach consensus on the process, understand how or if this effort fits with Dr. Gray's visions for IRIS, and develop a plan for next steps.[17]

The Subcommittee does not have the attachments referenced in this e-mail. Nor do we have further records relating to the next steps and the final outcome.[18] We do have EPA IRIS staff's own process charts designed to record this evolving process as it moved from 2004 through 2008. The next three graphics are reproductions of IRIS staff efforts at developing a flow chart that would reflect the process, as they understood it, at each moment in time.

17 . E-mail from Shannon Cunniff, Department of Defense, to Preuss, Beck and others, 02/02/2006, titled, "DoD, NASA, DoE comments on IRIS revisions." Appears as attachment "g" in the report.
18. Note that GAO's report of March 2008, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," shows a draft process which was under discussion in early 2008. See pages 46 and 47 of GAO-08-440.

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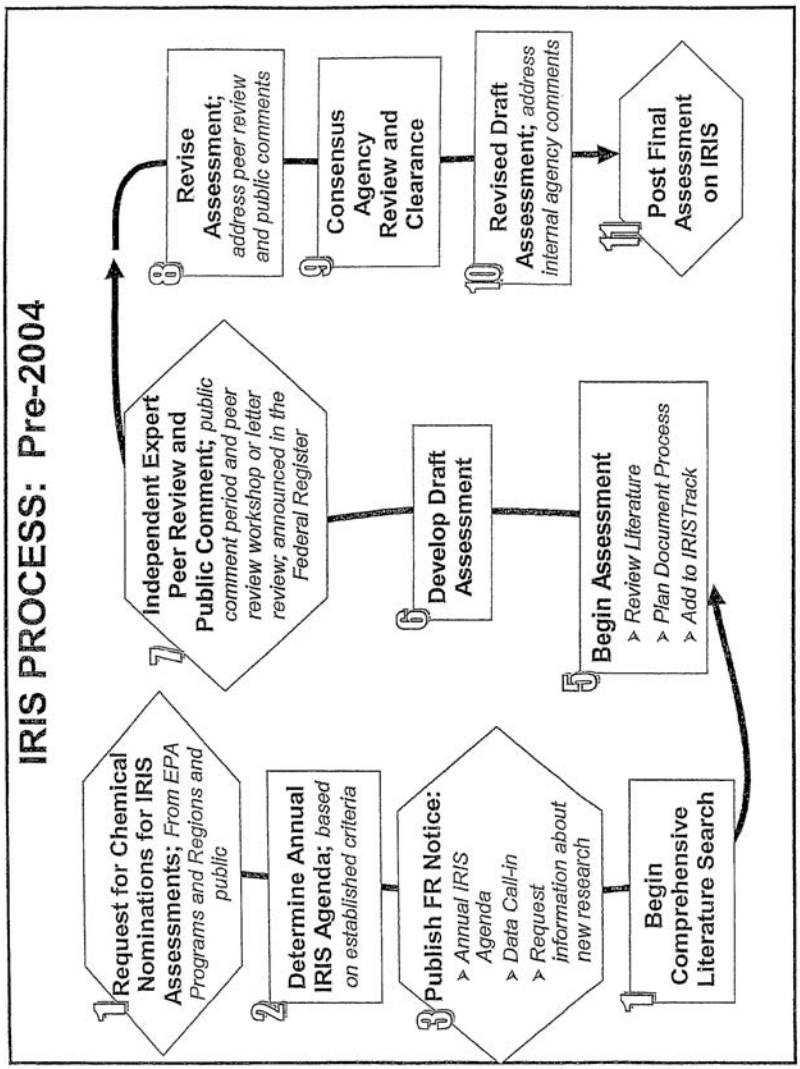
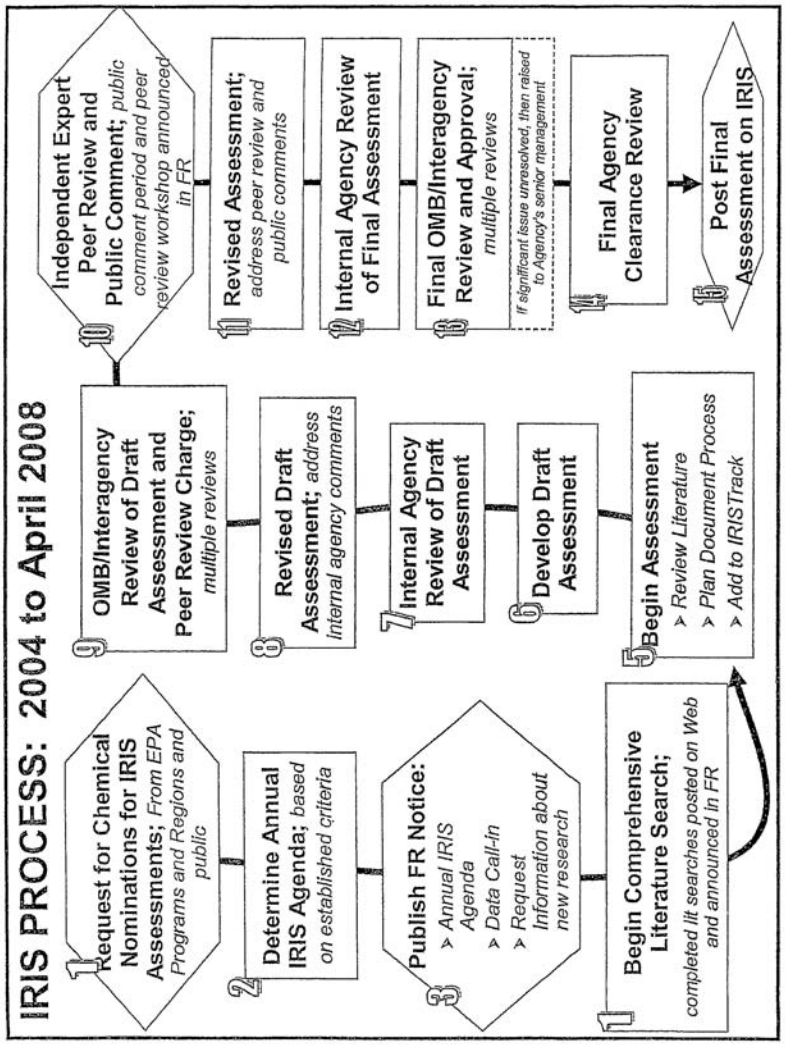
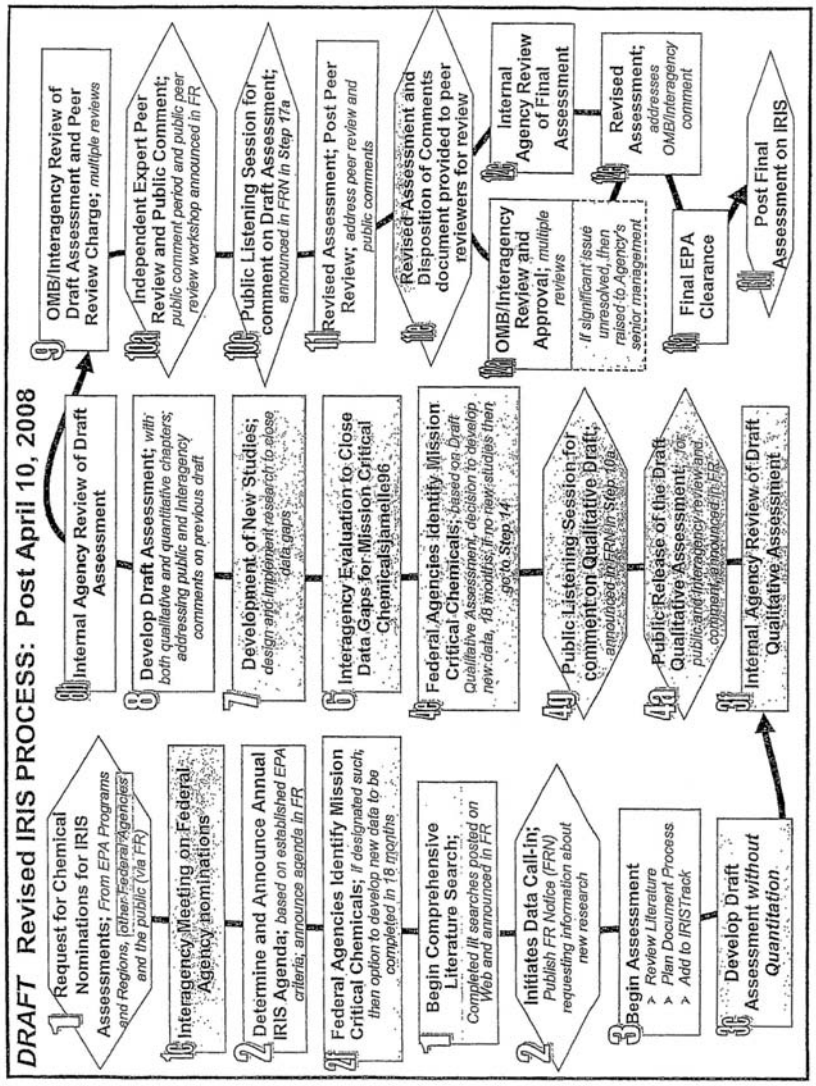

IRIS PROCESS: Pre-2004
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-in
Request information about new research
1 Begin Comprehensive Literature Search
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop or letter review; announced in the Federal Register
8 Revise Assessment; address peer review and public comments
9 Consensus Agency Review and Clearance
10 Revised Draft Assessment; address internal agency comments
11 Post Final Assessment on IRIS


IRIS PROCESS: 2004 to April 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
2 Determine Annual IRIS Agenda; based on established criteria
3 Publish FR Notice:
Annual IRIS Agenda
Data Call-In
Request Information about new research
4 Begin Comprehensive Literature Search;
completed lit searches posted on Web and announced in FR
5 Begin Assessment
Review Literature
Plan Document Process
Add to IRISTrack
6 Develop Draft Assessment
7 Internal Agency Review of Draft Assessment
8 Revised Draft Assessment; address Internal agency comments
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10 Independent Expert Peer Review and Public Comment; public comment period and peer review workshop announced in FR
11 Revised Assessment; address peer review and public comments
12 Internal Agency Review of Final Assessment
13 Final OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
14 Final Agency Clearance Review
15 Post Final Assessment on IRIS


DRAFT Revised IRIS PROCESS: Post April 10, 2008
1 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions, (other Federal Agencies) and the public (via FR)
1b Interagency Meeting on Federal Agency nominations
2 Determine and Announce Annual IRIS Agenda; based on established EPA criteria; announce agenda in FR
2b Federal Agencies Identify Mission Critical Chemicals; if designated such, then option to develop new data to be completed in 18 months
1 Begin Comprehensive Literature Search; Completed lit searches posted on Web and announced in FR
2 Initiates Data Call-In; Publish FR Notice (FRN) requesting information about new research
3 Begin Assessment
> Review Literature
> Plan Document Process
> Add to IRISTrack
3b Develop Draft Assessment without Quantitation
8 Internal Agency Review of Draft Assessment
6 Develop Draft Assessment; with both qualitative and quantitative chapters; addressing public and interagency comments on previous draft
7 Development of New Studies; design and implement research to close data gaps
6 Interagency Evaluation to Close Data Gaps for Mission Critical Chemicals/jamelle96
4b Federal Agencies Identify Mission Critical Chemicals; based on Draft Qualitative Assessment, decision to develop new data, 18 months; If no new studies then go to Step 14
4a Public Listening Session for comment on Qualitative Draft; announced in FRN in Step 10a
4a Public Release of the Draft Qualitative Assessment; for public and interagency review and comment, announced in FR
3 Internal Agency Review of Draft Qualitative Assessment
9 OMB/Interagency Review of Draft Assessment and Peer Review Charge; multiple reviews
10a Independent Expert Peer Review and Public Comment; public comment period and public peer review workshop announced in FR
10a Public Listening Session for comment on Draft Assessment; announced in FRN in Step 17a
11 Revised Assessment; Post Peer Review; address peer review and public comments
12 Revised Assessment and Disposition of Comments document provided to peer reviewers for review
12a OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
12b Internal Agency Review of Final Assessment
12c Revised Assessment; addresses OMB/interagency comment
13 Final EPA Clearance
13b Post Final Assessment on IRIS

The timeline reflected in these charts, and in the e-mails reviewed by the Subcommittee, suggests that it took three full years from the time OIRA's Graham triggered a formal effort to restructure the IRIS process until a new process had cleared all the internal hurdles. Remember that it was in February of 2006 that DOD's lead representative to interagency discussions was suggesting they should have another "multi-agency" meeting to hammer out an agreement. That agreement was not finalized until April of 2008.

Because the process continued to evolve, both before the process review began and during the formal review, IRIS staff was constantly trying to figure out what steps they needed to take to keep on track with IRIS proposals. These charts clearly reflect a process that became ever more complex and burdensome. But while the process was evolving, there was another level of chaos thrown into the IRIS mix. Uncertainties among EPA staff about how to proceed, absent a final approved process, show up in some documents in the Subcommittee's possession.

For example, in an e-mail from February 2, 2006, Vandenberg shares with IRIS staff comments that came from OIRA's Beck on dibutyl phthalates and writes,

> Our approach to these interagency comments (for perc and dichlorobenzenes) has been to carefully evaluate the comments and to develop a response to comments document. I recommend you create a document that addresses each comment (include their "comment" and our "responses" as one file) and provide a point-by-point evaluation. I encourage that the tone of our "responses" be thoughtful and that we make such changes as we deem warranted. If there are some larger science-policy issues or points made where it is unclear how to respond, then flag these for discussion.
>
> Please give me a sense of the time it may take you to respond to these comments (I'd expect a few weeks).

Vandenberg closes his note to staff with,

> Thank you for all your hard work on this document, it seems we'll soon be able to move ahead![19]

However, the IRIS Track currently shows the status of the dibutyl phthalate assessment start date as January 9, 2002 (four years prior to the Vandenberg e-mail quoted above) and now projects that just the draft development will be completed by the 4th quarter of 2010. Perhaps in the world of IRIS, taking eight years to move to complete the first milestone—of five—is considered as being "soon."[20]

Later in February 2006, Amy Mills, IRIS program director, writes to Vandenberg:

19 . "Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate." Attachment "B."
20 . The Track IRIS database was reviewed by Subcommittee staff on Friday, June 5.

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> John – Are we expected to send a *revised assessment* along with the response to interagency comments to OMB? [Assuming that at least some of the comments result in some level of change to the assessment] As I recall we've done so before, but is there a pattern established? *[emphasis in original]*

Vandenberg replies,

> For perc the comments didn't result in a revised assessment (changes to charge questions)... for phosgene we did send a revised assessment over. *[see attachment X]* I recommend going ahead and making revisions so we can have it ready for external peer review, and probably will send over. My view is that the disposition of comments/changes are up to us, but of course all this is evolving still.[21]

At the Subcommittee's IRIS hearing on May 21, 2008, Gray and Dudley both addressed the April 10, 2008 process. While Gray's testimony described the new process as being "announced by EPA," Dudley used language suggesting that EPA had done the revision:[22]

> In response to concerns both with delays in implementing IRIS assessments and lack of transparency in the IRIS process, EPA has recently revised the process to clarify the role of the public and interagency reviewers and promote greater communication and sharing of information between all interested parties and EPA.

Based on this testimony, a reasonable person would assume that the new EPA IRIS process was solely the product of EPA's work, but as a result of the documents cited above (and attached to this report), Subcommittee staff can confirm that the then-new process, and its evolution, were driven by changing demands from OIRA. Further, it is apparent that other agencies—notably agencies that have environmental pollution issues—played a substantial role in shaping that process. Again, neither Dudley nor Gray was candid with the public or the Congress in the way they portrayed this process.

CONCLUSION

The Subcommittee held two days of hearings on the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) in the last Congress. Chairman Miller was critical of the failure of IRIS to produce timely new listings of risk assessments for chemicals. The Chairman also noted that the process had devolved to the point that only two new entries were being finalized a year while approximately 700 new chemicals were entering the marketplace each year.

A key concern regarding the new IRIS process (see chart below) announced on May 20,

21. "Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE," attachment "A".
22 . "EPA's Restructured IRIS System," p. 53 for Gray and p. 58 for Dudley.

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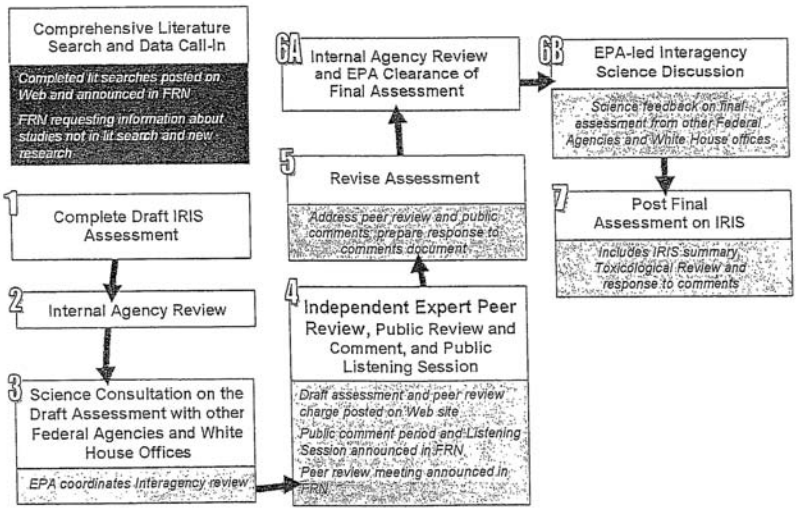
2009 is whether it will substantively empower EPA to push their entries forward. Because all interagency comments are to be solely about science, this new process could be interpreted as formally endorsing OIRA's past practice of having professional scientists on staff to discuss toxicology issues, scientist-to-scientist. Then the entire fiction of OIRA's role as merely a coordinator of an interagency process can fall away. So long as OIRA and OMB stand astride the top of the Administration as representatives for the White House in discussions with EPA or others, it is hard to see how transparency alone will limit OIRA's influence over EPA. The timelines that EPA announced with the new process may be helpful, but since there is no penalty for missing a goal, it may still come down to who has the most influence and EPA has rarely won that struggle in recent memory[23]

Given that so many of the same players who broke IRIS during the Bush years still stand in the agencies and in the White House complex, and that institutional powers and interests have not changed despite the November 2008 election results, it will take some time to determine whether EPA scientists really are calling the shots.

Assessment Development Process for New IRIS



23 . The timelines associated with the new process can be found at attachment "H" in the report.

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Attachment A

John Vandenberg/DC/USEPA/US
02/27/2006 10:02 AM

To Amy Mills/DC/USEPA/US@EPA
cc hammerstrom.karen@epa.gov, Mary Manibusan/DC/USEPA/US@EPA
bcc
Subject Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

For perc the comments didn't result in a revised assessment (changes to charge questions). EtO pending; for phosgene we did send a revised assessment over. I recommend going ahead and making revisions so we can have it ready for external peer review, and probably will send over. My view is that the disposition of comments/changes are up to us, but of course all this is evolving still.

John Vandenberg
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National Center for Environmental Assessment B243-01
Office of Research and Development, USEPA
Research Triangle Park, NC 27711

DC Research Triangle Park, NC
Tel: 202 564 3407 919 541 4527
Fax: 202 565 0090 919 541 5078
Amy Mills/DC/USEPA/US

Amy Mills/DC/USEPA/US
02/22/2006 10:17 AM

To John Vandenberg/DC/USEPA/US@EPA
cc Mary Manibusan/DC/USEPA/US@EPA, hammerstrom.karen@epa.gov
Subject Re: Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

John - Are we expected to send a *revised assessment* along with the response to interagency comments to OMB? [Assuming that at least some of the comments result in some level of change to the assessment.] As I recall we've done so before, but is there a pattern established?

Amy Mills
IRIS Program Dir.
(202) 564-3204
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Mailing address:
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1200 Pennsylvania Ave.
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Washington, DC 20460

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808 17th St., NW
Room 620E
Washington, DC 20007

PBDEs

John Vandenberg/DC/USEPA/US
02/22/2006 08:22 AM

To Mary Manibusan/DC/USEPA/US@EPA
cc Amy Mills/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, preuss.peter@epa.gov, Amanda
bcc
Subject Interagency Comments here: Fw: Draft IRIS assessments for 4 PBDE

History: This message has been replied to

Mary,
Attached below are the interagency comments for PBDE, please share these with the document co-authors.

The comments include general and detailed comments from OMB, a review by NIEHS that essentially used the charge questions as their charge with many references cited, and a short comment by CDC.

Our approach for dealing with comments has been to create a "Comment/Response" document which addresses each comment in turn. For many of the comments simple concurrence with the editorial suggestions may be noted. For others, a more detailed response is likely to be necessary, particularly if there is disagreement with the comment or if additional explanation is requested. Some comments also raise general issues regarding EPA risk assessment approaches, these can be flagged and discussed.

Please work with the PBDE authors to evaluate the comments and gauge the effort and time necessary to address the comments.

Thank you.
John

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Fax: 202 565 0090 919 541 5078

----- Forwarded by John Vandenberg/DC/USEPA/US on 02/22/2006 08:07 AM -----

"Beck, Nancy" <Nancy_Beck@omb.eop.gov>
02/15/2006 06:05 PM

To John Vandenberg/DC/USEPA/US@EPA
cc Peter Preuss/DC/USEPA/US@EPA
Subject RE: Draft IRIS assessments for 4 PBDE

– CDC, NIEHS, ATSDR – OK with substance.

INTERAGENCY DRAFT DELIBERATIVE

OMB Comments on PBDE's

General Comments applicable to all 4 draft documents:

- Has WHO or the EU completed any reviews? How are their findings similar or different to EPAs?

- In all 4 drafts, a section on mechanism of action is missing. Its not clear why. Additionally, studies that look at receptor binding are in the effects section—these studies belong in a section on mechanism of action. Binding to a receptor is not an adverse effect or a typical toxicological endpoint. Its not clear why EPA has treated it as such in these drafts.

- In distribution sections:
  - Its not clear why the summary is put first? This makes reading a bit confusing, suggest moving to the end of the distribution section to be consistent with format of other sections.
  - Please clarify: "Accordingly, the data are representative of exposure to a greater extent than distribution toxicokinetics and must be regarded in that fashion."
  - Throughout these sections for each study the sample size should be presented. Its very hard to know how representative the data are when these values are not transparently presented. In cases where EPA does not know the sample number, this should be stated. When samples are pooled, the number of samples that went into each pooled sample should be stated.
  - The tables in these sections should also provide sample number for each study and should also state the year the samples were collected as this seems very relevant and date of publication is not indicative of sample age.
  - For human data it would be useful to have a few sentences discussing how representative these data are/ are not.

- In metabolism sections:
  - These sections seem to include information on induction of metabolic enzymes (p450's, UDPGT) by BDE's, but induction of metabolic enzymes doesn't tell anything specific about how the compounds themselves are metabolized. Suggest moving this text to a section on mechanism of action in each document. It is not informative information when trying to determine how the BDE's are metabolized.

- In hazard ID sections:
  - Its not clear why studies looking at enzyme activity (PROD, EROD, etc) are discussed here. These studies should be discussed in a section on mechanism of action.
  - Its not clear why receptor interactions and receptor binding is discussed under "other studies" in this section. These studies should be discussed under mechanism of action sections in the document. Each document should have a section on mechanism/mode of action.
  - For the Viberg studies and Eriksson 2001 study it is never explained anywhere in the document what it means that there is hypoactivity and then later hyperactivity? Also

developmentally how does the time change between a 2 month old and 4 month old mouse relate to age changes in humans? What is the relevance of these spontaneous motor behavior changes in humans? How important is habituation in humans?

- Section on synthesis and evaluation of effects:
  - Discussion of enzyme induction should not be included here.
  - Discussion of human exposures does not seem to belong here

- Section on possible childhood susceptibility:
  - Its not clear why discussion of levels of BDEs in humans is included here. This information relates to exposure, not susceptibility. Exposure does not mean that there is differential susceptibility.
- Section on methods of analysis:
  - Documents should explain why BMD with 1 SD is being chosen, rather than another endpoint. Why didn't EPA also present BMD10 values? Text should mention that this gives an excess risk of 10% for the proportion of individuals above the 98th percentile for normally distributed effects.
  - In some documents a BMD of 0.5SD is presented in the appendix. How did EPA choose 1SD over 0.5SD?

- Justification for creating RfDs when uncertainty is so great is not clear.

General Comments on the charge:

- Has EPA given thought to the number and type of expertise on the review panel?
- The questions should not only ask if rationale and justification is transparent and objective, but should also ask experts if they agree with the EPA determinations.

Tetra (BDE-47):

- Page 11- for the Darnerud and Risberg study it would be useful to give the levels of radioactivity (or %'s) to help understand uptake. Its not clear what is meant by 'high' and 'intermediate'. What was the % labeling in the brain?

- Page 16- 3rd full paragraph- suggest deleting 1st sentence. Edit 2nd sentence to say "to assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 18- suggest deleting (or provide citation for) the following: "Induction of these enzymes would suggest metabolic transformation of BDE-47, and this could affect the levels of T4, as the produced metabolites may have effects on T4 homeostasis by replacing T4 at TTR binding sites."

- Page 18- what is the citation for the following sentence: "It is hypothesized that the lack of response on serum TSH levels to the reduction in T4 levels is due to BDE-47 and/or its metabolites mimicking thyroid hormones and possibly binding to thyroid hormone receptors in the pituitary, thereby blocking TSH release."

INTERAGENCY DRAFT DELIBERATIVE

- Page 18- Was the Eriksson study male mice only? If so this should be clearly stated. Were the "more pronounced aberrations" in behavior statistically significant (ie 2 month vs 4 month)?

- Page 20- suggest deleting: "Based on the data from the well-studied PCBs, CDDs and CDFs, the activation of these receptor sites is associated with immunotoxicity, reproductive effects and carcinogenesis, all endpoints of interest for PBDEs (Klaassen, 2001)." This sentence is unclear. Is there a page citation for Klaassen where this is stated?

- Page 22- please provide page citation for Klaassen, 2001 under section 4.4.1.2

- Page 24: edits in bold: "In summary, the mechanistic studies of the ER and Ah receptor indicate that the activity of the tetraBDEs are **much** lower than the activities of dioxin and PCBs. TetraBDE-77 appears to be the most active with the Ah receptor and most PBDEs appear to be **weak** antagonists for the Ah receptor rather than agonists**[what is citation for this?]**. Receptor-site mediated activity via the ER site appears to be minimal for the tetraBDEs."

- Page 25- Add that although the impact on CAR receptor is similar to non-coplanar PCBs, the implications of CAR activation is not well known.

- Page 26- since when is cell culture an endpoint in hazard ID? Suggest moving this text to sections on distribution and absorption as appropriate.

- Page 27: "Additional research is necessary to determine the ~~full~~ mutagenic potential of BDE-47."

- Page 27: Alterations of behavioral parameters, namely impaired motor functions and decreased habituation capability worsening with age, have been shown to occur in adult male mice neonatally exposed to BDE-47 (Eriksson et al., 2001). ~~These behavioral disturbances raise concerns about possible developmental neurotoxicity in children.~~

~~BDE-47 has been found in human milk, maternal and cord blood, and adipose tissues. Concentrations found are high in all human biological samples in the USA, relative to other countries. Fetuses and infants are exposed to BDE-47. Whether such exposure constitute a health risk for adverse neurodevelopmental effects in these population groups is not known at this time. An association between prenatal or neonatal exposures to BDE-47 and neurobehavioral dysfunction in humans has not been established.~~ This sentence is not about effects.

- Page 27: "Exposure of mice ~~and rats~~ to BDE-47 resulted in reduction of serum total and free thyroid hormone levels**, however no changes in TSH were seen** (Hallgren et al., 2001; Hallgren and Darnerud, 2002)."—the hallgren study was mice only and its not clear that any of the Hallgren and Darnerud effects were statistically significant, text does not say, thus I assume changes were not.

- Page 28- Additional *in vitro* or *in vivo* studies are not available to determine the ~~full~~ genotoxic potential of BDE-47."

- Page 29-under choice of study, its not clear why effects on MFO's are discussed here.

- Page 30-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occurred throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?
  - Please clarify the discussion of hormone change effects. How do the changes seen relate to the findings in the Eriksson study? Can EPA say anything more specific? How do we know the results are "relevant to exposure in people"? what is this based on? Hormone stores and half lifes in rodents are quite different than levels in humans. How do we know that these exposure levels are relevant? What is meant by: "Taken together, the results elevate concern for environmental exposure to BDE-47 and support the use of this study as a principal study for deriving the RfD for BDE-47." How does the data elevate concern and why do they support using Eriksson as the principal study?

- Page 30/31- The description of the concerns with the Eriksson study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study. The database is incredibly limited. There is one study—in one sex in one species with essentially no supporting similar studies and no information on mechanism of action. Only 2 doses were tested and the dose levels were an order of magnitude apart. This seems to be more of a range finding study than anything else. The UF EPA wants to apply is 3000 (with uncertainty in 4 different areas) and the certainty would be low. When uncertainty is so high, what is the value added of this RfD value? Is the science strong enough to support the use of this value for clean-ups conducted by program offices?

- Page 32-Choice of the database UF should not depend on whether or not cancer studies exist. Suggest deleting this reference.

- Page 32- "~~Neurobehavioral developmental toxicity~~ **Changes in spontaneous motor behavior** has been identified as the critical endpoint of concern in adult **male** mice following neonatal oral exposure to BDE-47 (Eriksson et al., 2001). ~~Since fetuses and infants are exposed to BDE-47 via maternal/cord blood and human milk, such exposure may constitute a health risk for adverse neurodevelopmental effects in these population groups.~~" Not clear why exposure is discussed here, specifically when doses are not put in a context of human body burden and actual exposure levels. Also the certainty in the RfD is so low its not clear that a risk to humans is real based on the data EPA has presented.

Penta (BDE-99):

- Page 4- in the Eriksson 2002 study were there any controls? Is it known if levels in the brain were DBE99 vs some metabolite that ended up with the radiolabel?

INTERAGENCY DRAFT DELIBERATIVE

- Page 5:
  - This may imply that different activities may expose different age groups more than others, or that some PBDE congeners may accumulate differently with age, **however the sample size here is very small and firm conclusions cannot be made**.
  - is Johnson-restrepo published yet?

- Page 7-
  - Please state if the strong positive relationship seen in Ohta is statistically significant.
  - Please add a citation for: "In another study in Japan, PBDEs were not detected in 8 pooled human milk samples collected in 1973."

- Page 8- "This may be explained by the fact that PBDEs are relatively new contaminants in the environment, the time period for human exposure is therefore relatively short, and different age groups (except the 0-4 years group), may thus have experienced a similar lifetime exposure (Thomsen et al., 2002)." Do you mean to say **dissimilar** lifetime exposure? also change "flame retarded" to "flame retardant".

- Page 10- Please state the dose in the Hakk 2002a study.

- Page 11- in the 2nd full paragraph, please provide the percent of uptake into each tissue. Also has Darnerud and Risberg been published yet?

- Page 13-
  - 1st full and 4th paragraph- please clarify that the Hakk conclusions are relevant to rats.
  - in the Darnerude et al 2005 study, was this with and without BDE-99? Its not clear how this relates to BDE-99.

- Page 14-1st full paragraph, is this an EPA conclusion or should there be a citation?

- Page 15-
  - 1st full paragraph under half-life: 6 days is relatively high compared to what?
  - 2nd full paragraph under half-life: why is this discussing hexa and tetra BDE? Can we say anything about sex differences with increasing degree of bromination? What were the penta half lives anyways?

- Page 16-2nd full paragraph- suggest deleting 1st sentence. Edit 2nd sentence to say "To assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 17- please explain why comparisons to Bromkal and Aroclor are reported. In the 4th paragraph was there any BDE-99 exposure?

- Page 18-Please state whether the elevations seen in Hakk 2002a were statistically significant.

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- Page 18- its not clear how studies are ordered in section 4.3.1. Chronological might make reading easier- or by author so readers can see how things develop (eg in 2002 Viberg tested 1 dose but in 2004 did essentially the same study with multiple doses).

- Page 19-The no-observed-adverse-effect level (NOAEL) for ~~developmental neurotoxic~~ **spontaneous motor behavior** effects in this study was 0.4 mg/kg.

- Page 21-In conclusion, the behavioral disturbances observed in adult mice following neonatal exposure to BDE-99 are induced during a defined critical period of neonatal brain development, and mice at PND 10 are m**ore** susceptible to the neurotoxic effects of BDE-99 **than at PND 3, 10 or 19 where minimal or no effects were seen**.

- Page 21- The purpose of the PDBE exposure in the Ankarberg study is not clear.

- Page 23- A two-day delayed appearance of screen climbing response was seen in the high-dose group (30 mg/kg/day); Please state if this was statistically significant.

- Page 26-The NOAEL/LOAEL values in this study indicate that rats are equally or perhaps less sensitive than mice to the **spontaneous motor behavior** ~~developmental neurotoxic~~ effects of BDE-99.

- Page 28-
  - "In summary, treatment of rats with BDE-99 on GD 6 resulted in a dose-dependent decrease in daily sperm production, spermatid count, and relative epididymis weight in rat offsprings at 0.06 and 0.3 mg/kg." Do you mean PND 140?
  - "The LOAEL in this study was 0.06 mg/kg based on increases in certain locomotor activity parameters on PND 36 and PND 71". Its not clear from the text that there were effects at this dose at PND 36.

- Page 40- the discussion of gender differences should note that many studies were conducted in males only.

- Page 40- this study mentions many supporting studies to support use of Viberg 2004a- however don't most of these studies have the same study design problems? Shouldn't this be stated? Are there other better designed studies that support using Viberg and neurobehavioral effects, particularly since so little is known about mode of action? How do we know that these exposure levels are relevant? What is meant by: "Taken together, the results elevate concern for environmental exposure to BDE-99 and support the use of this study as a principal study for deriving the RfD for BDE-99." How does the data elevate concern and why do they support using Eriksson as the principal study?

- Page 43-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies

included exposures that occured throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Page 44- it would be useful to present a table with all the BMD values from the different studies

- Page 45-Does it make sense to set an RfD with an UF of 3000 with low confidence? Is there anything EPA is confident of? Are there any data on mechanism of action that may help? This is an order of magnitude lower than the previous RfD, yet the certainty in the data does not appear to have increased.

- Page 47- Not clear why exposure is discussed here, specifically when doses are not put in a context of human body burden and actual exposure levels.

Hexa (BDE-153):

- Page 4: "Of the hexaBDE congeners, BDE-153 is ~~therefore~~ present at higher levels than BDE-154 in both the penta- and octaPBDE commercial products."

- Page 5-" This property of hexaBDE is ~~quite~~ evident from the data on distribution in humans. The human data come from monitoring of PBDEs in human populations rather than from measured dosing studies."

- Page 5- what were the levels of hexaBDE in adipose?

- Page 6- unclear why the following is included in this section: "Concentrations of PBDEs were, on average, similar to those for PCBs. PBDE concentrations did not increase with increasing age of the subjects, whereas concentrations of PCBs increased with increasing age in males but not in females. These results suggest differences between PBDEs and PCBs in their sources or time course of exposure and disposition."

- Page 7-
  - in liver section, suggest deleting text regarding BDE 47 and 99, is not relevant.
  - the human milk section talks of PDBE levels being higher than those in Japan or Europe. How do the Hexa BDE levels compare?
  - Focus throughout the distribution and elimination sections should be on hexa and not total or other BDEs

- Page 11-1st paragraph under 4.1: suggest deleting 1st sentence. Edit 2nd sentence to say "To assess whether PBDE's may be detrimental to neurodevelopment, Mazdai….."

- Page 14- "The NOAEL for BDE-153 (92.5% pure) in this study (Viberg et al., 2003) was 0.45 mg/kg, and the LOAEL 0.9 mg/kg for changes in spontaneous motor behavior, worsening with increasing age, and for effects on learning and memory ability." What is meant by learning and memory ability? Is this relearning?

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- Page 14- suggest deleting: "Based on the data from the well-studied PCBs, CDDs and CDFs, the activation of these receptor sites is associated with immunotoxicity, reproductive effects and carcinogenesis, all endpoints of interest for PBDEs (Klaassen, 2001)." This sentence is unclear. Is there a page citation for Klaassen where this is stated? Please also provide a citation for: "Xenobiotic compounds with the strongest Ah receptor binding affinity tend to be those with the greatest toxic potency."

- Page 16- please provide a page citation for: "Receptor induced mitogenic activity has been linked to tumor formation in the affected organs (Klaassen, 2001)."

- Page 17: "In summary, the mechanistic studies of ~~the Ah receptor and~~ the estrogen receptor indicate that the activity of BDE-153 and BDE-154 are significantly lower than the activities of dioxin and PCBs." Isnt there essentially no ER activity? Why not just say this?

- Page 18- Please state what binding to the CAR receptor mean as far as effect goes.

- Page 18: "The **meaning** ~~importance~~ of this observation for humans has yet to be resolved."

- Page 18: "Alterations of behavioral parameters, namely impaired spontaneous motor behavior worsening with age, and effects on learning and memory capability have been shown to occur in adult male mice neonatally exposed to BDE-153 (Viberg et al., 2003). These behavioral disturbances raise concerns about possible developmental toxicity in children." Considering the problems with study design, is this truly a concern? How do these disturbances relate to what we may see in humans? Are the disturbances actually adverse?

- Page 20- The description of the concerns with the Viberg study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study. The database is incredibly limited. There is one study—in one species (its not clear if it is males only-text seems to go back and forth with this) with essentially no supporting similar studies and no information on mechanism of action. The UF EPA wants to apply is 3000 (with uncertainty in 4 different areas) and the certainty would be low. When uncertainty is so high, what is the value added of this RfD value? Is the science strong enough to support the use of this value for clean-ups conducted by program offices?

- Page 20-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occured throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Page 21-Does it make sense to set an RfD with an UF of 3000 with low confidence? Is there anything EPA is confident of? Are there any data on mechanism of action that may help?

INTERAGENCY DRAFT DELIBERATIVE

Deca (BDE-209):

- Page 4- in the Swedish studies how is EPA sure that internal dose is due to inhalation and not dermal absorption?

- Page 7- in the distribution section it would be useful to discuss the age-dependent differences in distribution that are mentioned.

- Page 14- says the half live is "short". What is this relative to? For some chemicals a half life of a week would be considered long.

- Page 14- what species are the studies referred to in the last paragraph in the half life section? Are these data from rodents?

- Page 31-"Together, these studies suggest that decaBDE has very limited potential to activate the AhR signal transduction pathway, which **is considered to be a key** ~~is the critical~~ toxicological mechanisms for many persistent aromatic hydrocarbons." Please also add a citation for this?

- Page 32-
  - "Results from these studies provide ~~no~~ evidence that parent decaBDE in the presence or absence of exogenous liver metabolic system **does not** react directly or indirectly with DNA to cause either gene mutations, DNA damage, or chromosomal effects."
  - suggest deleting the 1st paragraph in 4.5. this section should not present hypotheses, particularly when the previous text does not support them. It makes things confusing.
  - much of the discussion in this section is on mechanism and does not belong here.
  - -~~"Given that the critical toxicological mechanism for many persistent aromatic hydrocarbons involves binding to the aryl hydrocarbon receptor (AhR), DNA binding, and gene expression,~~ Several *in vivo* and *in vitro* studies……"

- Page 33
  - "DecaBDE also caused thyroid gland follicular cell hyperplasia in male mice and thyroid tumors in male and female mice**[previous text says thyroid tumors were in male mice only]**, effects that are indicative of thyroid toxicity (NTP, 1986). ~~Based on these effects, decaBDE may share the general property of organohalogenated compounds in which *in vivo* exposure in rodents results in reduction of serum total and free thyroid hormone (T_4) levels (Legler and Brouwer, 2003).~~ Its not clear why this is relevant here.
  - the doses in Zhou were up to 100mg/kg. Seems odd to say that lack of effects is due to insufficient target dose—isnt it really just a lack of effect, considering the high dose?
  - seems odd that the Norris, 1973 study is mentioned for the first time here and is not discussed earlier.

- Page 34- suggest deleting sentence beginning with "a number of studies.." as its not clear what studies these are and all the IRIS drafts find no effect. Also the text says no studies

were found that looked at deca, however the last sentence in this paragraph discusses findings of such a study. This is confusing.

- Page 41-
  - in discussing the choice descriptor it would be useful to provide more information- e.g. the effects are seen at extremely high doses only. Is this a situation where the classification should be dependent on exceeding a certain dose?
  - What does the information on mechanisms and dosing tell us about likelihood of effects at environmental doses? Should this factor into EPAs decision to quantitate?
  - Why does EPA believe the evidence is on the strong end of the spectrum? This is not explained at all. The cancer guidelines call for a narrative discussion. This assessment could do a better job providing this information, in conjunction with the descriptor label.
  - Why is a dose response assessment deemed appropriate here? Considering the high doses tested and the lack of genotoxicity, what is EPAs rationale for doing dose response assessment? This needs to be further bolstered. It seems as though effects in each study were quite limited, particularly considering the doses.

- Page 42- "The increase in the radioactivity in the brain coupled with the behavioral disturbances on exposure to decaBDE on postnatal day 3 appear to suggest that differences may exist in the absorption and metabolism of decaBDE between neonates and slightly older ones and that the effect persisted and also worsened with age." When did the increase in radioactivity occur? Its not clear that significant differences in absorption and metabolism exist.

- Page 44
  - Does it make sense to use the Viberg study for the RfD? There is one study—in one species, in one sex, with essentially no supporting similar studies and no information on mechanism of action. Only 2 doses were tested. The UF EPA wants to apply is 300 and the certainty would be likely low. Is the science strong enough to support the use of this value for clean-ups conducted by program offices?
  - what does the following sentence mean: "In some respects the observation that effects occurred with such limited dosing argues for the importance of this study."?
  - The description of the concerns with the Viberg study is very good. It seems that other than the fact that the neurotox guidelines list functional neurotoxicity as an effect, and that there are PDBEs in human tissues, there is there is no support for relying on this study.

- Page 45-
  - 1st full paragraph: please provide a citation for the discussion of critical windows.
  - Its not clear that MeHg is a great example as there is very little data on specific windows during development that may lead to effects in humans- the large epi studies included exposures that occurred throughout development and into childhood. Suggest deleting this as an example. For lead, do we know of specific developmental windows where there is an effect?

- Is 20mg/kg a reasonable dose to expect humans to receive? Is this dose level relevant to todays exposure levels?
- Does it make sense to set an RfD in this situation?? Is there anything EPA is confident of? Are there any data on mechanism of action that may help?

- Page 48
  - suggest deleting: 'Furthermore, a developmental neurotoxicity study in mice has been conducted (Viberg et al., 2003)." Considering all the problems with the study design, its hard to believe that EPA believes this study fulfills all the criteria for DNT testing.
  - Its not clear to me why an UF for database is not needed here. What is it that makes the Deca database so much stronger than the other BDEs?
  - Is this sentence true: "When an RfD is based on systemic NOAEL of 1120 mg/kg/day from the NTP study, a database UF should be applied." Doesn't it depend on the database not the actual study that was used?

- Page 49-discussion of EPAs confidence in the proposed RfD is missing.

- Page 52-
  - Just because the data can be modeled, doesn't explain why quantitation is conducted, when the weight of evidence is only suggestive and for each endpoint the strength of evidence is relatively weak. Did EPA choose to model only because it could be done? What is EPAs confidence in the values that come out of the model considering the WOE?
  - why did EPA choose to use the linear multistage model? Were any other options discussed or tried? Does the fact that not mutagenicity is seen decrease EPAs confidence in doing this quantitatively?

- Page 53
  - what has changed since 1987, when EPA decided not to do a quantitative cancer value?
  - how does the NRC cancer slope factor derivation differ from the EPA derivation? Did they use similar methodologies and similar studies? If not, why were EPAs choices different?

- Page 54
  - "DecaBDE also has been shown to induce **spontaneous motor behavior changes in one study of male mice** ~~neurobehavioral toxicity~~."
  - "These data suggested that there is a critical window for the induction of behavioral disturbances, and the neurotoxic effect of neonatal decaBDE exposure was persistent and also worsened with age **in male mice.**

- Page 55
  - more narrative discussion of the cancer classification is needed.

- "In addition, only **one study** ~~limited tests~~ on motor activity **was** ~~were~~ conducted. This paragraph certainly undermines EPAs rationale for why a database UF is not needed.

- Page 56- considering that the evidence is suggestive, EPA should discuss how reliable the slope factor value is believed to be. What is the confidence in this number? Does EPA suggest that it be broadly used? Is there a dose level above or below which is should be used?

NIEHS comments:

December 2005
CHARGE TO EXTERNAL REVIEWERS FOR THE IRIS TOXICOLOGICAL REVIEWS OF
2,2',4,4'-Tetrabromodiphenyl Ether (BDE-47) CASRN 5436-43-1
2,2',4,4',5-Pentabromodiphenyl Ether (BDE-99) CASRN 60348-60-9
2,2',4,4',5,5'-Hexabromodiphenyl Ether (BDE-153) CASRN 68631-49-2
2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl Ether (BDE-209) CASRN 1163-19-5
The U.S. EPA is conducting a peer review of the scientific basis supporting the human health assessment of BDE-47, BDE-99, BDE-153 and BDE-209 that will appear on the Agency's online database, the Integrated Risk Information System (IRIS). The draft documents for the external peer review contain a description of the oral database, reference dose, qualitative cancer assessment for BDE-47, BDE-99 and BDE-153, and a quantitative cancer assessment for BDE-209. Please provide detailed responses to the charge questions below.

GENERAL QUESTION
Are you aware of other published peer-reviewed toxicological studies not included in these Toxicological Reviews that could be of relevance to the health assessment of BDE-47, BDE-99, BDE-153 or BDE-209?

1. QUESTIONS RELATED TO THE DERIVATION OF THE REFERENCE DOSE FOR BDE-47, BDE-99, BDE-153 and BDE-209
1.1 Have the rationale and justification for deriving RfDs on the basis of the neurobehavioral toxicity studies been transparently and objectively described in the Toxicological Reviews of BDE-47, BDE-99, BDE-153 and BDE-209? Are there additional studies that should be considered for deriving the RfDs for any of the four PBDE congeners?

The Eriksson, Viberg et al group at the Uppsala Univeristy, Sweden have reported on various neurotoxic effects of the PBDE isomers. Generally it is appropriate to use these studies for the RfDs.

1.2 Are the Eriksson et al., 2001 (BDE-47), Viberg et al., 2004 (BDE-99), Viberg et al., 2003a (BDE-153) and the Viberg et al., 2003b (BDE-209) studies appropriate for determining the point of departure?

1.3 Have the most appropriate critical effect and point of departure been selected? And hasthe rationale for the point of departure been transparently and objectively described?

1.4 Have the rationale and justification for each uncertainty factors (UFs) selected in the draft Toxicological Reviews of BDE-47, BDE-99, BDE-153 and BDE-209 been transparently described? If the selected UFs are not appropriate, what alternative UFs would you suggest and what are the scientific rationales for those suggested?

2. BODY BURDEN APPROACH

2.1 Are there adequate data for considering body burden as an alternative dose metric to administered doses in any of the RfD derivations?

The Birnbaum and Burka references on TK of the PBDEs need to be added and analyzed.

Sanders JM, Burka LT, Smith CS, Black W, James R, Cunningham, ML. 2005. Differential expression of *CYP1A*, *2B*, and *3A* genes in the F344 rat following exposure to a polybrominated diphenyl ether mixture or individual components. Toxicological Sciences, 88:127-33.

Sanders JM, Chen L-J, Lebetkin EH, Burka LT. 2006. Metabolism and disposition of 2,2',4,4'-tetrabromodiphenyl ether following administration of single or multiple doses to rats and mice. Xenobiotica (in press).

2.2 Do you agree with the rationale described in the Toxicological Review of BDE-99 that the data on the window of susceptibility of the cholinergic receptors to BDE-99 tend to minimize body burden concerns?

3. QUESTIONS RELATED TO THE CARCINOGENICITY ASSESSMENT OF BDE-209

3.1 Is the weight of evidence for the carcinogenicity of BDE-209 in the draft Toxicological Review appropriately described? Are there additional studies that should be included?

No – see additional comments below.

3.2 Do the available data support the descriptor *Suggestive evidence of carcinogenic potential* for BDE-209 according to the U.S. EPA. (2005) Guidelines for Carcinogen Risk Assessment? If not, what alternative descriptor would be supported by the existing data and what is the scientific rationale?
OK, but not complete.

3.3 Is the estimation of a cancer slope factor for BDE-209 in the Toxicological Review appropriate? Have the rationale and justification for the use of linear low-dose extrapolation been objectively and transparently presented?

3.4 Are there alternative modeling approaches that should have been considered instead of or in addition to the low-dose extrapolation approach?

See comment on added references.

1-09-06 - EPA Review of PBDEs

The major data gap in our knowledge on the toxicity of the polybrominated diphenyl ethers, is the toxic/cancer potential after long term exposures to these chemicals. The NTP's studies of these compounds is focused on filling this datagap, particularly after in utero/postnatal/adult exposures. It will be several years before these studies are completed.

I. EPA Toxicological Review of BDE-209, BDE-47, BDD-99, and BDE-153

a. The carcinogenicity assessment of BDE-209 is primarily based on the 1986 NTP TR study of decabromodiphenyl ether. The NTP TR reference (and also the NTP web site reference) should be added to the reference list for this report. This NTP study is used for the EPA Benchmark dose modeling.

The oral RfD for BDE-209 is 7 ug/kg/day (NTP Study, 1986); Viberg 2003).

The oral RfD for BDE-47 is 0.1 ug/kg/day (Eriksson, 2001; neurobehavioral study in mice).

The oral Rfd for BDE-99 is 0.1 ug/kg/day (Viberg, 2004 reference – locomotion and rearing habituation in mice).

The oral Rfd for BDE-153 is 0.2 ug/kg/day (Viberg 2003 reference – spontaneous motor behavior, learning, and memory endpoints in mice).

b. Missing from the EPA Toxicologic review of decabromodiphenyl ether (BDE-209) is a complete analysis of BDE-209 to the environment and the resultant chemical exposures.. When decabromodiphenyl ether is released into the environment does the chemical break down to lower brominated diphenyl ethers? If so, the hazard from exposure may be more extensive.

Decabromodiphenyl ether - does this chemical break down to lower brominated diphenyl ethers?

1. Stapleton, H.M., R.J. Letcher, and J.E. Baker, *Debromination of polyhrominated diphenyl ether congeners BDE 99 and BDE 183 in the intestinal tract of the common carp (Cyprinus carpio).* Environmental Science & Technology, 2004. **38**(4): p. 1054-1061.
2. Eriksson, J., et al., *Photochemical decomposition of 15 polybrominated diphenyl ether congeners in methanol/water.* Environmental Science & Technology, 2004. **38**(11): p. 3119-3125.
3. Bezares-Cruz, J., C.T. Jafvert, and I. Hua, *Solar photodecomposition of decabromodiphenyl ether: Products and quantum yield.* Environmental Science & Technology, 2004. **38**(15): p. 4149-4156.

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4. Watanabe, I. and S. Sakai, *Environmental release and behavior of brominated flame retardants.* Environment International, 2003. **29**(6): p. 665-682.
5. Gouin, T. and T. Harner, *Modelling the environmental fate of the polybrominated diphenyl ethers.* Environment International, 2003. **29**(6): p. 717-724.
6. Keum and Li. *Reductive debromination of polybrominated diphenyl ethers by zerovalaent iron.* Environ Sci Techonology, 2005.
7. Hites, *Global assessment of polybrominated diphenyl ethers in farmed and wild salmon.* Environ Sci Technol. 38: 4945-9, 2004

c. Calculations to determine the amount of PBDEs released into the environment, and how this correlates to environmental concentrations should be calculated. An update on the CDC nhanes data for the PBDE monitoring program would be helpful.

d. The EPA reviews of PBDEs omit the ATSDR Reference for the Toxicologic Profiles for these chemical: ATSDR Profile on PBDEs

http://www.atsdr.cdc.gov/toxprofiles/tp68.html

d. Other References:

McDonald, T. A. Polybrominated diphenylether levels among United States residents: daily intake and risk of harm to the developing brain and reproductive organs, Integrated Enviroinmental Assessment and Management 1: 343-354, 2005.

D'Silva et al. Brominated organic micropollutants – igniting the flame retardant issu. Critical Reviews in Environmental Science and Technology 34: 141-207, 2004.

Other References:

Kodavanti and Ward, Differenctial effects of commercial polybrominated diphenyl ether and polychlorinated biphenyl mixtures on intracellular signaling in rat brain in vitro Toxicologic Sciences 85: 952-962, 2005.

Stapleton et al Polybominated diphenyl ethers in house duse and chlotes dryer lint, Envi Science Technology 39: 925-931,2005.

Brown et al. Analysis of AH receptor pathway activation by brominated flame retardants. Chemosphere 55: 1509-1518,2004.

Weber and Kuch. Relevance of BFRs and thermal conditions of the formation pathways of brominated and bromanted-chlorinated dibenzodioxins and dibenxofurans. Environmental Internation 29: 699-710, 2003.

Gallard et al Rate contants of reactions of bromine with phenols in aqueous solution. Water Research 37: 2883-2892, 2003.

Talsness et al Ultrastructural changes observed in rat ovaries following in utero and lactational exposure to low doses of a polybrmonated flame retardant. Tox. Let 157: 189-205, 2005 .

Kuriyama et al. Developmental exposure to low-dose PBDE-99 effects on male fertility and neurobehaviro in rat offspring. Envi Health Persp. 113:149-154, 2005.

Smeds and Saukko. Brominated flame retardants and phenolic endocrine disrupters in Finnish human adipose tissue. Chemosphere 53: 1123-1130, 2003.

Darnerud and Risberg. Tissue localization of tetra- and pentabromodiphenyl ether congeners 9BDE-47,-85-, and -99) in perinatal and adult C57Bl mice. Chemosphere 62; 485-93, 2006.

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Background Information on Chemicals with hormone action

Book I

I. General Background

1. de Wit, C.A., *An overview of brominated flame retardants in the environment.* Chemosphere, 2002. **46**: p. 583-624.
2. Birnbaum, L.S. and D.F. Staskal, *Brominated flame retardants: Cause for concern?* Environmental Health Perspectives, 2004. **112**(1): p. 9-17.
3. Darnerud, P.O., *Toxic effects of brominated flame retardants in man and in wildlife.* Environment International, 2003. **29**(6): p. 841-853.
4. Legler, J. and A. Brouwer, *Are brominated flame retardants endocrine disruptors?* Environment International, 2003. **29**(6): p. 879-885.
5. Vos, J.G., et al., *Brominated flame retardants and endocrine disruption.* Pure and Applied Chemistry, 2003. **75**(11-12): p. 2039-2046.
6. Alaee, M., et al., *An overview of commercially used brominated flame retardants, their applications, their use patterns in different countries/regions and possible modes of release.* Environment International, 2003. **29**(6): p. 683-689.

INTERAGENCY DRAFT DELIBERATIVE

II. Polybrominated Diphenyl Ethers

A. PBDE Hormone action

1. Zhou, T., et al., *Effects of short-term in vivo exposure to polybrominated diphenyl ethers on thyroid hormones and hepatic enzyme activities in weanling rats.* Toxicologic Sciences, 2001. **61**: p. 76-82.
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3. Stoker, T.E., et al., *Assessment of DE-71, a commercial polybrominated diphenyl ether (PBDE) mixture, in the EDSP male and female pubertal protocols.* Toxicological Sciences, 2004. **78**(1): p. 144-155.
4. Meerts, I.A.T.M., et al., *In vitro estrogenicity of polybrominated diphenyl ethers, hydroxylated PBDEs, and polybrominated bisphenol A compounds.* Environ. Health Perspect., 2001. **109**: p. 399-407.

B. PBDE General Exposure information

1. Sjodin, A., et al., *Retrospective time-trend study of polybrominated diphenyl ether and polybrominated and polychlorinated biphenyl levels in human serum from the United States.* Environmental Health Perspectives, 2004. **112**(6): p. 654-658.
2. Hites, R.A., *Polyhrominated diphenyl ethers in the environment and in people: A meta-analysis of concentrations.* Environmental Science & Technology, 2004. **38**(4): p. 945-956.
3. Petreas, M., et al., *High body burdens of 2,2 ',4,4 '-tetrabromodiphenyl ether (BDE-47) in California women.* Environmental Health Perspectives, 2003. **111**(9): p. 1175-1179.
4. Alcock, R.E., et al., *Understanding levels and trends of BDE-47 in the UK and North America: an assessment of principal reservoirs and source inputs.* Environment International, 2003. **29**(6): p. 691-698.
5. Covaci, A., S. Voorspoels, and J. de Boer, *Determination of brominated flame retardants, with emphasis on polybrominated diphenyl ethers (PBDEs) in environmental and human samples - a review.* Environment International, 2003. **29**(6): p. 735-756.
6. Law, R.J., et al., *Levels and trends of polybrominated diphenylethers and other brominated flame retardants in wildlife.* Environment International, 2003. **29**(6): p. 757-770.
7. Hale, R.C., et al., *Polybrominated diphenyl ether flame retardants in the North American environment.* Environment International, 2003. **29**(6): p. 771-779.
8. Sjodin, A., D.G. Patterson, and A. Bergman, *A review on human exposure to brominated flame retardants - particularly polybrominated diphenyl ethers.* Environment International, 2003. **29**(6): p. 829-839.
9. Hooper, K. and J.W. She, *Lessons from the polybrominated diphenyl ethers (PBDEs): Precautionary principle, primary prevention, and the value of community-based body-burden monitoring using breast milk.* Environmental Health Perspectives, 2003. **111**(1): p. 109-114.

Book II

C. Other PBDE biological effects

1. Helleday, T., et al., *Brominated flame retardants induce intragenic recombination in mammalian cellsMutation Research.* Mutation Research, 1999. **439**: p. 137-147.
2. Kemmlein, S., D. Herzke, and R.J. Law, *BFR - governmental testing programme.* Environment International, 2003. **29**(6): p. 781-792.
3. Hakk, H. and R.J. Letcher, *Metabolism in the toxicokinetics and fate of brominated flame retardants - a review.* Environment International, 2003. **29**(6): p. 801-828.
4. Viberg, H., A. Fredriksson, and P. Eriksson, *Neonatal exposure to polybrominated diphenyl ether (PBDE 153) disrupts spontaneous behaviour, impairs learning and memory, and decreases hippocampal cholinergic receptors in adult mice.* Toxicology and Applied Pharmacology, 2003. **192**(2): p. 95-106.
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III. Tetrabromobisphenol A

1. Meerts, I.A.T.M., et al., *Potent competitive interactions of some brominated flame retardants and related compounds with human transthyretin in vitro.* Toxicologic Sciences, 2000. **56**: p. 95-104.
2. Kitamura, S., et al., *Thyroid hormonal activity of the flame retardants tetrabromobisphenol A and tetrachlorobisphenol A.* Biochemical and Biophysica Research Communications, 2002. **293**: p. 554-559.
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4. Samuelsen, M., et al., *Estrogen-like properties of brominated analogs of bisphenol A in the MCF-7 human breast cancer cell lines.* Cell Biology and Toxicology, 2001. **17**: p. 139-151.
5. Brown, D.J., et al., *Analysis of Ah receptor pathway activation by brominated flame retardants.* Chemosphere, 2004. **55**: p. 1509-1518.
6. Hayama, T., et al., *Determination of tetrabromobisphenol A in human serum by liquid chromatography-electrospray ionization tandem mass spectrometry.* Journal of Chromatography B-Analytical Technologies in the Biomedical and Life Sciences, 2004. **809**(1): p. 131-136.
7. Szymanska, J.A., J.K. Iotrowski, and B. Frydrych, *Hepatotoxicity of tetrabrombisphenol-A: effects of repeated dosage in rats.* Toxicology, 2000. **142**: p. 87-95.

8. Inouye, B., et al., *Effects of aromatic bromine compounds on the function of biological membranes.* Toxicol Appl. Pharmacol, 1979. **48**: p. 467-477.

IV. Sodium chlorate

1. Hooth, M.J., et al., *Subchronic sodium chlorate exposure in drinking water results in a concentatio-dependent increase in rat thyroid follicular cell hyperplasia.* Toxicol Pathol, 2001. **29**: p. 250-259.

Book III

V. Hexachlorobenzene

1. National Toxicology Program, *Final Report on the 13-Week toxicity study of Hexachlorobenzene.* Battelle Columbus, 2001.

VI. 3,3',4.'-Tetrachlorazobenzene

1. National Toxicology Program, *Final Report on the 13-Week toxicity study of 3,3",4,4'-tetracloroazobenzene.* Battelle Columbus, 2001.

VII. Decabromodiphenyl ether - does this chemical break down to lower brominated diphenyl ethers?

1. Stapleton, H.M., R.J. Letcher, and J.E. Baker, *Debromination of polyhrominated diphenyl ether congeners BDE 99 and BDE 183 in the intestinal tract of the common carp (Cyprinus carpio).* Environmental Science & Technology, 2004. **38**(4): p. 1054-1061.
2. Eriksson, J., et al., *Photochemical decomposition of 15 polybrominated diphenyl ether congeners in methanol/water.* Environmental Science & Technology, 2004. **38**(11): p. 3119-3125.
3. Bezares-Cruz, J., C.T. Jafvert, and I. Hua, *Solar photodecomposition of decabromodiphenyl ether: Products and quantum yield.* Environmental Science & Technology, 2004. **38**(15): p. 4149-4156.
4. Watanabe, I. and S. Sakai, *Environmental release and behavior of brominated flame retardants.* Environment International, 2003. **29**(6): p. 665-682.
5. Gouin, T. and T. Harner, *Modelling the environmental fate of the polybrominated diphenyl ethers.* Environment International, 2003. **29**(6): p. 717-724.

CDC comments:

CDC/ATSDR General Comments:

We have very few comments concerning the approach taken for the assessment of the

new RfD for BDE-47, BDE-99 and BDE-153. We are happy to see that EPA is now basing the risk assessment to a large extent on the work of Erikson and co-workers as the most sensitive endpoint of PBDE exposure, while at the same time describing in an objective manner the limitations of these studies.

Page 1, line 3 in the BDE-153 document: At this location please change BDE-99 to BDE-153.

Attachment B

DBT

John Vandenberg /DC/USEPA/US
02/07/2006 02:34 PM

To: Bob Benson/P2/R8/USEPA/US@EPA, Mary Manibusan/DC/USEPA/US@EPA, Amy Mills/DC/USEPA/US@EPA, Karen preuss.peter@epa.gov, George Alapas/DC/USEPA/US@EPA
cc:
bcc:
Subject: Interagency/OMB comments on Draft IRIS assessment of Dibutyl Phthalate

Please see below for a number of specific comments from CDC and also OMB, it is possible other comments from CPSC will be provided later. In general, I see many technical edits and corrections, with a few bigger issues as well (e.g., the comments on pages 74-85).

Our approach to these interagency comments (for perc and dichlorobenzenes) has been to carefully evaluate the comments and to develop a response to comments document. I recommend you create a document that addresses each comment (include their "comment" and our "responses" as one file) and provide a point-by-point evaluation. I encourage that the tone of our 'responses' be thoughtful and that we make such changes as we deem warranted. If there are some larger science-policy issues or points made where it is unclear how to respond, then flag these for discussion.

Please give me a sense of the time it may take you to respond to these comments (I'd expect a few weeks). Thank you for all your hard work on this document, it seems we'll soon be able to move ahead!

John

John Vandenberg
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National Center for Environmental Assessment B243-01
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----- Forwarded by John Vandenberg/DC/USEPA/US on 02/07/2006 02:21 PM -----

"Beck, Nancy" <Nancy_Beck@omb.eop.gov >
02/07/2006 09:50 AM

To: John Vandenberg/DC/USEPA/US@EPA
cc: Peter Preuss/DC/USEPA/US@EPA
Subject: RE: Draft IRIS assessment of Dibutyl Phthalate

OMB coms
- sim to OMB rags
- precursor events of adversity. Reduced testosterone. Biochem. change.
- moa rel to humans? (Ag. trad'y assumes relevance). (Hormone)
(what level in rodent rel. to humans ??) --> clinical link to change.
- concordance
(need epi data?)
(- precursor effects OK vis cancer g/lines.)
- where's data coming from - rodent only?

Hi John,
Attached are agency comments on the draft. Its possible CPSC may have some comments as well, but here are some to get you started.

Please let me know if you would like to talk through EPA responses to comments or if EPA will provide a written response. I'm happy to answer and questions and facilitate any needed dialogue with CDC as well. Otherwise, we will look forward to seeing a revised draft and responses to comments.

Many thanks,
Nancy

-----Original Message-----
From: Vandenberg.John@epamail.epa.gov
[mailto:Vandenberg.John@epamail.epa.gov]
Sent: Friday, December 02, 2005 12:34 PM
To: Beck, Nancy
Cc: Boone.Amanda@epamail.epa.gov; Mills.Amy@epamail.epa.gov; preuss.peter@epamail.epa.gov
Subject: Draft IRIS assessment of Dibutyl Phthalate

Hi Nancy,
Here is the next draft IRIS assessment for you to look at (if you want!). Attached is the draft dibutyl phthalate tox review and draft charge questions.
This has been developed within the agency and has completed intra-agency review by the IRIS reviewers. It has not been shared with other agencies and we are not aware of any particular interest by other agencies. Our plan is to announce the availability of the document in the FR and have the document externally reviewed through a panel review (organized and managed by a contractor, timed to allow public comments to be provided prior to panel meeting).
Let me know if you have any questions about the draft.
Thanks,
John
(See attached file: Charge DiBP ext peer review3.wpd) (See attached file: Tox R DiBP ext peer review2.wpd)

John Vandenberg
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DibutylPhthalateAgencycomments.doc

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February 6, 2006 (there may be more comments coming from CPSC)

CDC Comments

Page 6, 2nd paragraph, 2nd sentence: It needs to be mentioned that there are esterases in some biological matrices, including amniotic fluid, saliva, and breast milk, that could hydrolyze DBP to MBP. Therefore, MBP could be detected in some tissues as a result of contamination with DBP that it is hydrolyzed to MBP by esterases.

Page 7, section 3.2: The Silva et al., 2003 ref (2nd line of 1st paragraph) doesn't have rats data: It should be deleted.
Last sentence of paragraph: It is not that the omega and omega-1 oxidation products of MBP were not detected, but that they were not measured. The sentence should be rewritten: Monobutyl phthalate and monobutyl phthalate glucuronide have been found in human blood and urine, but the products of omega and omega-1 oxidation have not been MEASURED (Silva et al., 2003).

Page 8, Figure 1: The correct name of the structure at the bottom right of the scheme is: 3-carboxypropyl NOT 4-carboxypropyl

Page 9, 1st paragraph: The concentrations reported in the draft from the Silva et al., 2003 paper are MEDIAN, not mean (as stated). Also, indicate the number of human samples analyzed: 283.

Page 16, 2nd paragraph, line 7: As written, it appears that in the Silva et al., 2003 paper the concentration values 14.4 and 4.2 were given. However, this statement is incorrect: The value 14.4 was given in Silva et al., 2003 (Table 2 of the manuscript). The value of 4.2 was not. If this value was calculated by EPA from data provided in Silva et al., 2003, this should be clearly indicated.

Page 16, 2nd paragraph, line 4: The presence of MBP in tissues other than urine could come, at least partially, from the hydrolysis by esterases present in the tissues of the ubiquitous DBP introduced in the sample during sampling or storage. Furthermore, the concentrations of MBP in tissues/fluids other than urine in humans are relatively low when compared to urinary concentrations. For these reasons, urinary data may be more reliable than serum data for MBP: higher MBP concentrations in urine than in serum, and minimal esterase activity in urine compared to serum. Urine, however, unlike blood/serum, is a non-regulated fluid, so dilution of urine due to hydration status may complicate calculations.

Page 17, 2nd paragraph: The Calafat et al. (2005) reference (in press at the time the draft was written) has been published. The correct citation is Calafat et al. (2006):
Calafat, A.M., Brock, J.W., Silva, M.J., Gray, L.E., Reidy, J.A., Barr, D.B., Needham, L.L., 2006 Urinary and Amniotic Fluid Levels of Phthalate Monoesters in Rats after the Oral Administration of Di(2-ethylhexyl) Phthalate and Di-n-butyl Phthalate. Toxicology 217, 22-30.
This citation can also be updated in page 90 (reference list)

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Page 19, 1st line: Colon et al. (2000) didn't measure monobutyl phthalate in serum. They measured the parent compound, dibutyl phthalate (DBP). Therefore, the reference to this study should be deleted.
Page 19, 2nd paragraph: Data from NHANES 2001-2002 are available at www.cdc.gov/exposurereport/, so Table 3-5 could be updated to also include these data.

Page 19, 2nd paragraph: In CDC's publication using the NHANES 1999-2000 data (Silva et al, 2004a), it was shown that women of reproductive age (30-39 years old) DID NOT have higher concentrations of MBP than younger or older women. This is shown in Figure 4 of the Silva et al., 2004a paper. This finding is not mentioned in this draft and it should, especially because the draft does mention the findings from the NHANES III dataset in the 1st paragraph of this page regarding pregnant women.

Page 21: The calculation of the estimated dose conducted by Kohn et al. in 2000, used the phthalates NHANES III dataset, which was NOT representative of the U.S. population. Therefore, in page 21, the 7 microg/Kg-day dose for the general U.S. population was taken from 192 individuals and the 32 microg/kg-day for U.S. women of childbearing age was taken from only 97 women. I think here it would be a good place again to indicate the estimated exposure from the NHANES 1999-2000 and NHANES 2001-2002 data.

Page 24, last line of 1st paragraph: Specify that the NHANES samples are from NHANES 1999-2000.

Page 67, 1st paragraph, 3rd line: Delete Silva et al. 2003. In this manuscript no attempt was made to measure analytes other than MBP.

Page 67, 4th paragraph: Rewrite sentence as follows: Two studies have documented an association between some adult human semen measures with exposure to dibutyl phthalate (Murature et al., 1987) and phthalate monoesters (Duty et al., 2003a).

Page 89, end of 1st paragraph: There is only one study that suggests that "the 95th percentile for the general population is approximately 7 μg/kg-day and for women of childbearing age approximately 32 μg/kg-day." Insert the Kohn et al. 2000 reference at the end of the last sentence of the paragraph: this will indicate to the reader the source of the data. I would also suggest that the dose is calculated for the U.S. general population and for women of childbearing age using the NHANES 1999-2000 data presented in Silva et al. 2004a. The phthalates NHANES 1999-2000 and 2001-2002 were representative of the general U.S. population, the NHANES III dataset was not.

OMB Comments

- Page 1 and throughout- please use original, not 2002 recommended RfD definition.

- Page 5, the Anderson 2001 study is referred to as being 'conducted with an ethically approved protocol'. Please clarify in the text what it is that this means.

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- Page 9, in discussing Silva 2003 and elimination, the text should state what the dose (exposure) was otherwise the urine value is not informative regarding elimination rates.

- Page 14 states: "*Although a completed physiologically based pharmacokinetic model for both the rat and human is not yet available, it might be possible to use other data to provide an estimate of the relative exposure of the rat and human fetus to the toxicologically active metabolite, monobutyl phthalate, during the critical window for development of the male reproductive tract. Information on relative exposure could be used to inform the selection of the interspecies uncertainty factor used to derive a reference value.*" These statements are very broad. What is meant by "other data" and in 1st sentence? In the 2nd sentence how might relative exposure information be used to inform an UF? Its not clear how UF's take relative exposure into account-do you mean organ specific internal dose?

- Page 15, how significant is the variability of monobutyl phthalate glucuronide, as discussed in Silva 2003?

- Page 17, for monobutyl phthalate, the range of partition coefficients is 1.9-2.8. Is there a citation for this? Its not clear where the numbers come from.

- Page 18, plots from Kremer 2005a are referred to. This citation is only an abstract. Did it really contain plots?

- Page 19, please state that the 289 samples from Blount, although part of NHANES, should not be considered to be representative as it is not a full NHANES dataset.

- Page 19, table 3-5 is confusing. Its not clear what data is being referred to-is it from the Blount study or Silva or DHHS? Also it would be useful to know if the values are for males or females or both.

- Page 20/21, its not clear at all where the values of 7ug/kg for a 95th percentile and 32 ug/kg for US women comes from. Please clarify. This is very confusing. Also, is the 32ug/kg data a mean or a 95th percentile?

- Page 22, please state whether or not the decrease in mean sperm density seen in Murature was statistically significant?

- Page 22, please state the sample size for the comparison group in Duty et al.

- Page 23, in discussing Duty, 2004, it says the dose response was 'suggestive negative'. Please clarify what this means-was it not statistically significant?

- Page 26, please state whether or not the associations with enzyme levels in Fukuoka and the decreases in Zhou were statistically significant.

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- Page 28, in discussion of Fukuoka please state whether or not changes in testicular fructose and glucose were statistically significant. Also, what may explain the fact that blood concentrations did not change? Is this to be expected?

- Page 35, why are no NOAELs and LOAELs provided for the Gray study?

- Page 43, a NTP 2002 abstract is referred to. Is there no final report to update these data?

- Page 54, refers to a weight of evidence pointing to a dec. in testosterone in leydig cells. Where is this weight of evidence coming from? Its not clear what studies are being referred to here, as the 2 most recently cited studies in the text are both abstracts.

- Page 61, its not clear where or how the studies in 4.3.2 clearly show that monbutyl phthalate is responsible for the toxic effect. Please clarify the reasoning behind this.

- Page 66, states that Dibutyl phthalate is metabolized to monobutyl phthalate and n-butanol. How come n-butanol is never mentioned in section 3.2?

- Page 68, please insert the language in bold in the following 2 sentences:
There are extensive studies documenting developmental toxicity of dibutyl and monobutyl phthalate **in rodents**. A number of studies have examined gene expression for the enzymes involved in steroid biosynthesis **in rodents**.

- Page 69, discussion of MOA should be clear that this is for rodents. Also, there seems to be no discussion about the relevance of this in humans. Is it known that the pathways in humans are the same and that levels of hormones and hormone reserves are similar?

- Page 72, please clarify that this is a proposed MOA in rodents. Also in the figure suggest saying that reduced testosterone and dihydrotestoterone **can** result in… Also reduced Ins3 **may** result in…unless all these effects are proven-although the language in the text makes it sound as though causality is possible but not known with certainty. Also in the figure its not clear if the MOA is for the testis or leydig cell?

- Page 74, why is the decrease in testosterone levels throughout the document referred to as a NOAEL and LOAEL? Isn't it really an NOEL? this should be changed throughout the document (page 85 etc) Even the Lehmann paper itself talks about a NOEL and a LOEL. Page 75 is clear that this is not an adverse effect but is a precursor for all other effects. Is it clear that all adverse developmental effects stem from the decrease in testosterone? From figure 2 it seems as though Ins3 effects are independent of testosterone.

- Page 74, is there a developmental effect in humans that is predicted by retained areolas or nipples in the male fetus? Has EPA relied on this endpoint before?

- Page 75, in perchlorate there is a precedent for regulating based on an upstream precursor effect in humans. However, here EPA is using a precursor effect in rats. A discussion of how levels of testosterone in humans and rodents may be similar in levels, reserves, metabolism, or

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stores is not provided at all. In order to justify using this endpoint, EPA needs to discuss this thoroughly and there needs to be strong evidence that pathways and regulation in humans and rodents, not just for testosterone but also for dibutyl phthalate metabolism are similar.

- Page 75, its not clear how the effect could be due to a single exposure. Text cites Carruthers and Foster, which was a multiday exposure, Thompson was an abstract only which used a 2 day exposure, and its not clear what in EPA 1991 is being referred to. The Developmental guidelines are getting pretty old and the endpoint of changes in hormone levels is not even referred to in this document-the guidelines do not discuss whether or not exposure to a precursor on a single day could justify an adverse effect.

- Page 76, figure 3 and 4 should be made more clear. It would be helpful to perhaps break these into 2 arrays—one showing responses in the 0-400 range and the other showing higher levels. The resolution at the low exposures is what is important here and it is lacking most. Also please be clear about which effects are not adverse.

- Page 79, regarding the # notation, please see the comments for page 75 regarding the exposure window.

- Page 85, in table 5-4, why is BMDL 1SD shown? Its not clear why this endpoint was chosen.

- Page 85, there is discussion as to why the BMD approach was not used and this seems to depend on limitations of the study (position in litter was not considered, gender effects, etc). How do these limitations affect the confidence in the NOEL? It seems that they likely lead to an increase in variability. Also this section is the first time the biological significance of testosterone changes is mentioned. Shouldn't there be more discussion of the levels required for significance in the MOA section of the chapter?

- Page 86, see comment on page 75 regarding single exposures. Suggest deleting this sentence.

- Page 87, its not clear why there is a discussion in the database UF section that is talking about the lack of cancer bioassays and the mode of action for tumors. Suggest deleting this language.

- Page 87, its not clear that the data support an acute, short term, or subchronic RfD. Discussion is not sufficient to support this (see comment regarding page 75).

- Page 88, besides the old RfD, are there any other safety values in existence (ATSDR or CALEPA or other?). It would be useful to mention these.

- Page 89, please change NOAEL to NOEL; please clarify where 7 and 32ug/kg come from and discuss how representative they are; why is the confidence high when there are no human developmental or reproductive data—how dose data in 7 animals translate to high confidence for the RfD?

- B-1, is it normal to use a nested model? What does this imply about the data?

- B-5, Were the data used based on the F1 litter 3 or results from all 5 litters analyzed together?

editorial comments:
Page 16- Saliva 2005 should be Silva 2005
Page 17- in discussing the boron assessment, the ref given is to the cancer guidelines, which does not seem correct
Page 19- refers to "thelarche", do you mean "menarche"?
Page 44- refers to a 10,000ppm:0ppm exposure group. Is this a common way to describe this treatment group?

Other comments:
- What expertise will EPA have on the review panel? How many reviewers in each area?
- Has EPA set an RfD before based on a precursor effect in rodents? Based on retained nipples?
- The charge should be modified to reflect that there is no discussion of an RfC or quantitative cancer assessment
- If EPA continues to rely on the NOEL, the charge will have to have some questions asking about relevance of this precursor to humans, MOA in humans, whether or not this is adverse and at what levels, whether or not this prevents all developmental effects, etc.

Attachment C

Comments from OMB (Margo Schwab)
4-19-05

Comments on the Toxicological Review of Toluene (Feb 2005 draft)

General Comments on RfC

1. Clarity:

We suggest improving the clarity of presentation for both this document and the actual IRIS entry file. Specifically, the document reads like a hybrid of the old focus on "color vision" and the new focus on a suite of "neurological effects."

We suggest a stronger first paragraph that reviews the potential options for the critical endpoint and clearly states that you are using an array or suite of effects, considered together as the critical endpoint. The reasons EPA determined it makes sense to use a suite of endpoints should be more clearly stated here as well.

The detailed comments below provide additional comments designed to help improve the clarity of the document.

2. Description of the Methods Used:

The "Weight of Evidence" method should be clearly explained before presenting the results (although a weight of evidence approach is common for hazard ID, but not for dose-response, thus the need for an explanation). The actual criteria that are used should be described as well. See comments below for page 75.

Some confusion might be due the apparent disconnect between the usual use of "weight of evidence," which describes an approach which weighs all of the evidence, versus it use here to describe a method of classifying available studies based on adequacy. It may be better to describe the choice of the critical endpoint as based on "weight of evidence" approach rather than the choice of the principal study. That is, EPA reviewed all of the studies, and determined that as a whole they present evidence of the potential for neurological effects. However, in determining a point of departure, EPA selected a subset of the highest quality studies to determine an "average" or "typical" level of effect.

3. Transparency with Respect to the Limitations of the Methods:

We suggest adding discussions that clearly lay out the limitations/caveats/concerns and utility associated use of **both** 1) a suite of neurological endpoints as the critical effect and 2) an average or typical metric as the point of departure. Both of these discussions would provide risk managers with the information that they need to understand what she/he is protecting against when they use this RfC.

With respect to the former, the discussion could be added to the paragraph that initially introduces the use of a **suite of endpoints**. The added discussion should highlight (based in part on peer reviewers comments) that some of these neurological endpoints may not actually be "adverse" and others may exhibit fairly high baseline population variability.

With respect to the latter, use of an average **point of departure** from a group of studies that are not strong enough in and of themselves begs the question as to meaning of the relationship being described. The reader needs some guidance as to what it means to

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be "above" or "below" this number since it is not a simple NOAEL or BMD. Perhaps it would be helpful to explain it as a range: "we expect the NOAEL for this suite of neurological effects to be between x and y ppbs." Then go on to explain that you are using the average as a surrogate because of the instability of each of the individual numbers (given both EPA's and the peer reviewer concerns about utility of the individual studies). Perhaps you can show how sensitive the average is to the inclusion of certain studies or the similarity of the average with the use of specific principal studies.

Specific edits re: RfC section:

pg 73, 1st paragraph, line 2: documentation of the "developmental effect in newborn children" is not provided in the prior literature review. pls add cites to the "numerous cases" or delete

pg 73, 2nd paragraph, end of second sentence add "for individual neurological effects"

pg 73, 2nd paragraph, fourth sentence: add "at least one of the following neurological effects" between "on" and "color vision, auditory evoked....."

pg 73, 2nd paragraph, last sentence: it is not clear what the connection is between the two parts of the sentence. Should the Campagna et al 2001 study be cited in with the lower exposure studies at the beginning of the paragraph? Also, isn't this the same thought that is in the second sentence of the next paragraph?

pg 73, 3rd paragraph, second line, add "have" between "or" and "inadequate" (or change it to "do not have adequate").

pg 74, paragraph beginning on prior page: rework 1st sentence on page to focus on the key point: "For example, the study that showed effects at the lowest level of exposure (i.e., color vision at 8 ppb) included individuals who had substantial exposure to compounds other than toluene (Compagna et al. 2001).

pg 74, paragraph beginning on prior page: how does this sentence relate to the theme re: confounding? are you implying that effects were not found due to confounding? If this is so, say so and present the specific ways in which these studies were confounded that the positive studies were not. The sentence, as is, however, could just be moved to the end of the prior paragraph (it would provide the balance to the positive studies listed there.)

pg 75, line 2, insert "the potential for" or "the relationship between" after the phrase "evidence indicating"

pg 75, line 3: see comment above re: term weight of evidence. Since this is the first place this concept is introduced, please clearly define the method used to review and categorize the literature here.

pg 75, 1st full paragraph: please define the basis for determining "adequacy" here - lay out the criteria that used.

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pg 75, 2nd full paragraph: suggest not using the term "discounted" (either here or in the subsequent paragraphs and summary document) because a weight of evidence approach weighs ALL of the evidence. It does not "discount" studies. It does give more weight to stronger studies, but the way the term is being used in this and subsequent pages, it implies the studies were not included. A more appropriate way of explaining would be to describe why lesser weight was given to certain studies (e.g., lower quality or strength, etc).

Table 2: Suggest a more balanced presentation in which highlights both the positive and negative results from the 10 studies are presented - that is, if several endpoints were explored, it is inadequate to just present the positive results given the impact of problem of multiple comparisons on the statistical significance of findings. Some of the information appears to be in the tables, perhaps it is an issue of re-labeling the columns?

Pg 81: 1st paragraph, line 2: not sure why effects other than neurological are being discussed here within the context of the "principal study" given that principal effect has been determined (this whole paragraph seems misplaced – perhaps it belongs as part of the first paragraph on page 72?)

Pg 81: 2nd and 3rd paragraphs, and the 1st paragraph on the next page: all three of these paragraphs discuss on deficits in visual perception, but the context for that discussion is not clear – since the "critical effect" is now a suite of neurological effects, please indicate why one set of effects is discussed.

Comments on the RfD

- It is unclear why the UF of 3 for data base sufficiency is necessary, especially given peer reviewer comments to the contrary.
- If the UF is 3000, it is unclear how the confidence could be "medium"

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Attachment D

December 30, 2003

Summary of OMB comments and EPA responses -
External review draft of the Toxicological Review of Toluene (December 2003)
Prepared by Lynn Flowers, chemical manager for toluene

OMB comment #1: There is concern about precedent being set by using color vision as a critical endpoint and a related concern that there is not sufficient reviewer expertise to address this, particularly the biological relevance. Specific comments included:

-Are there appropriate reviewers to look at this?

-Only 50% of reviewers on previous panel were ok with this and one of these reviewers did not think documentation was sufficient.

-Others asked for increased discussion on biological relevance. This still seems to be missing from the draft.

-The added reviewer with this expertise is an author whom EPA cites for having used this test for environmental relevance in the past, thus he may not be seen as an unbiased reviewer.

-The charge question 2b should directly ask "Is this effect biologically relevant"? This would mean there needs to be experts on the panel that can answer the question. Reviewers from the previous panel sounded like they could not and these same reviewers are on the panel again.

EPA response: The peer review contractor is trying to find another color vision expert and has contacted the panel members with neurotoxicity expertise to inquire about their capability to review/comment on color vision. Additional discussion on the choice of color vision as the critical effect and biological relevance of this endpoint has been added to Section 5.2.1 of the Toxicological Review. The charge question (2b) has been clarified as follows: "The critical effect is identified as impaired color vision. Is this the correct critical effect and is it adequately described? Is the biological basis for choosing this effect adequately explained?"

OMB comment #2: Appendix A is unclear in that all reviewers agreed with the RfD principal study, yet it was changed anyway. Reads as very contradictory and needs to be clarified. Uncertainty factor discussion needs to be clarified.

EPA response: The rationale for the change in the principal study for the RfD has been clarified in Appendix A to better explain that additional key studies were identified as a result of public comment. The discussion on the application of uncertainty factors to the point of departure for the RfD has been corrected.

OMB comment #3: It is unclear why kidney weight changes are used instead of liver weight changes or in addition to liver changes. This is not explained well (especially considering distribution of toluene in the body).

EPA response: The rationale for selecting kidney weight changes as the critical effect for the derivation of the RfD has been further clarified in Section 5.1.1 of the Toxicological Review.

OMB comment #4: It is unclear if discussion of immunological studies belongs in Section 1.A.2 or 1.A.4 of the IRIS summary.
EPA response: The discussion of immunological effects from toluene exposure has been moved to Section 1.A.4 of the IRIS Summary.

OMB comment #5: Use of male rat data instead of male and female data for the RfD does not appear to be supported well, especially considering Section 4.7.2 of the Toxicological Review. If both sexes were used, how different would the value be?
EPA response: Male rat data were used for the derivation of the RfD. The response in male rats was greater than that seen in female rats as indicated in Section 4.2.1.1 of the Toxicological Review. As indicated in Section 4.7.2, male rats and mice have been shown to be more sensitive, in general, to the effects of toluene than females. Thus, the use of data from male rats is supported by the available studies.

Attachment E

John Vandenberg/DC/USEPA/US

John
Vandenberg/DC/USEPA/US
09/13/2004 10:39 AM

To Peter Preuss/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US
cc George Alapas/DC/USEPA/US@EPA, Amy Mills/DC/USEPA/US@EPA
Subject naphthalene - OMB request for briefing

Nancy Beck called me this morning and conveyed several things:

1) John Graham wants a briefing on the naphthalene assessment, focused on process from here (e.g., interagency review, consideration of peer review comments). We should arrange in next couple of weeks if possible.

2) She (Nancy) considers some of the external peer review comments to be significant.

3) they've heard a rumor we plan to have the document out by end of September.

I told her we're evaluating the draft in light of peer review comments, that we've heard DOD plans to comment but we have not received any commentsfrom them and I urged her to get them to share their comments. I sketched out the IRIS process insofar as it would normally proceed, noting that a formal interagency review would change the process (and that we'd share a document that reflects our revisions following external peer review). I mentioned IRIS Track (Paul Gilman had also mentioned it, they're interested in seeing it). I didn't give any specific dates to her (perhaps fortunately IRIS track was offline this morning!)

We should talk through how we want interagency review to occur, including any groundrules we want to get set up front to avoid paralysis (e.g., fixed time for other agencies to provide review comments; final disposition/decisionmaking by EPA/ORD on assessment document completion; criteria or conditions calling for additional external peer review). Especially for "biggies" that have interagency review we need to stake out a process that will lead us to be successful in terms of timeliness, clarity, consistency, etc.

John

John Vandenberg
Associate Director for Health
National Center for Environmental Assessment B240-01
Office of Research and Development, USEPA
Research Triangle Park, NC 27711

DC Research Triangle Park, NC

Attachment F

John Vandenberg/DC/USEPA/US
05/24/2005 02:52 PM

To: Amy Mills/DC/USEPA/US@EPA, preuss.peter@epa.gov, George Alapas/DC/USEPA/US@EPA, Bettyjo Overton/DC/USEPA/US@EPA, Linda
cc:
bcc:
Subject: IRIS process comments from OMB, next steps

In brief, Nancy Beck (and, she says, Dr. Graham) were expecting more detail than provided in the flow chart and 2-pager to address the 'details'. I pushed back, not wanting to have us wait several months to develop new SOPs, as this is premature. Nancy seemed to concur, though she is checking with Dr. Graham.

We ended up agreeing to slightly revise the 2-pager to add a bullet on next steps (i.e., public workshop to discuss process and details/issues) and to emphasize or elaborate on the improvements the process will bring. I've discussed these changes with Amy and she'll revise the 2-pager sent to OMB in preparation for Amy Farrell. Nancy will send over her comments by fax by tomorrow (to DC office, BettyJo - please keep an eye out for this and give copies to addressees here).

Further, I agreed that in our Federal Register notice announcing the workshop, we'll identify some of the topics and issues for discussion including, for example, the attribution of comments to specific reviewers, the criteria for selection of QA Check reviewers, the proposal with respect to a NAS risk assessment panel, the availability of relevant information on web sites, etc. OMB wants to review this FR notice. I emphasized the FR notice will not be exhaustive on what issues will be raised and discussed at the workshop but it will be sufficiently illustrative to inform potential participants as to the details that we will likely seek input on.

We discussed Interagency review and I informed her perc was soon to arrive for interagency review (estimate about a month from now). She clearly is concerned that OMB/OSTP have not worked out a plan for interagency review. I offered that we could help in getting materials prepared for the review process, but it is essential that the request for review come from OMB/OSTP. She asked that the bullet on interagency review refer to EOP rather than "OMB and OSTP will manage interagency review".

Next steps:
1) Amy will revise 2-pager and look also at Nancy's comments to see if any final changes are needed before 2-pager and flowchart are sent to Amy Farrell
2) I'll send a note to Amy Farrell noting that we've discussed with OMB and expect to make final draft revisions to information by end of this week and offer to brief her
3) George, please send (or have BettyJo send) revised 2-pager and flow chart to Amy Farrell later this week.
4) Linda, Amy and IRIS staff should initiate or continue FR development and workshop planning.

John

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Attachment G

OSD-ATL"
<Shannon.Cunniff@osd.mil>
02/02/2006 10:18 AM

To Peter Preuss/DC/USEPA/US@EPA

cc "'Beck, Nancy'" <Nancy_Beck@omb.eop.gov>, "Noe, Paul R." <Paul_R._Noe@omb.eop.gov>, "Beehler, Alex, Mr, OSD-ATL" <Alex.Beehler@osd.mil>, John Vandenberg/DC/USEPA/US@EPA, "Richard Wickman (richard.a.wickman@nasa.gov)" <richard.a.wickman@nasa.gov>, "Bill McGovern (bill.mcgovern@dhs.gov)" <bill.mcgovern@dhs.gov>, "Blaine Rowley (blaine.rowley@em.doe.gov)" <blaine.rowley@em.doe.gov>, Carl Ma <carl.ma@faa.gov>, "Dave Belluck (David.Belluck@fhwa.dot.gov)" <David.Belluck@fhwa.dot.gov>, "James Leatherwood (James.Leatherwood-1@nasa.gov)" <James.Leatherwood-1@nasa.gov>, "'JLeather@hq.nasa.gov'" <JLeather@hq.nasa.gov>, "Juan Reyes (juan.reyes@dhs.gov)" <juan.reyes@dhs.gov>, Keith Holman <keith.holman@sba.gov>, "Martin, Mary" <Mary.Martin@nnsa.doe.gov>, Mike Savonis <michael.savonis@dot.gov>, Paul Atelsek <patelsek@comdt.uscg.mil>, David Moses <David.Moses@hq.doe.gov>

Subject DoD, NASA, DoE comments on IRIS revisions

Peter,
OSD, NASA and DOE Sr. staff have reviewed ORD's proposed IRIS revisions chart and detailed explanation of some of the boxes and attached are our comments and suggestions. DHS and DOT were not on our last calls due to scheduling conflicts, so I can not assert to what degree they support these comments. I will get you a confirmation on that.

What you have attached is a) the flow chart - we added numbers to all the boxes but also retained your numbering of the latter 10 boxes that correspond to your detailed explanation -- and b) an expanded detailed explanation of the boxes that includes, as we discussed, an proposed explanation for every step to help us all achieve clarity and eventually agreement.

These inserts and changes were drafted by a committee of federal staff and recorded by Mitretek (so you might see Mitretek identified as a "commentor". All of our insertions or changes are in color and underlined.

We suggest that after you look this over that we set up another multi-agency meeting to bring all the interested federal agencies together to discuss the process steps and see if together can reach consensus on the process, understand how or if this effort fits with Dr. Gray's visions for IRIS, and develop a plan for next steps.

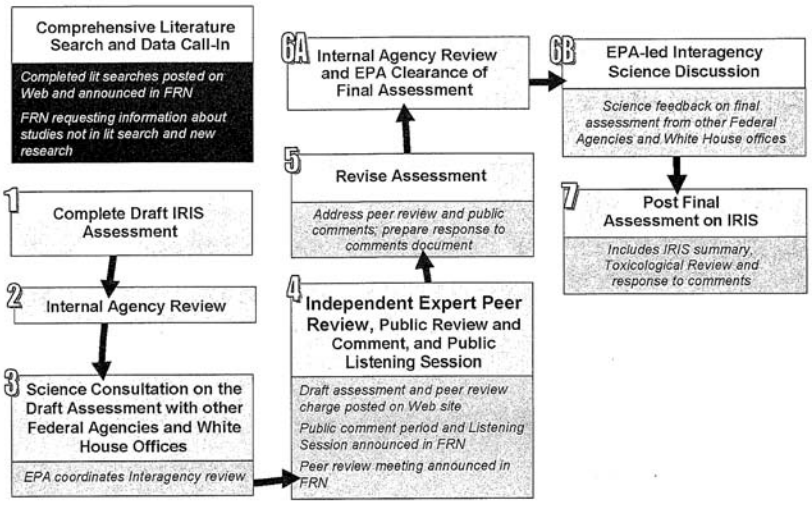
Please call me if you have any questions or comments.

Shannon E. Cunniff
Executive Lead, MERIT
Special Assistant for Emerging Contaminants

Proposed IRIS Process 012406.ppt Detailed Steps 0202061.doc

Attachment H

Assessment Development Process for New IRIS



May 20, 2009

EPA's Integrated Risk Information System

Assessment Development Process

Introduction:

The Integrated Risk Information System (IRIS) is an U. S. Environmental Protection Agency (EPA) database that contains quantitative and qualitative risk information on human health effects that may result from exposure to environmental contaminants.

Through IRIS, EPA provides the highest quality science-based human health assessments to support Agency regulatory activities. IRIS is a key program in EPA's Office of Research and Development (ORD).

The Assessment Development Process:

Prior to the start of the development of the draft IRIS assessment, EPA conducts a scientific literature search and initiates a data call-in:

- Scientific Literature Search
  - ORD appoints a chemical manager for each chemical on the proposed Agenda.
  - The chemical manager(s) direct an EPA contractor to conduct and complete a comprehensive search of the scientific literature for the chemical.
  - Completed literature searches are posted on the EPA's Web site
- Data Call-In
  - After the literature search has been completed for each chemical, EPA publishes a Federal Register Notice (FRN) that notifies the public that completed literature searches for a set of chemicals are available on the IRIS Internet site.
  - FRN invites the public and other agencies to submit additional scientific information (peer reviewed studies, reports, other assessments, etc.) on the chemical.
  - FRN requests information on new research that may be planned, underway, or in press.
  - FRN includes information on how and where to submit scientific information.

After the literature search and data call-in are complete, EPA begins development of the IRIS human health assessment.

All draft human health assessments developed in the IRIS Program are subjected to rigorous, open, independent external peer review. Selected IRIS assessments considered being of major importance or high profile may be peer reviewed by panels of experts convened by EPA's Science Advisory Board or by the National Academy of Sciences. In addition, IRIS assessments developed under the seven step process outlined below, are expected to be completed within approximately two years from the Step 1 start date. Some IRIS assessments, however, because of their complexity, large scientific literature base, or high profile may take longer.

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1. EPA Develops and Completes a Draft IRIS Toxicological Review (Duration 345 days)

A. ORD assembles an IRIS assessment team.

B. ORD assesses the data in the scientific literature and any information submitted as a result of the data call-in and develops a draft assessment for the chemical being assessed, including:

a. summary of potentially important health effects;

b. summary of information on potential mode(s) of action;

c. summary of information about potentially susceptible populations;

d. a quantitative assessment, including application of uncertainty factors, default approaches, mode of action information, and dose-response modeling; and

e. identification of potential uncertainties that impact the qualitative and quantitative aspects of the assessment.

C. ORD completes the draft IRIS Toxicological Review.

2. Internal EPA Review (Duration 60 days)

A. ORD submits the draft IRIS Toxicological Review for internal Agency review.

B. Internal Agency review includes scientists from EPA programs and regions.

C. Internal agency review identifies any scientific issues to determine the level of peer review, needed panel member disciplines, and the scope of the review.

3. EPA Initiates Interagency Science Consultation on Draft IRIS Toxicological Review (Duration 45 days)

A. EPA sends the draft IRIS Toxicological Review and draft external peer review charge to other Federal agencies and White House offices for a science consultation.

B. The science consultation step is managed and coordinated by EPA

a. EPA provides a specified date for receipt of written comments.

b. EPA hosts meeting of other agencies and White House offices to discuss issues raised by comments.

C. All written comments received during Interagency Science Consultation become part of the public record

D. ORD revises the draft assessment documents, as appropriate.

E. If EPA considers appropriate, science questions that arise during science consultation may be included as part of a charge question to the peer review panel.

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4. EPA Initiates Independent External Peer Review of Draft IRIS Toxicological Review, Public Review and Comment on Draft IRIS Toxicological Review, and Holds a Public Listening Session (Duration 105 days)

A. External Peer Review

a. EPA provides the draft IRIS Toxicological Review and peer review charge questions for independent external peer review.

b. EPA publishes an FRN at least 30 days prior to the peer review meeting notifying the public about the time and place of the meeting.

c. Peer reviews are public meetings, generally through a face-to-face meeting of panelists, though some may be held via public teleconference.

d. The report of the external peer review panel becomes part of the official public record for the IRIS assessment

B. Public Review and Comment

a. EPA releases the draft IRIS Toxicological Review for public review and comment.

b. ORD prepares an FRN announcing a public comment period of 60 days.

i. The draft IRIS Toxicological Review is released on EPA's Web site on the day that the FRN is published.

ii. The FRN includes detailed instruction for submitting public comments.

iii. The public comment period is open to all stakeholders, including other Federal Agencies and White House offices.

c. Public comments are submitted to ORD

i. All comments received during the official public comment period will be submitted through E-Gov (www.regulations.gov).

ii. All public comments will be part of the official public record.

iii. Public comments submitted by the close of the comment period will be provided to the peer reviewers at least 10 working days prior to the peer review meeting.

iv. Only those comments received by the close of the public comment period are guaranteed of being provided to the external peer review panel in advance of the peer review meeting.

v. If an extension of a comment period is requested and granted, and a second FRN is published, the comments submitted during the extension may not be able to be provided to the peer reviewers before the meeting.

C. Public Listening Session

a. EPA holds a Public Listening Session after the public release of the draft assessment and before the peer review meeting.

b. The Listening Session provides an opportunity for interested parties to present scientific and technical comments on the draft IRIS health assessment to EPA and other interested parties.

c. An FRN announcing the Listening Session is generally published as least 30 days prior to the Listening Session meeting.

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d. FRN includes all logistical information regarding the meeting.

e. All Listening Sessions are held in the Washington, DC metropolitan area.

5. EPA Revises IRIS Toxicological Review and Develops IRIS Summary (Duration 60 days)

A. ORD evaluates the external peer review panel report and all public comments.

B. ORD revises the draft IRIS Toxicological Review, as appropriate, and develops the IRIS Summary.

C. Length of revision process may depend on the complexity of the IRIS Toxicological Review and complexity and number of peer reviewer and public comments.

D. ORD develops a disposition of peer reviewer and public comments and provides these as an appendix to the IRIS Toxicological Review.

6A.Internal EPA Review of Final IRIS Toxicological Review and IRIS Summary (Duration 45 days)

A. ORD sends the IRIS Toxicological Review and IRIS Summary for final internal Agency review.

B. This review is intended as a final check-in with Agency program and regions.

6B. EPA-led Interagency Science Discussion (Duration 45 days – concurrent with Step 6A.)

A. EPA provides other agencies and White House offices with the final draft of the IRIS Summary and Toxicological Review and appendix describing disposition of peer review and public comments.

B. Other agency and White House Office scientists have opportunity to provide written scientific feedback.

C. EPA hosts meeting with White House offices and other agencies to discuss any scientific issues related to the final draft of the IRIS Summary and Toxicological Review and appendix.

D. All written comments by other agencies and White House offices documented in the record.

7. EPA Completion of IRIS Toxicological Review and IRIS Summary (Duration 30 days)

A. ORD completes the IRIS Toxicological Review and IRIS Summary.

B. ORD prepares the final assessment for Agency's Web site posting.

C. ORD insures 508 Compliance and EPA Web site compliance.

D. ORD posts the assessment to the IRIS data base.

E. ORD completes and maintains the public record.

TOTAL: 23 Months

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The IRIS Information Roadblock:

How Gaps in EPA's Main Toxicological Database Weaken Environmental Protection

by CPR Member Scholars Rena Steinzor and Wendy Wagner and
CPR Policy Analyst Matthew Shudtz

CPR CENTER FOR PROGRESSIVE REFORM

©Center for Progressive Reform White Paper #904
June 2009

The IRIS Information Roadblock: How Gaps in EPA's Main Toxicological Database Weaken Environmental Protection

Executive Summary

The Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) is considered by many to be the gold standard database for toxicological information and human health effects data, used by risk assessors around the world. Information for chemicals that are included in the database is authoritative and accessible to anyone with an Internet connection, and the IRIS website receives as many as 20,000 hits daily.

IRIS profiles serve as a "cornerstone" for a host of decisions in the public and private sector. In regulating hazardous air pollutants under the Clean Air Act, determining what type of remediation is proper for a particular brownfield development, or any number of other important decisions to protect public health, worker safety, and the environment, the ultimate choices are based on what is in essence a two-step process – (1) scientists conduct a risk assessment and (2) policymakers use that risk assessment to inform their decisions about risk management.[1]

Data in the IRIS database can be used to answer some of the fundamental questions in the risk assessment step, which is what makes the database so important. Individual chemical profiles found in the database present the acceptable numerical dose of each chemical that, if ingested (eaten), inhaled, or absorbed through the skin could cause cancer, brain damage, respiratory illness, and a raft of other adverse health effects. To come up with these crucial cornerstones for pollution control, EPA scientists compile the best available scientific research, study and debate disparate and sometimes contradictory research findings, and consider the "weight of the evidence" to derive the numbers. All of this is done according to a step-by-step process, and informed by detailed guidelines. EPA's scientists are well-respected internationally and the agency is the final arbiter of environmental protections at home, so the imprimatur placed on toxicological values at the end of the IRIS process gives them great weight.

Unfortunately, EPA's efforts to update and supplement IRIS have slowed to crawl in recent years as special interests—especially the Office of Management and Budget (OMB), the

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The authors thank Leila Ashkeboussi for her assistance in developing the tables in this report and analyzing the current coverage of hazardous air pollutants in the IRIS database.

[1] *See* NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *Science and Decisions: Advancing Risk Assessment* (2009), and NATIONAL RESEARCH COUNCIL, NATIONAL ACADEMY OF SCIENCES, *Risk Assessment in the Federal Government: Managing the Process* (the "Red Book") (1983).

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Department of Defense (DOD), the Department of Energy (DOE), and the National Aeronautic and Space Agency (NASA) have thrown unwarranted barriers in its path. The result is that IRIS, which should provide a crucial foundation for protection, is outdated, incomplete, and ultimately ineffective. As just one central example of the implications of IRIS sabotage, this report examines how many "hazardous air pollutants" (HAPs) identified by Congress in 1990 for rapid regulatory controls are either omitted from IRIS or characterized inadequately in the database:

- 17 percent of the hazardous air pollutants—32 HAPs in all--are missing completely, including highly toxic and pervasive chemicals like hydrogen fluoride and chloroprene; and
- 67 percent (the 32 without profiles, plus 94 others that have only partial profiles), including formaldehyde and methanol, lack information about the most relevant data point needed to devise controls for toxic air pollution – the inhalation reference concentration.

Unfortunately, the widespread use of IRIS has motivated potential targets of these decisions – including regulated industries, defendants in toxic tort lawsuits, and government agencies that use and dispose of toxic chemicals--to demand a prominent role in changing the numbers developed by EPA scientists. These special interests recognize that IRIS profiles can result in decisions that will increase their operating expenses, and have become adept at influencing the process by which chemical profiles are included in IRIS. During the Bush Administration, they had important allies at the Office of Management and Budget (OMB) who successfully imposed so many opportunities for review and second-guessing that EPA found it very difficult to update IRIS.

The process for crafting a new IRIS profile underwent two rounds of revision during the Bush Administration. Both increased the opportunity for special interests and OMB economists to challenge EPA scientific findings. Recognizing the implications of these biased and unwarranted procedures for scientific integrity within the government, on May 20, 2009, EPA Administrator Lisa Jackson revised these procedures for a third time, making strides toward streamlining the process but failing to go far enough to liberate the process from inappropriate interference.

The Jackson reforms leave two major issues unresolved. First, the process still offers too much opportunity for other government agencies to wield excessive influence over decisions that should be left to EPA scientists and IRIS program staff. The revised process maintains an interagency review process that grants agencies with a vested interest in the final content of an IRIS profile special opportunities for input and influence. As a result, DOD, which, as the nation's largest source of toxic waste has a decidedly parochial interest in the outcome of IRIS decisions, will continue to have privileged access to the development of the profile. This privileged treatment is unwarranted because, for the purposes of IRIS profiles, DOD has no more

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expertise to offer, and exactly the same underlying motivation, as the private sector actors who are provided an ample, but single, opportunity to comment on the profile. Just as it would be wrong for EPA to give any other special interest privileged access beyond what is available during the public comment period, so too should special interests within the government be denied this second opportunity to distort the agency's scientific deliberations. **The entire interagency review process undermines the scientific integrity of the IRIS process and should be abandoned.**

The second issue left unresolved by Administrator Jackson's revisions is how EPA will determine which new chemicals should be added to the database and which existing IRIS profiles need to be updated. **EPA should revise its agenda for expanding the IRIS database so as to ensure that the agency has the tools necessary to achieve its statutory mandates. For instance, EPA should commit to completing individual profiles for Clean Air Act HAPs within specific, reasonable periods of time.**

Introduction

Originally created in 1985 as a centralized source of health effects information that was previously scattered throughout the agency's program and regional offices, EPA's IRIS database is an important source of information about the potential human health effects of chemicals for individuals, groups, and institutions that need accessible and accurate information about toxic chemical risks. The database is accessed thousands of times daily, by users around the world. The health effects information contained in the database is used by EPA staff making risk management decisions about air and water quality standards, hazardous waste site remediation and more, as well as by litigants in toxic tort cases, state-level environmental regulators, and academic researchers.

In its final form, an IRIS profile will contain both quantitative and qualitative information about a toxic chemical. The qualitative aspects of a profile provide information about the potential adverse health effects posed by exposure to the chemical. The quantitative information estimates the level of daily exposure to a chemical that will result in adverse health effects, and is expressed as an oral reference dose (RfD), inhalation reference concentration (RfC), oral slope factor, or oral and inhalation unit risks for carcinogenic effects. The profile will also contain qualitative discussion of the studies that EPA staff considered in developing the RfD, RfC, or other data point. IRIS profiles also describe the uncertainties encountered in the assessment process and EPA's confidence in its conclusions.

The scientific validity of the end result is important because the information in an IRIS profile can be used to answer vital questions in the risk assessment/risk management process, the fundamental decisionmaking paradigm that drives most environmental and public health decisions. Under the Clean Air Act, Safe Drinking Water Act, and various other statutes, the

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basic structure of EPA's regulatory program is a two-step process: (1) risk assessment, and (2) risk management. In its influential "Red Book" (the most widely cited resource on basic risk assessment policy), the National Academy of Sciences provides a concise explanation of the risk assessment/risk management process:

> Risk assessment is the use of the factual base to define the health effects of exposure of individuals or populations to hazardous materials and situations. Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.[2]

IRIS profiles are most pertinent to the risk assessment stage of environmental and public health decisions. Risk assessment involves four distinct steps: (1) hazard identification; (2) dose-response assessment; (3) exposure assessment; and (4) risk characterization.[3] IRIS profiles can be used to complete the first two steps, making the database a powerful utility for anyone involved in risk assessment/risk management decisionmaking.

In short, the data in IRIS reflect, or at least ought to reflect, the best information available to the government about the risks associated with a broad range of chemicals in commerce. That information ought to be accurate, current, and comprehensive.

But as IRIS has become an important central repository for health effects information, it has also become a focal point of advocates' efforts to promote or staunch new decisions to protect public health. The final conclusions posted in a chemical's IRIS profile can have a significant impact on how a party might be regulated under the Clean Air Act or Safe Drinking Water Act, what controls or cleanup might be required for a hazardous waste site containing the chemical, or whether a company will incur liability for exposing workers or the public to the chemical. Obviously, these decisions can have important implications for public health and private firms' bottom lines, so the skilled advocates who are employed to promote those interests will do what they can to shape the information posted in IRIS profiles.

With this increased interest in the IRIS program by special interests, there has been increased interest in the process the EPA staff use to update profiles, particularly the amount and forms of "peer review" undertaken for each profile as it goes from initial staff draft to final posting in the database. In fact, the process for crafting a new IRIS profile has undergone major revisions three times in the last five years and the focus of each revision has been to change which institutions will have the power to review the IRIS program staff's work, when they will be able to exercise those powers, and what effect the outside reviewers' comments will have on the further development of the IRIS profile.

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[2] The "Red Book," at 3.
[3] *Id.*

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In the end, we believe that recurrent review of IRIS profiles by other federal agencies needs to be curtailed. The underlying scientific research supporting IRIS profiles has already been peer reviewed. IRIS program staff have the experience, education, and training to adequately review the existing literature and make scientifically valid decisions, and each additional layer of review threatens the integrity of the process and delays the development of new profiles and updates to existing profiles. Some review – such as review by other EPA program staff and independent experts – is useful and necessary, but some – particularly interagency review – is, in effect, nothing but stakeholder interference masked as "peer review."

After discussing the most recent changes to the IRIS process, we will present evidence of a major gap in the IRIS database – the lack of information about hazardous air pollutants that EPA is responsible for regulating under the Clean Air Act Amendments of 1990.

The IRIS Process: New Revisions and Old Problems

Before 2004, the process for adding a chemical profile to the IRIS database was far less complex, and it produced the quality of information that gave the database its reputation as a useful source of information for a variety of risk assessment/risk management decisions. Yet, in the intervening years there have been three attempts to redesign the assessment process, all of which have made it more complex, mainly through additional opportunities for government agencies outside of EPA to review the IRIS program staff's work.

On May 20, 2009, EPA Administrator Lisa Jackson wrote a memorandum asking the Office of Research and Development (ORD) "to immediately implement a new IRIS process that will be more responsive to the needs of the Agency and its government partners in protecting the health of Americans."[4] In a thinly veiled rebuke of the Bush-era changes to the IRIS process and the problems caused by those revisions, Administrator Jackson explained that the IRIS process

> …will be more transparent and timely, and it will ensure the highest level of scientific integrity. The process will be entirely managed by EPA, which will have final responsibility for the content of all IRIS assessments after considering the scientific input of experts at other agencies and White House offices. To guarantee the scientific quality of the IRIS assessments, the process will include the opportunity for public comment and rely on a rigorous, open, and independent external peer review. Changes in EPA's scientific judgments during this public process will be clearly documented and explained, maximizing the transparency of the final product. While still robust, the assessment development process will be shortened to 23 months, speeding the availability of IRIS

[4] Memorandum from Lisa P. Jackson, Administrator, Environmental Protection Agency, to Assistant Administrators et al., Re: New Process for Development of Integrated Risk Information System Health Assessments (May 21, 2009), *available at* http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=489350 (accessed June 5, 2009).

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assessments to the risk assessor community and the public and providing for more timely action to protect public health.[5]

Administrator Jackson outlined the new process in seven steps:

1. EPA develops and completes a draft IRIS toxicological review
2. EPA conducts an internal agency review of the draft
3. EPA initiates interagency science consultation on the draft IRIS toxicological review
4. EPA initiates independent external peer review of the draft IRIS toxicological review, public review and comment on the draft IRIS toxicological review, and holds a public listening session
5. EPA revises IRIS toxicological review and develops an IRIS summary
6. (a) EPA conducts an internal review of the final IRIS toxicological review and IRIS summary
   (b) EPA-led interagency science discussion
7. EPA completion of IRIS toxicological review and IRIS summary

EPA deserves credit for several of these changes. It was a wise decision to abandon the practice of allowing outside parties to name certain chemicals as "mission critical," a designation that enabled other government agencies to essentially hijack the IRIS process. Similarly, Administrator Jackson has done well to remove the unnecessary step of designing and implementing new studies to fill data gaps. Certainty in this area of science is extremely rare, and IRIS profiles are only meant to describe the current state of the science on a given chemical. It was also important for EPA to improve transparency with respect to interagency review of IRIS profile development, insofar as interagency review is necessary. (It is important to note, as the Government Accountability Office (GAO) has,[6] that White House involvement in IRIS profile development is generally through oral communications, which are not explicitly covered in the new policy.) Finally, it was good for EPA to establish its primacy in developing IRIS profiles by eliminating the OMB-led review procedures.

However, the new process leaves two major issues unresolved: it still has potential for allowing institutions other than EPA to wield excessive influence over decisions that should be left to IRIS program staff, and it fails to adequately address the problem of establishing priorities to guide which as-yet un-profiled chemicals will be added to the database first.

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[5] *Id.*

[6] U.S. 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, GAO-08-440, *at* 23 (March 2008).

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The Problem of Interagency Review

One problematic change to the IRIS process implemented during the Bush Administration and retained in Administrator Jackson's new policy is the privileged access to the process for federal agencies outside of EPA. GAO has concluded that several layers of interagency review can actually limit the credibility of an IRIS assessment.[7] The problem is that these agencies are often more concerned about potential future regulation than the efficient development of a high-quality IRIS profile. In other words, their interests align more with special interest groups than with IRIS program staff, creating a situation where they can be tempted to abuse their ability to influence the development of a particular IRIS profile. Moreover, GAO has warned that interagency review is a key factor in "EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database."[8] GAO's concerns have been echoed by EPA's congressional overseers: The U.S. House of Representatives' Committee on Science and Technology, Subcommittee on Investigations and Oversight, released a report detailing how the White House Office of Management and Budget (OMB) exploited the interagency review process to engage in debates that are better suited to other modes of review, like independent external review by scientific experts.

Rocket Fuel in Drinking Water Forces IRIS into Slow Motion

EPA's effort to update the IRIS profile for perchlorate illustrates the delay and obfuscation linked to interagency review. Perchlorate is used as a main ingredient in rocket fuel and in very small doses may disrupt thyroid hormone production by the thyroid gland. Thyroid hormone imbalances can, in turn, negatively impact fetal and neurological development. In recent years, scientists have discovered that substantial portions of waters in the Western United States are contaminated with perchlorate. Some 20 million residents of Western states may be exposed to elevated levels of perchlorate in their drinking water.

Perchlorate's ubiquity is due mainly to the Cold War arms race. During that time, solid fuel rockets and missiles were developed as an alternative to liquid-fueled propellants. But as the hundreds of thousands of missiles manufactured during the Cold War reach the end of their useful lives or become obsolete, the military must find some way to dispose of them. For many years, the Army, Navy, and Air Force have disposed of unused munitions using the Open Burning/Open Detonation (OB/OD) method. OB/OD simply entails digging a hole, placing unused missiles in it, filling it, and detonating the missiles. This method is preferred by the military because it is quick and, in the short term, cheap.

Unfortunately, one of the primary constituents of solid rocket fuel is ammonium perchlorate, and when perchlorate-containing munitions are disposed of using the OB/OD method, significant

[7] *Id. at* 43-55.
[8] *Id. at* 22.

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amounts of perchlorate are released into the soil. In some military ranges used for OB/OD, perchlorate has been measured in concentrations of tens of thousands of parts per million. As water leaches through the soil, perchlorate anions attach to chemicals in the water and seep into the groundwater.

Several Western states, particularly California, have begun pushing the Department of Defense (DOD) to clean up perchlorate on its bases before any additional groundwater contamination occurs. Recognizing the monumental costs that it could incur as a result of being forced to clean up all of the perchlorate-contaminated soils on its lands, DOD has refused to start cleanup until a national perchlorate drinking water standard is established.

Recognizing that EPA's development of a national drinking water standard (a risk management decision) is predicated on the development of a robust risk assessment for perchlorate, DOD has made a concerted effort to inject its own policy preferences into the risk assessment process, a campaign that not only slowed the process significantly, but also limited the credibility of the final IRIS profile for perchlorate. EPA began work on a new IRIS profile for perchlorate in 1998. By 2002, EPA staff had come up with a draft assessment and had ushered it through both internal and external peer reviews. But as the agency neared completion of the final IRIS profile, DOD, with the White House and OMB at its side, insisted that EPA ask the National Academy of Sciences to review the draft IRIS assessment. This second, more time-consuming round of external peer review gave DOD another opportunity to try to poke holes in the work of the EPA scientists who had been laboring on the perchlorate assessment for the previous four years. But DOD's critique of the IRIS program staff's work strayed far beyond the scientific questions confronting the panel. DOD sent Colonel Daniel Rodgers to deliver this message to the panel:

> We support this review because we very much want to get the science right, because only credible science can lead to credible decisions.... Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others.... [T]here is no room for reliance on science policy precaution for its own sake.... Every layer of policy precaution inhibits our ability to train ... [putting] our combat forces and, ultimately, our nation at risk.[9]

The fact that DOD and OMB pressured EPA to hold another round of external peer review just so that they could inject these risk management issues into the risk assessment process is disturbing. So too is the fact that it took until 2005 before the final IRIS profile for perchlorate was posted, some seven years after EPA began the process of adding it to the database. The delay was due, in large part, to DOD's obstructionism.

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[9] Colonel Daniel Rodgers, U.S. Air Force, presentation to the National Academy of Sciences Committee to Assess the Health Implications of Perchlorate Ingestion, October 27, 2003, 2-3, *quoted in* Rena I. Steinzor, MOTHER EARTH AND UNCLE SAM: HOW POLLUTION AND HOLLOW GOVERNMENT HURT OUR KIDS (Univ. of Texas Press, 2008).

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Most disturbing about the incident is the fact that the Bush-era creation of a strong interagency review process was designed specifically to give DOD and other potentially affected agencies the opportunity to engage in similar chicanery for any future IRIS profile update. The history of the development of the interagency review process is outlined in the U.S. House Science Committee, Subcommittee on Investigations and Oversight report, "Nipping IRIS in the Bud." The report shows that OMB – not EPA – drove the development of the 2004 and 2008 revisions to the IRIS process and served as a conduit for other agencies suggest how EPA should gather and respond to their concerns on future IRIS profile updates. The report also documents how the evolution of a new interagency review process caused confusion and delay in the ongoing work of IRIS program staff.

GAO has cited interagency review as a primary culprit in decreased credibility and delayed development of at least two other IRIS profiles – naphthalene and trichloroethylene (TCE). These chemicals implicated the interests of the Department of Energy and National Aeronautics and Space Administration (NASA), resulting in multi-year delays that GAO linked to EPA's sister agencies.

A Partial Fix: The Jackson Revisions to IRIS Process

To her credit, Administrator Jackson has made it clear that she intends for EPA to have complete power in managing the interagency review process. However, the powers granted to other agencies under the old process were hard-won and are unlikely to be simply returned to EPA. We are confident that EPA's commitment to holding the reins during the development of new or revised IRIS profiles will be tested by both OMB and other federal agencies.

In fact, we have already observed OMB scientists injecting themselves into other aspects of EPA's work during the Obama Administration. Most notably, the docket for EPA's proposed "endangerment finding" with respect to carbon dioxide under the Clean Air Act is riddled with documentation of OMB scientists critiquing the minute details of EPA scientists' work. In doing so, OMB staff stray beyond both their expertise and mandate. Neither EPA's endangerment finding, nor a particular IRIS profile is a regulatory action with which OMB should be involved. OMB has an Executive Order mandate[10] (albeit one that is subject to some criticism) to review and coordinate federal agencies' rulemaking. It does not have a mandate to review "pre-regulatory" work like IRIS assessments. Yet, we expect OMB will continue to avail itself of its considerable powers and we are concerned that OMB could inappropriately impact the development of new or revised IRIS profiles.

Ideally, Administrator Jackson should abandon the interagency review stage, but encourage other federal agencies to critique draft IRIS profiles during public comment period – at the same time, and under the same procedures, as all of the other potentially affected interest groups.

[10] Executive Order 12,866, 58 Fed. Reg. 51735 (Oct. 4, 1993).

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If that solution is not adopted, EPA must at minimum improve the mechanisms it uses to ensure that EPA staff and other agencies will be held accountable for problems and delays caused by interagency review. For instance, in order to avoid unnecessary delay, EPA should establish strict timelines for other agencies' comments. In addition, all communications between EPA and other government officials, whether oral or written, should be placed immediately in a publicly accessible docket. As GAO affirms, "transparency in the IRIS assessment process can provide assurance that these scientific assessments are appropriately based on the best available science and that they are not impacted by policy issues and considerations."[11] Unfortunately, such accountability mechanisms are missing from Administrator Jackson's May 20 memorandum.

A Case Study of IRIS's Gaps: Clean Air Act Hazardous Air Pollutants

Also missing from the most recent revisions to the IRIS process is any discussion of how EPA will prioritize the chemicals that need to be added to the database and the chemicals whose IRIS profiles need to be updated. Some 548 substances are currently listed in the IRIS database. While that is a significant number given the work required to get information posted in the database, EPA is responsible for protecting Americans from literally thousands of chemicals. Roughly 700 new chemicals enter commerce each year. Obviously, EPA cannot complete an IRIS profile for every new chemical – not only would such an effort demand prodigious resources, but there simply is not enough information available to accomplish the task for many chemicals.[12]

The simple fact that a chemical exists in commerce is not sufficient reason to put it on the IRIS agenda. IRIS program staff make decisions about which chemicals to add to the database and which existing profiles need to be updated based on the availability of new scientific information, personnel and resource constraints, program office need, and public interest. Congressional objectives play a smaller role, often through the proxies of EPA program staff. Below, we present research showing that those proxies are not enough to ensure that Congress's major public health objectives are fully integrated into the IRIS agenda, particularly in the realm of air toxics.

In the 1990 amendments to the Clean Air Act, Congress listed 188 hazardous air pollutants (HAPs) and mandated that EPA establish regulations to protect Americans from the dangers posed by those HAPs. EPA's regulations were to occur in two stages. First, EPA was to establish "technology-based" emissions standards. Congress instructed EPA to devise regulations that would promote the implementation of the maximum achievable control

[11] GAO Report on IRIS, *supra* note 6, *at* 54.
[12] *See, e.g.*, ENVIRONMENTAL PROTECTION AGENCY, *HPV Chemical Hazard Data Availability Study*, *available at* http://www.epa.gov/HPV/pubs/general/hazchem.htm (accessed June 5, 2009) (noting that 93 percent of chemicals produced or imported at rates over 1 million pounds per year are missing one or more of the basic toxicity screening tests that are necessary for even a minimum understanding of the chemical's toxicity).

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technologies, in particular, "the average emission limitation achieved by the best performing 12 percent of the existing sources" of each HAP.[13] Recognizing that "technology-based" regulation is an expedient but imperfect solution, Congress added another provision to the Clean Air Act to ensure that public health would not remain threatened even after implementation of the maximum achievable control technologies. That provision calls on EPA to assess the residual risks posed by each HAP and promulgate further regulation of any HAP "to provide ample margin of safety to protect public health."[14] In other words, Congress instructed EPA to double-check its work, directing EPA to come up with technology-based regulation, do a risk assessment to see how well that technology-based regulation works in terms of delivering public health benefits, and then, if necessary, promulgate regulations to reduce any excess residual risk.

The creation of an IRIS profile for each HAP should be an integral part of EPA's efforts to control residual risks under the Clean Air Act. For each HAP, if IRIS program staff were to develop a profile that listed an inhalation Reference Concentration (RfC), the uncertainty factors applied, and a description of the reasoning behind their assessment, staff from other EPA offices could then use that information in conjunction with exposure monitoring data, information on environmental fate and transport, and other relevant data to complete a full risk assessment for each HAP. From there, risk management decisions could be formulated and regulations could be designed.

This idealized process, however, will not be realized because the IRIS agenda does not give sufficient weight to congressional mandates and program office needs, as evidenced by the poor coverage of HAPs in the IRIS database. Today, nearly 20 years after Congress gave EPA a list of priority chemicals, some 17 percent are not listed in IRIS at all. Worse, two-thirds of the Clean Air Act HAPs do not have inhalation RfCs listed in the database. Specific chemical identities are listed in Appendix A to this report, but the numbers alone provide a clear picture of the problem:

- Of the 187 HAPs,[15] only 155 (83 percent) have IRIS profiles
- Of the 187 HAPs, 126 (67 percent) are missing inhalation RfC values.

The potential consequence of not taking the necessary steps toward regulating these HAPs is profound. In Tables 1 and 2, below, we provide basic data on environmental releases of some HAPs not adequately profiled in the IRIS database. The data come from EPA's Toxic Release Inventory (TRI), which provides access to chemical release information submitted by the firms that produce and use the chemicals. We ranked all 32 HAPs not listed in the database and all 94 HAPs whose IRIS profiles are missing inhalation RfCs, based on total air releases reported in

[13] 42 U.S.C. § 7412 (d).
[14] 42 U.S.C. § 7412 (f)(2).
[15] One of the 188 originally listed HAPs was dropped under procedures provided for in the statute.

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TRI.[16] The top ten chemicals in each category are presented in Table 1, which show that the unlisted chemicals are released at a rate of hundreds of thousands of pounds per year. In Table 2, we present information about the health effects of some of these chemicals, compiled from information available through the Center for Disease Control and Prevention's Agency for Toxic Substances Disease Registry (ATSDR), and the chemicals' materials safety data sheets (MSDS).

Table 1: TRI Data for HAPs with Inadequate IRIS Profiles

	CAA § 112 HAP	Fugitive Air Releases (lbs)	Point-source Air Releases (lbs)	Total TRI-listed Air Releases (lbs)
Chemicals Missing IRIS Profiles	Hydrogen fluoride	2,452,724	65,156,022	67,608,746
	Chloroprene	64,747	656,681	721,428
	Ethylene oxide	132,988	152,247	285,235
	Diethanolamine	161,693	22,411	184,103
	Ethyl acrylate	29,944	40,548	70,492
	Cobalt compounds	7,209	48,181	55,390
	Titanium tetrachloride	39,825	8,029	47,854
	o-Toluidine	6,146	9,291	15,437
	Cadmium compounds	1,929	7,537	9,467
	4,4'-Methylenedianiline	7,135	1,083	8,218
Chemicals with IRIS Profiles, But No Inhalation RfC	Methanol	32,762,661	96,585,081	129,347,741
	Carbonyl sulfide	138,196	19,761,297	19,899,493
	Formaldehyde	1,008,494	8,238,753	9,247,247
	Dicholormethane	2,088,462	3,159,631	5,248,093
	Chlorine	376,275	4,721,400	5,097,675
	Trichloroethylene	1,964,316	2,393,993	4,358,309
	Phenol	608,149	3,306,085	3,914,234
	Ethylene glycol	1,208,014	1,215,586	2,423,600
	Tetrachloroethylene	779,616	990,373	1,769,989
	Lead compounds	285,344	517,365	802,709

[16] For information about the air releases reported to TRI under the Emergency Planning and Community Right-to-Know Act, see http://www.epa.gov/tri/triprogram/whatis.htm (accessed June 9, 2009).

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Table 2: Health Effects Information for Certain HAPs Listed in Table 1

Hydrogen fluoride	Hydrogen fluoride and other fluoride compounds released into the environment from industry are subsequently carried by the wind and rain to surrounding water, soil, and food sources. Hydrogen fluoride accumulates in plants and animals, and will not degrade in the natural environment. Humans come into contact with hydrogen fluoride through exposure to contaminated soil, water, and food. The health effects associated with hydrogen fluoride vary depending on the magnitude of exposure. Low to moderate level exposure results in irritation to the skin, eyes, and respiratory tract. High level exposure results in increased bone density in adults and dental fluorosis (causing fragility of the teeth) in children. Extremely high level exposure results in brittle bones and damage to the heart.
Chloroprene	Acute exposure to chloroprene via inhalation may result in coughing, dizziness, drowsiness, headache, sore throat, unconsciousness, and chest pain. Exposure through inhalation can occur very rapidly because harmful contamination of the air is reached quickly upon evaporation of Chloroprene at 20°C. At short-term exposure, chloroprene is a respiratory irritant and may cause adverse effects on the kidneys, liver, and central nervous system. Exposures that far exceed the safe occupational exposure limit may result in death. Chloroprene is a possible human carcinogen.
Formaldehyde	Formaldehyde is used in many industries and laboratories. Although most of the general population is exposed to low levels on a daily basis, Formaldehyde can cause irritation of the skin, eyes, nose, and throat. High levels of exposure may cause some types of cancers. Formaldehyde is given off as a gas from the manufactured wood products used in new mobile homes. Ingestion of large quantities of formaldehyde can cause vomiting, coma, and death.
Methanol	At low level inhalation exposure, methanol is an irritant to the mucous membranes and has toxic effects on the nervous system, specifically the optic nerve. Once absorbed into the body it is slowly eliminated, but symptoms of poisoning may include headache, nausea, vomiting, drowsiness, blurred vision, blindness, and possibly coma or death. Chronic exposure to methanol may lead to significantly impaired vision. People with pre-existing skin or eye disorders, or impaired liver or kidney function, may be more susceptible to toxicity.

As any risk assessor knows, "the dose makes the poison," and the old adage explains why it is important for EPA to develop IRIS profiles for these chemicals. To develop residual risk regulations under the Clean Air Act, EPA first needs to conduct a full risk assessment for each chemical. EPA program staff could use information like what we have presented in Tables 1 and 2 to complete the hazard identification and exposure assessment steps of the risk assessment process, but without a full IRIS profile, the all-important dose-response assessment step is missing.

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In short, EPA needs to do a better job of prioritizing its IRIS agenda based on statutory and program need. The Clean Air Act HAPs list is an obvious place to start, but there are other programs that are also in need of high quality health effects information (e.g., the Safe Drinking Water Act Contaminant Candidate List).

Conclusion

EPA's IRIS database is an important tool for both the agency itself and for risk assessors around the world. Development of new and revised profiles is too important to be mired in interagency squabbles masked as "peer review." To improve the utility and maintain the credibility of the database, EPA should prioritize new assessments based on statutory and program need and should eliminate the interagency review process, which gives privileged status to agencies that have a financial or operational interest in a chemical.

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. The Center for Progressive Reform is grateful to the Public Welfare Foundation and the Deer Creek Foundation for their generous support of CPR's work on regulatory issues.

The Center for Progressive Reform
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