THE EPA'S IRIS PROGRAM

HEARINGS

BEFORE THE

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

ONE HUNDRED TENTH CONGRESS

SECOND SESSION

MAY 21, 2008
and
JUNE 12, 2008

Serial No. 110–104
and
Serial No. 110–108

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
42–370PS WASHINGTON : 2008

For sale by the Superintendent of Documents, U.S. Government Printing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512–1800; DC area (202) 512–1800
Fax: (202) 512–2104 Mail: Stop IDCC, Washington, DC 20402–0001

COMMITTEE ON SCIENCE AND TECHNOLOGY

HON. BART GORDON, Tennessee, *Chairman*

JERRY F. COSTELLO, Illinois
EDDIE BERNICE JOHNSON, Texas
LYNN C. WOOLSEY, California
MARK UDALL, Colorado
DAVID WU, Oregon
BRIAN BAIRD, Washington
BRAD MILLER, North Carolina
DANIEL LIPINSKI, Illinois
NICK LAMPSON, Texas
GABRIELLE GIFFORDS, Arizona
JERRY MCNERNEY, California
LAURA RICHARDSON, California
PAUL KANJORSKI, Pennsylvania
DARLENE HOOLEY, Oregon
STEVEN R. ROTHMAN, New Jersey
JIM MATHESON, Utah
MIKE ROSS, Arkansas
BEN CHANDLER, Kentucky
RUSS CARNAHAN, Missouri
CHARLIE MELANCON, Louisiana
BARON P. HILL, Indiana
HARRY E. MITCHELL, Arizona
CHARLES A. WILSON, Ohio

RALPH M. HALL, Texas
F. JAMES SENSENBRENNER JR., Wisconsin
LAMAR S. SMITH, Texas
DANA ROHRABACHER, California
ROSCOE G. BARTLETT, Maryland
VERNON J. EHLERS, Michigan
FRANK D. LUCAS, Oklahoma
JUDY BIGGERT, Illinois
W. TODD AKIN, Missouri
JO BONNER, Alabama
TOM FEENEY, Florida
RANDY NEUGEBAUER, Texas
BOB INGLIS, South Carolina
DAVID G. REICHERT, Washington
MICHAEL T. MCCAUL, Texas
MARIO DIAZ-BALART, Florida
PHIL GINGREY, Georgia
BRIAN P. BILBRAY, California
ADRIAN SMITH, Nebraska
PAUL C. BROUN, Georgia

SUBCOMMITTEE ON INVESTIGATIONS AND OVERSIGHT

HON. BRAD MILLER, North Carolina, *Chairman*

JERRY F. COSTELLO, Illinois
EDDIE BERNICE JOHNSON, Texas
DARLENE HOOLEY, Oregon
STEVEN R. ROTHMAN, New Jersey
BRIAN BAIRD, Washington
BART GORDON, Tennessee

F. JAMES SENSENBRENNER JR., Wisconsin
DANA ROHRABACHER, California
DAVID G. REICHERT, Washington
PAUL C. BROUN, Georgia
RALPH M. HALL, Texas

DAN PEARSON *Subcommittee Staff Director*
EDITH HOLLEMAN *Subcommittee Counsel*
JAMES PAUL *Democratic Professional Staff Member*
DOUGLAS S. PASTERNAK *Democratic Professional Staff Member*
KEN JACOBSON *Democratic Professional Staff Member*
BART FORSYTH *Republican Counsel*
TOM HAMMOND *Republican Professional Staff Member*
STACEY STEEP *Research Assistant*

CONTENTS

EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?

May 21, 2008

Appendix: Additional Material for the Record

Toxic Communities: How EPA's IRIS Program Fails the Public

June 12, 2008

Opening Statements

Witnesses:

Appendix: Additional Material for the Record

EPA'S RESTRUCTURED IRIS SYSTEM: HAVE POLLUTERS AND POLITICS OVERWHELMED SCIENCE?

WEDNESDAY, MAY 21, 2008

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

The Subcommittee met, pursuant to call, at 11:10 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON SCIENCE AND TECHNOLOGY

SUITE 2320 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6301
(202) 225-6375
TTY: (202) 226-4410
http://science.house.gov

Subcommittee on Investigations and Oversight

Hearing on

EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?

Wednesday, May 21, 2008
11:00 a.m. – 1:00 p.m.
2318 Rayburn House Office Building

Witness List

PANEL I

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

PANEL II

Dr. George Gray
Assistant Administrator for Research and Development,
United States Environmental Protection Agency

Ms. Susan Dudley
Administrator, Office of Information and Regulatory Affairs,
Office of Management and Budget

HEARING CHARTER

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

EPA's Restructured IRIS System: Have Polluters and Politics Overwhelmed Science?

WEDNESDAY, MAY 21, 2008
11:00 A.M.–1:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

The Subcommittee on Investigations and Oversight will hold the first of two hearings on the Integrated Risk Information System (IRIS) at the Environmental Protection Agency (EPA).

We have three excellent witnesses who can place the role of IRIS in perspective as well as address questions regarding the Bush Administration's evolving system to draft and review IRIS entries:

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

Dr. George Gray, *Assistant Administrator for Research and Development, United States Environmental Protection Agency.*

Ms. Susan Dudley, *Administrator, Office of Information and Regulatory Affairs, Office of Management and Budget.*

What Is IRIS and Why Does It Matter?

IRIS was established in the 1980s to provide a single source of information on the risks associated with exposure to chemicals. The IRIS database provides a hazard identification and dose-response analysis, scientific information that when combined with estimates of exposure allow regulatory agencies to produce a risk assessment. Historically, entries to the database were the result of extensive in-house development by the science staff at EPA, peer review processes with experts from outside the agency, and opportunities for public input and comment. To the degree interagency communications occurred, they were managed by EPA (See Figure 1).

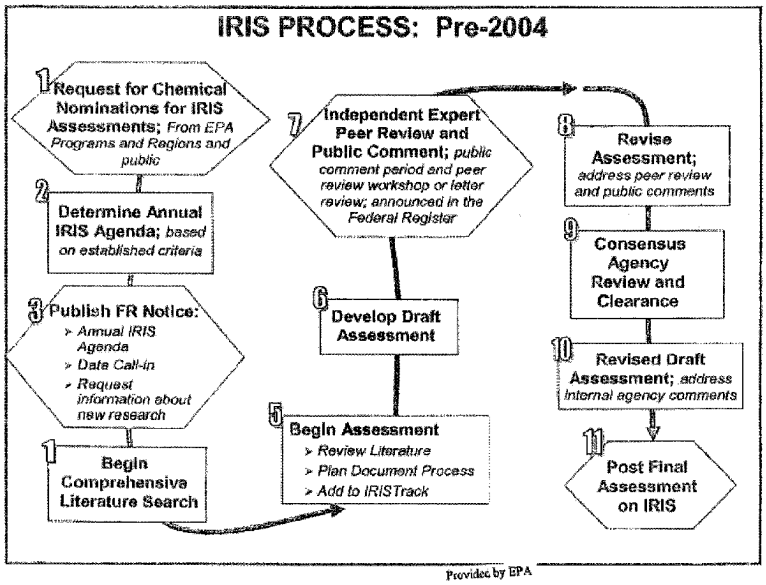
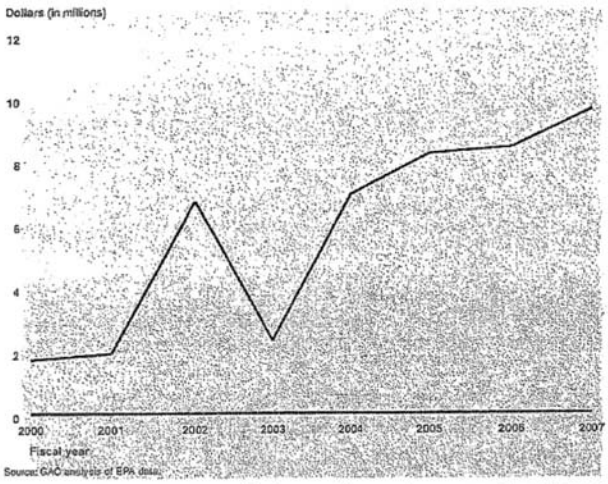


Figure 1. Pre-2004 IRIS Process (EPA).

While not a regulatory product itself, IRIS is designed to help regulators set priorities about what to regulate and inform regulators about what level of exposure workers or communities can absorb safely. A long-recognized principle in the U.S. approach to regulation has been the distinction between risk assessment—the characterization of what science tells us regarding a particular hazard—and risk management, or what you want to do about the hazard (including choosing to do nothing). Science can point to where regulation may be needed, but science may not be the sole consideration in setting a regulatory standard or approach. IRIS is designed to be a risk assessment tool. Government officials in federal agencies, in State and county governments and even in foreign countries, have come to rely upon IRIS for the most reliable, most comprehensive statements on what science tells us about the risk associated with a particular chemical.

A long-standing challenge for the IRIS database is meeting the requests for information on the many chemicals that are manufactured and utilized in global commerce, and updating information on chemicals that have been previously evaluated. IRIS is loosing ground to the torrent of new chemicals introduced to the marketplace. Approximately 700 new chemicals enter commerce each year. Those new chemicals are added to the over 80,000 currently reported under the *Toxic Substances Control Act* (TSCA) as being in the market. In addition, about one half of the assessments on approximately 480 chemicals currently in the database need to be updated according to EPA staff estimates. To keep IRIS relevant would require aggressive moves to speed the production and approval of entries. Congress has actually increased funding for IRIS staff in recent years in an effort to address this severe backlog (this committee supported increased funding in Chairman Boehlert's FY 2007 Views and Estimates Report to the Committee on the Budget—see Figure 2 for a representation of the IRIS budget).



Note: In fiscal year 2002, a congressional appropriations conference committee designated $5 million to accelerate the development of new IRIS values and to update current IRIS values. According to EPA officials, this funding was provided to various EPA program offices to support the IRIS assessments that program offices were leading at that time. In addition, EPA has reprogrammed funds from some of its other programs to expand the IRIS program to support the development of IRIS assessments, especially high-priority chemicals.

Figure 2. Funding for the IRIS Program, Fiscal Years 2000-2007 (GAO).

IRIS Slows to a Crawl

Instead of seeing IRIS entries spike with funding and personnel increases, additions and updates to IRIS have slowed to a crawl (Figure 3). Only four IRIS listings have been finalized in the past two years. In comparison, the State of Minnesota requested new or updated assessments of 52 chemicals of concern in the 2006 solicitation for the 2007 Program.[1]

[1] Submission by the Minnesota Department of Health to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for the 2007 Program. Docket ID No. EPA–HQ–ORD–2006–0950.

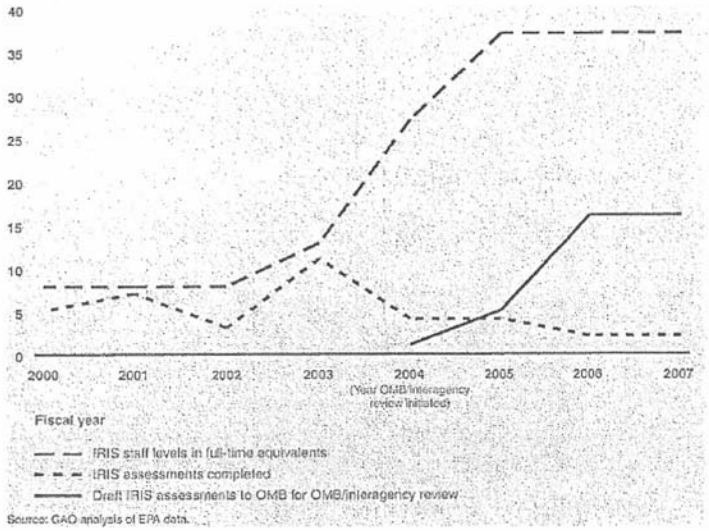


Figure 3. Number of Completed IRIS Assessments, Draft Assessments sent to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007 (GAO).

This outcome appears to be tied to the intervention of OMB in the IRIS review and approval process. Beginning in 2004, OMB established a formal system of interagency review (Figure 5). This system, ostensibly designed to improve the quality of IRIS entries, appears to have all but stopped IRIS entries. On April 10 of this year, EPA announced a new IRIS review and approval system that is even more elaborate than its predecessors (Figure 4).

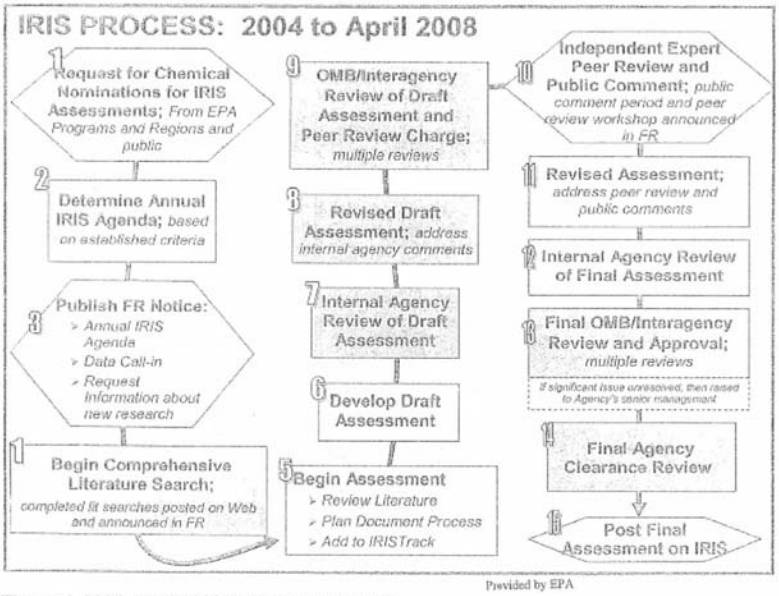


Figure 4. 2004-April 2008 IRIS Process (EPA).

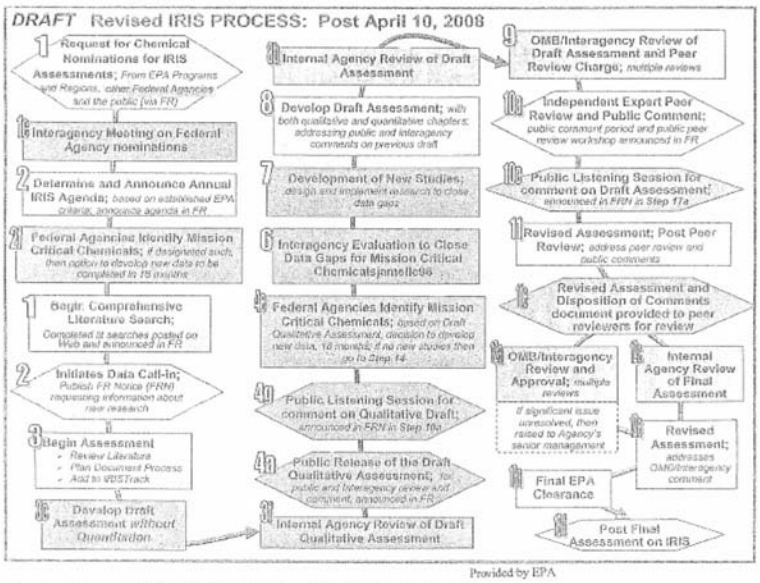


Figure 5. Post April 10, 2008 Revised IRIS Process (EPA).

It appears that any IRIS listing that is the least bit controversial will take six years or more to be completed. The interagency process allows agencies with a direct

conflict of interest multiple opportunities to influence the development and content of IRIS assessments all within a process that lacks any transparency for Congress or the public. The Department of Defense, the Department of Energy and NASA all are responsible for pollution on the federal lands they manage and for the health and safety of the personnel that manage their facilities and operations. Rocket fuel, jet fuel, solvents, munitions, nuclear waste all contain hazardous materials that can become pollutants contaminating aquifers and air, and exposing workers and families to real harm.

IRIS Entries Become a Political Science

EPA leadership has agreed to OMB establishing a review that gives polluting agencies lengthy, unmonitored opportunities to try to convince OMB that the risks of a particular substance should not be set at a particular level. It is hard to understand what special science expertise these other agencies bring to the table such that OMB needs to set up an interagency review to discuss science.

Remember that the development of IRIS assessments and, the risk assessment process generally, is supposed to be separate from the risk management process. There you would expect interested parties, including other federal agencies, to discuss how to manage risks by weighing costs and benefits in a search for the best option given a particular configuration of risk and need. IRIS is supposed to be solely about what science says regarding health and environmental risk associated with the listed chemicals. With 7000 scientists, and mandated by law and appropriation to be the Nation's lead agency on environmental science, EPA really has no peers when it comes to understanding the science at stake in IRIS listings.

The process established on April 10 allowing agencies to discuss a particular IRIS listing is closed to the public. Because that work represents pre-deliberative discussions, any materials from that process are not subject to the *Freedom of Information Act*. Because these processes are managed by OMB, it will be very difficult for Congress to learn of what is happening due to OMB's consistent assertions that all of their work should be shielded from Congress and the public. Whether the proposals that come out of this lengthy, secretive process are based solely on science, or whether other considerations held sway, would be very hard for anyone to ever prove.

IRIS is withering. It is loosing its relevance due to the sweep of time, new science and new substances as well as its own inability to refresh its data. The process put in place on April 10 appears guaranteed not to improve this situation, but to make it worse. But even if the process was somehow producing more entries, more quickly, the integrity of the process is itself in question and that alone will undermine the utility of the IRIS database. If policy-makers and the public believe the science has been cooked to meet a polluter's agenda, then they will not have confidence in the science. It is a simple problem and one that the April 10 revision puts at center stage.

The Subcommittee hopes to explore these issues with witnesses on Wednesday morning.

The Minnesota Department of Health Submission to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for 2007 Program (Docket ID No. EPA–HQ–ORD–2006–0950)

The Health Risk Assessment staff at the Minnesota Department of Health wish to nominate a list of chemicals to be included in the Integrated Risk Information System (IRIS); Request for Chemical Substance Nomination for 2007 Program. These chemicals are of concern to the Minnesota Department of Health because they are among contaminants found in Minnesota groundwater. In Minnesota, health-based values are derived for such contaminants. When conducting risk assessments, the Minnesota Department of Health has relied upon the IRIS summaries as a resource for the development of these health protective values. Therefore, it is our hope that you take our nominated chemicals in consideration. By obtaining IRIS summaries of these chemicals it will result in a more thorough and accurate risk assessment process.

1,2,3—Trichloropropane
1—Methylnaphtalene
1—Methylphenol
2,2—Dichloropropane

2,3,4,5—Tetrachlorophenol
2,3,5,6—Tetrachloroterephthalic acid
2,6—dinitrotoluene
2,6—diethylaniline (Alchlor degradate)
2—Nitrophenol
3,5—Dichlorophenol
4—Isopropyl toluene
Acetochlor ESA
Acetochlor OA
Alachlor ESA (degradate of Alachlor)
Alachlor OA (degradate of Alachlor)
Aluminum
Deaminated diketomethribuzin (degradate of Metribuzin)
Deaminated metribuzin (degradate of Metribuzin)
Deethylatrazine (degradate of Atrazine and Propazine)
Deisopropylatrazine (degradate of Atrazine, Cyanazine and Simazine)
Diallate
Diazion
Dichlorofluoromethane
Diketometribuzin (degradate of Metribuzin)
Dimethenamid
Dimethenamid ESA (degradate of Demethenamid)
Dimethenamid OXA (degradate of Dimethenamid)
Ethafluralin
Hydroxyatrazine
Iron
Isopropyl ether
Isoxaflutole
Lithium
Metolachlor ESA
Metsulfuron-methyl (Ally)
Monomethyl tetrachloroterephthalic acid
n-Butylbenzene
Nicosulfuron
n-Propylbenzene
Primisulfuron-methyl (Beacon)
Radionuclides (all)
Sec-Butylbenzene
Sodium
Thifensulfuron methyl
Tin
Total petroleum hydrocarbons
Tribenuron-methyl
Triclopyr
Trinitro-phenylmethylnitramine
Triphenyltin hydroxide
Vanadium

In addition, the Minnesota Department of Health currently needs and uses reference concentrations and reference doses for less than chronic periods of exposure to assess risks from a variety of exposure scenarios. These scenarios include less than chronic exposures that commonly occur at contaminated sites resulting in the need for less than chronic toxicity values to assess current risks. The EPA 2002 "A review of the reference dose and reference concentration processes" has guided much of the practice of the Department in this area.

The Department has found that health effects that result from less than chronic periods of exposure, when combined with high drinking water exposures associated with specific life stages (e.g., childhood), result in drinking water values that are lower and therefore more appropriate as drinking water standards for the general population than the value calculated using a chronic reference dose and lifetime average dose. As a result, the Department is very interested in recent efforts by IRIS to develop less than lifetime reference values, and urges the EPA to continue to develop and publish these analyses. The Department also urges the EPA to consider the potential that effects observed in chronic studies result from early exposures rather than continuous exposure. To the extent that studies are available; the Department urges the EPA to present acute, short-term, longer-term, and chronic evaluations (recommendations for critical studies for each and resulting reference doses) for each chemical that undergoes review in the future.

Chairman MILLER. Good morning. This hearing will now come to order.

More than 80,000 chemicals are now in use, and another 700 new chemicals enter the marketplace each year. Americans need an efficient system to evaluate the risk to public health and the environment of chemicals on a regular basis and to have ready access to that information. That is the mission of the Integrated Risk Information System, or IRIS, but IRIS now has evaluations of only about 480 chemicals.

In recent years, IRIS's assessments have not been the open discussions among scientists we associate with scientific peer review but have become a secretive process managed by OMB. OMB's mission does not include scientific analysis, nor does OMB appear to have the expertise to perform such work. As a result of OMB's control of IRIS evaluation procedures, however, four chemicals have been listed by IRIS in the last two fiscal years. EPA scientists produced 15 or so assessments in each of those years, but the assessments disappeared into an abyss of elaborate, endless reviews, mostly behind closed doors. A weighing of the need for assessments against the productivity under IRIS appears to show that the system is fundamentally broken and in desperate need of reform.

Instead, EPA and OMB appear intent upon choking productivity under IRIS further still and depriving the assessments of what credibility they have left. Just last month, EPA unveiled its new process for developing and reviewing IRIS assessments. The solution offered by EPA and OMB is to take an already-broken system and to make it more convoluted, more secretive, and more suspect.

The new system establishes an interagency process that gives polluting agencies even more opportunity than they had before to slow walk the IRIS process to avoid the consequences of their own conduct. With the new process announced April 10, we may view two new entries a year as the golden era of IRIS assessments. As GAO will testify this morning, it is highly likely that no new chemical entry that is the least bit controversial will ever come out of this system in less than six years and probably more like eight years.

If the goal of the IRIS review process is to produce new IRIS entries, this system, designed by OMB and dutifully blessed by EPA's leadership, would be judged an abysmal failure. However, if the goal is to avoid new IRIS entries, or at least troublesome, inconvenient entries, this new system should perform beautifully. It effectively kills IRIS without honestly acknowledging that intent.

How does it kill IRIS?

Any new entry or revision that will make it into IRIS will be of very dubious reliability. Any entries that make it into IRIS will emerge from a largely secretive process that allows polluters to urge EPA to shift its science so that it is acceptable to the polluting agencies. The public will never have confidence that EPA stood firm on scientific principle or fought off the combined forces of OMB, the Department of Defense, the Department of Energy, or any other agencies that may have a desire to avoid cleaning up their practices or their messes. If the science appears to have been reworked behind closed doors to protect the interests of polluters, at the instance of polluters, who can believe the science?

The Office of Information and Regulatory Affairs, OIRA, at OMB say that they are just managing an interagency process. That is a fiction. EPA is the agency that Congress directed in statute to do environmental science and charged with protecting public health and the environment. EPA is given billions of dollars a year in tax funds to carry out that research and regulatory work.

There is no need for the secretive interagency process that OMB is requiring. The Department of Defense and National Aeronautics and Space Administration, the Department of Energy have entirely different missions and entirely different areas of expertise. Their interest in IRIS is that of an agency using the very chemicals that are being evaluated, not of a scientific agency making decisions based upon science. OMB is using that interagency process to undermine IRIS's integrity and take it away from EPA's control.

EPA says that this really is their process, honest. They control it and are happy with it, but it is headed by political appointees. Dr. Gray is a political appointee. His testimony has been vetted and approved by OMB. EPA's official response even to the GAO report we will hear today was vetted and approved by OMB. And no IRIS entry can go forward without OMB approval.

The Oversight and Government Reform Committee this week, just yesterday, held a hearing and issued a report that demonstrates the degree to which the White House has controlled the opinions of the EPA scientists on regulatory matters. With IRIS, we see that even in the realm of science, before policy should have a role, before economic consideration should have a role, EPA appears to follow the dictates of OMB. Thousands of career scientists must answer to political appointees without scientific expertise not about how to manage risk, whether risk management measures are justified by the economic costs, but about what risks chemicals pose to public health and to the environment in the first place, a question in which political considerations should have no role.

Whatever your personal views of motive or intent by the EPA, the political leadership of the EPA, or by OMB, I hope almost everyone would agree that two new entries a year when 700 chemicals are entering the marketplace every year, is just not acceptable. I look forward to GAO's testimony today for offering advice to Congress on how to make IRIS relevant again and responsive to the needs of the American public again and not just to agencies that are using chemicals and do not want to be disturbed, do not want to be inconvenienced, and their friends at OIRA.

[The prepared statement of Chairman Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

More than 80,000 chemicals are now in use, and another 700 new chemicals enter the marketplace each year. Americans need an efficient system to evaluate the risk to public health and the environment of chemicals on a regular basis and have ready access to that information. That is the mission of the Integrated Risk Information System, or IRIS, but IRIS now has evaluations of only about 480 chemicals.

In recent years, IRIS' assessments have not been the open discussions among scientists we associate with scientific peer review, but has become a secretive process managed by OMB. OMB's mission does not include scientific analysis, nor does OMB appear be have the expertise to perform such work. As a result of OMB's control of IRIS evaluation procedures, four chemicals have been listed on IRIS in the last two fiscal years. EPA scientists produced 15 or so assessments in each of these years, but the assessments disappeared into an elaborate, endless series of reviews, mostly behind closed doors. A weighing of the need for assessments against the pro-

ductivity under IRIS, appears to show that the system is fundamentally broken and cries out for reform.

Instead, EPA and OMB appear intent upon choking productivity under IRIS further still, and depriving the assessments of their remaining credibility. Just last month, EPA unveiled its new process for developing and reviewing IRIS assessments. The solution offered by EPA and OMB is to take a broken system and to make it more convoluted, secretive and suspect.

The new system establishes an interagency process that gives polluting agencies even more opportunity than they had before to slow walk the IRIS process to avoid the consequences of their own conduct. With the new process announced April 10, we may view two new entries a year as the golden era of IRIS assessments. As GAO will testify, it is highly likely that no new chemical entry that is the least bit controversial will ever come out of this system in less than six years, and probably eight years.

If the goal of the IRIS review process was to produce new IRIS entries, this system—designed at OMB and dutifully blessed by EPA's leadership—would be judged an abysmal failure. However, if the goal is to avoid new IRIS entries, or at least troublesome entries, then this new system should perform beautifully. It effectively kills IRIS without honestly acknowledging that purpose.

How does it kill IRIS?

Any new entries or revisions that make it into IRIS will be of dubious reliability. Any entries that make it into IRIS will emerge from a largely secretive process that allows polluters to urge EPA to shift its science so that it is acceptable to the polluting agencies. The public will never have confidence that EPA stood firm on scientific principle, and fought off the combined forces of OMB, the Department of Defense, the Department of Energy or any other agencies that may have a desire to avoid cleaning up their practices or their messes. If the science appears to have been reworked behind closed doors to protect the interests of polluters, who can believe the science?

The Office of Information and Regulatory Affairs at OMB say that they are just managing an interagency process. That is a fiction. EPA is the agency that Congress directed in statute to do environmental science and charged with protecting public health and the environment. EPA is given billions of dollars to carry out that research and regulatory work.

There is no need for the secret interagency process that OMB is mandating. The Department of Defense, the National Aeronautics and Space Administration and the Department of Energy have entirely different missions and entirely different areas of expertise. Their interest in IRIS is that of a polluter, not of a science agency. OMB is using this interagency process to subvert the IRIS process and take it away from EPA's control.

EPA will say this is really their process—honest—they control it and are happy with it. Dr. Gray is a political appointee of the Administration. His testimony has been vetted and approved by OMB. EPA's official response to the GAO report we will hear about today was vetted and approved by OMB. And no IRIS entry can go forward without OMB approval.

The Oversight and Government Reform Committee this week held a hearing and issued a report that demonstrates the degree to which the White House has controlled the "opinions" of EPA on regulatory matters. With IRIS, we see that even in the realm of science, EPA appears to follow the dictates of OMB. Thousands of career scientists must answer to political appointees without scientific expertise not about how to manage risk, whether risk management measures are justified by the costs, but about what risks chemicals pose to public health and to the environment, a question in which political considerations should play no part.

Whatever your personal views of motive or intent of EPA or OMB, I think almost everyone would agree that just two new entries a year is simply not acceptable. I look forward to GAO's testimony today for offering advice to Congress on how to make IRIS relevant and responsive to the needs of the American public and not just a handful of polluters and their friends at OIRA.

Chairman MILLER. At this time I would like to recognize Mr. Reichert of Washington who is sitting in for Mr. Sensenbrenner of Wisconsin.

Mr. REICHERT. Thank you, Mr. Chairman. I ask unanimous consent to submit a statement from Ranking Member Sensenbrenner and a memo from the EPA into the Committee records.

Chairman MILLER. Without objection.
Mr. REICHERT. I yield back.
[The prepared statement of Mr. Sensenbrenner follows:]

PREPARED STATEMENT OF REPRESENTATIVE F. JAMES SENSENBRENNER JR.

The Integrated Risk Information System (IRIS) process was originally developed for a specific task. Different offices throughout the Environmental Protection Agency (EPA) were relying on different assessments of the health effects of chronic exposure to toxic chemicals. IRIS was intended to establish a uniform database within EPA.

Over time, however, IRIS became an authoritative resource on chemical toxicity. 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.

The Government Accountability Office (GAO) recently issued a scathing condemnation of the current state of the IRIS program. The report's title, *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System,* accurately sums up GAO's findings. But IRIS' actual production numbers are worse. EPA currently has a backlog of 70 ongoing assessments and has managed to complete only two assessments in each of the last two years. At the current pace, it will take 35 years for EPA to finish its current backlog.

EPA has attempted to develop a uniform process for IRIS assessments. The agency argues that it can expedite the IRIS process by involving other agencies earlier in the process. While preventing last minute delays is an important reform, the ability of other agencies to extend the timeframe of assessments should be sharply limited. Data gaps in risk assessments will always exist as better science is always developing. EPA needs to limit the timeframe of assessments to prevent other agencies from indefinitely delaying the process.

EPA must balance its need to complete assessments with the rights of interested parties to comment. The best way to achieve this balance would be to give more notice of its assessments. EPA already publishes an annual agenda of the chemical it intends to assess in the *Federal Register.* If EPA moves the date of that publication forward, providing more notice, interested parties will have a longer period to comment on what they deem to be insufficiencies in the scientific record. During this comment period, EPA can focus on its backlog. Because it offered a comment period, EPA can then fairly limit the ability of outside parties to delay assessments once they are underway. The result would be a more efficient process that preserves taxpayers' money and promotes public health.

I urge EPA to consider these proposals, because IRIS must be fixed. In April, this subcommittee held a hearing on formaldehyde levels in trailers provided to the victims of Hurricane Katrina. In that hearing, we investigated how the Agency for Toxic Substances and Disease Registry struggled to identify the proper "level of concern" for long-term exposure to formaldehyde. EPA determined its formaldehyde assessment was outdated in 1997, but eleven years later, that assessment is still incomplete. These hurricane victims are the real world result of EPA's bureaucratic failures.

[The prepared statement of Mr. Costello follows:]

PREPARED STATEMENT OF REPRESENTATIVE JERRY F. COSTELLO

Mr. Chairman, I appreciate the Subcommittee's attention to this important matter. The role of the Environmental Protection Agency's (EPA) IRIS program cannot be understated. Created in the 1980s, the program is a primary resource for information on the risks associated to exposure of chemicals. Government officials, State and local governments and many scientists have come to rely on the comprehensive analysis completed by the IRIS program.

However, the rate at which information requests have been processed over the years is troubling. Recent revisions to the program have received conflicting reviews as to whether these steps will increase productivity or continue to slow the process further. A March 2008 GAO report concluded that the IRIS database is at serious risk of becoming incomplete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments. That a total of four assessments were completed over the course of fiscal years 2006 and 2007 is unacceptable.

I look forward to hearing our witnesses' testimony today and working with my colleagues on the Committee to improve and increase efficiency within this important program. Thank you, Mr. Chairman, I yield back.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF REPRESENTATIVE EDDIE BERNICE JOHNSON

Thank you, Mr. Chairman. The mission of the Environmental Protection Agency is to protect both environmental quality and human health through effective regulations and other policy implementation.

What is confounding to me, regarding the Integrated Risk Information System, is why only four IRIS listings have been finalized in the past two years.

After all, approximately 700 new chemicals enter commerce each year. There are more than 80,000 chemicals reported under the *Toxic Substances Control Act* as being in the market.

It seems implausible to me that only four chemicals should be investigated to completion and published in the IRIS database at E.P.A.

The Government Accountability Office report, published in March 2008, concluded that, "the IRIS database is at serious risk of becoming obsolete because E.P.A. has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments."

The statement of George M. Gray, Ph.D., who is Assistant Administrator for Research and Development at E.P.A., explains that IRIS began as "an internal E.P.A. resource."

Even if that explanation is true, then why would E.P.A. compile only four IRIS listings in the past two years?

It makes me question what E.P.A. is doing, when it comes to chemical toxicity and public health.

Dr. Gray's statement also says that the risk assessment process "consists of both 'science' and 'science policy' components."

It goes on to say that, "although there are some instances at E.P.A. where 'pure science' is involved, . . . much of the work done at E.P.A. . . . involves both science and science policy. . . .Due to the uncertainty in IRIS assessments, judgments and choices must be made about the most appropriate assumptions . . . to use in deriving toxicity data."

Mr. Chairman, I chafe at this testimony.

These statements insult the scientific community that publishes data on these matters. They also insult the talented scientists who are working at E.P.A., who are perfectly capable of interpreting peer-reviewed literature and making public health decisions.

This subcommittee has concerns that the IRIS system has become politicized, when it should be based solely on scientific facts regarding health and environmental risk associated with the listed chemicals.

Although I understand that E.P.A. is making moves to re-evaluate the IRIS System, there are only so many patches that may be placed on a sinking ship.

For me, what is truly sinking is the feeling I get when I consider the good scientists who have dedicated their entire careers to environmental safety at E.P.A. I suspect that those who remain must be frustrated at this gross politicization of science and wide scale destruction of our environment.

Mr. Chairman, you will know that I have a near-perfect voting record with environmental groups, and I will be swift to act, should I see a way to rectify the situation.

Thank you, and I yield back the remainder of my time.

Panel I:

Chairman MILLER. It is now my pleasure to introduce our witnesses today. Mr. John Stephenson is the Director of Natural Resources and Environment Division at the Government Accountability Office, which just released a report on IRIS's new interagency review process. Mr. Stephenson, you will have five minutes for your spoken testimony. Your written testimony will be included in the record for the hearing. When you complete your testimony, we will begin with questions, and each Member will have five min-

utes to question you. It is a practice of the Subcommittee to take testimony under oath. Do you object to swearing an oath?

Mr. STEPHENSON. No.

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

Mr. STEPHENSON. I do.

Chairman MILLER. Mr. Stephenson, the Committee also provides that you may be represented by counsel. Are you represented by counsel at today's hearings?

Mr. STEPHENSON. I am not.

Chairman MILLER. Then Mr. Stephenson, please begin.

TESTIMONY OF MR. JOHN B. STEPHENSON, DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE

Mr. STEPHENSON. Thank you, Mr. Chairman, and other Members of the Committee. I am here today to discuss our recently issued report on IRIS, a database that contains the scientific position on health effects of exposure to more than 540 toxic chemicals. IRIS is a critical component of EPA's capacity to support scientifically sound environmental decisions, policies, and regulations. Our March 2008 report concluded that the IRIS database is at serious risk of becoming obsolete because EPA has not been able to complete timely, credible assessments or decrease its back-load of 70 ongoing assessments. In summary, we found that EPA efforts to improve IRIS since 2000 have been thwarted by a combination of factors including OMB interagency reviews, EPA decisions to delay assessments to wait for new research or additional uncertainty analysis, and the compounding effect of continuous delays.

The two new OMB interagency reviews involve other federal agencies in a manner that limits the credibility of IRIS assessment and hinders EPA's ability to manage them. In addition, OMB is inserting itself into the decision-making process by, for example, requiring EPA to terminate five assessments EPA's own office of theirs said that it needed to implement the *Clean Air Act.* The effect of all of these changes to what should be a scientific process is that chemicals remain in the assessment phase indefinitely, and few assessments are ever finalized. Indeed, EPA staff have prepared over 32 draft assessments of toxic chemicals in the past two years, yet only four have been finalized.

Our report includes eight specific recommendations for streamlining the IRIS program, improving the transparency and credibility of the assessments, and ensuring that EPA has the requisite independence to achieve its goals, recommendations that EPA in February agreed to consider before finalizing the IRIS process. However, EPA released its final IRIS process on April 10th as you mentioned, and instead of seeking public comment, as OMB promised in responding to our report, made it effective immediately. To say that we are disappointed is a gross understatement. The new IRIS process is not responsive to our recommendations and is in many respects worse than the draft we reviewed. For example, the draft process would have made comments from other federal agencies part of the public record. However, the new process expressly defined such comments as deliberative, excluding them from the

public record. EPA's position that the IRIS process is transparent because final assessments must undergo public and external peer review is ludicrous. Transparency at a late stage after OMB and other federal agencies have had multiple opportunities to influence the content of the assessment without any disclosure of their input does not compensate for its absence earlier.

In addition, the estimated timeframes under the new process will likely perpetuate the cycle of delays and exacerbate the problems we identified in our report and sought to address with our recommendations, all of which were aimed at preserving the viability of this critical database which is integral to EPA's mission of protecting the public health from exposure to toxic chemicals. Instead of significantly streamlining IRIS, EPA has institutionalized an assessment process from the outset that will take 6 to 8 years to complete.

We all understand that science regarding the toxicity of a given chemical is never perfect, but at some point EPA must complete assessments so that it can take the next step of exploring what regulatory options are appropriate for protecting human health. My testimony includes several examples of dangerous chemicals that are stuck in the endless loop of assessment and reassessment. I would like to summarize just one very quickly.

In 1998, EPA initiated a toxic risk assessment of trichloroethylene, a degreasing agent used widely by the Department of Defense and others. Numerous studies have linked TCE to cancer and birth defects over the last decade. EPA completed a draft risk assessment in 2001 which was then peer reviewed by the science advisory board and released for public comment. During the comment process, questions were raised about the assessment by DOD and others that led to a request for the National Academies of Science to review it in 2004. In 2006, the Academies concluded that the weight of evidence of cancer from TCE had actually strengthened since EPA's 2001 assessment. Nevertheless, after more than 10 years, TCE is back at the draft development stage, and the public continues to be exposed to this dangerous chemical. EPA estimates that its final assessment will not be completed until 2010. In frustration, five Senators, spurred by the TCE contamination in the drinking water at Camp Lejeune, North Carolina, introduced a bill last year that would require EPA to complete its risk assessment and issue a drinking water standard within 18 months.

Mr. Chairman, IRIS is a critical process that is clearly broken and needs to be fixed. We believe that the Congress should consider directing EPA to suspend implementation of its new process and develop one that is transparent and otherwise responsive to our recommendations. If EPA is unable or unwilling to take the steps necessary to improve this critical program, we believe that other approaches including legislative action may be needed.

That concludes my comments, and I will be happy to take questions.

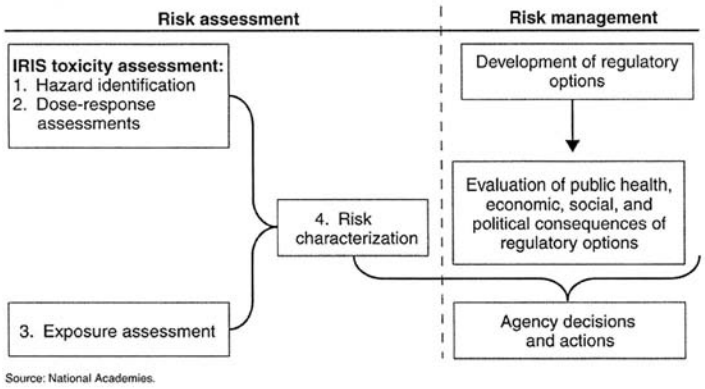
[The prepared statement of Mr. Stephenson follows:]

PREPARED STATEMENT OF JOHN B. STEPHENSON

Mr. Chairman and Members of the Subcommittee:

I am pleased to be here today to discuss issues associated with the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS)—one of the most significant tools that EPA has developed to effectively support its mission of protecting people and the environment from harmful chemical exposures. IRIS contains EPA's scientific position on the potential human health effects that may result from exposure to more than 540 chemicals in the environment and is a critical component of EPA's capacity to support scientifically sound risk management decisions, policies, and regulations. IRIS is also relied upon by State and local environmental programs and some international regulatory bodies for managing their environmental protection programs. As shown in Figure 1, the toxicity assessments in the IRIS database fulfill the first two critical steps of the four-step risk assessment process—providing hazard identification and quantitative dose-response assessments. IRIS information can then be used with the results of exposure assessments (typically conducted by EPA's program or regional offices) to provide an overall characterization of the public health risks for a given chemical in a given situation. The development of health risk assessments is thus directly dependent on the development of toxicity assessments such as those developed in the IRIS program.

Figure 1: National Academies' Risk Assessment and Risk Management Model Used by EPA



Source: National Academies.

Under the National Academies' risk assessment and risk management paradigm, policy considerations are relevant in the risk management phase, which occurs after the risk assessment phase.[1] With risk assessment information, decision-makers can make informed risk management decisions on how to protect public health, reflecting other important data and considerations, such as the costs and benefits of mitigating identified risks, the technological feasibility of managing risks, and the concerns of various stakeholders. Examples of risk management decisions include deciding how much of a chemical a company may discharge into a river, determining the extent to which a hazardous waste site must be cleaned up, and setting allowable levels of contamination in drinking water.

Thus, although IRIS assessments are not regulatory in nature, the quantitative IRIS values may influence many risk management decisions and serve as a basis for regulatory consideration. However, EPA's productivity in finalizing IRIS assessments is poor, and EPA has a significant backlog of incomplete IRIS assessments and a growing number of outdated assessments. Importantly, EPA has not been able to complete assessments of key chemicals of concern to public health, including dioxin, formaldehyde, trichloroethylene (TCE), naphthalene, and tetrachloroethylene (perc) (see Appendix I).

In this context, my testimony today discusses (1) highlights of our March 2008 report, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information Sys-*

[1] The National Academies comprises four organizations: the National Academy of Sciences, the National Academy of Engineering, the Institute of Medicine, and the National Research Council.

tem[2] and (2) key aspects of EPA's revised IRIS assessment process, released on April 10, 2008. For our March 2008 report, we examined the outcome of steps EPA has taken to ensure that IRIS contains current, credible chemical risk information; to address the backlog of ongoing assessments; and to respond to new requirements from the Office of Management and Budget (OMB). We also examined the potential effects of planned changes to the IRIS assessment process on EPA's ability to ensure that IRIS provides current, credible risk information. In conducting our work, we obtained and analyzed information on EPA's productivity and the resources provided to the program for fiscal years 2000 through 2007, user needs, and EPA's assessment completion goals. We also interviewed EPA's National Center for Environmental Assessment officials who manage the IRIS assessment program; officials from other EPA program offices and federal science and health agencies involved in the IRIS assessment process; and officials from the Department of Defense, the Department of Energy (DOE), the National Aeronautics and Space Administration (NASA), and OMB. For this testimony, we supplemented our report with a review of the IRIS assessment process that EPA released on April 10, 2008. We conducted this work from May 7 to May 21, 2008, in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit 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.

Background

IRIS was created in 1985 to help EPA develop consensus opinions within the agency about the health effects of chronic exposure to chemicals. Its importance has increased over time as EPA program offices and the states have increasingly relied on IRIS information in making environmental protection decisions. Currently, the IRIS database contains assessments of more than 540 chemicals. According to EPA, national and international users access the IRIS database approximately nine million times a year. EPA's Assistant Administrator for the Office of Research and Development has described IRIS as the premier national and international source for qualitative and quantitative chemical risk information; other federal agencies have noted that IRIS data are widely accepted by all levels of government across the country for application of public health policy, providing benefits such as uniform, standardized methods for toxicology testing and risk assessment, as well as uniform toxicity values. Similarly, a private-sector risk assessment expert has stated that the IRIS database has become the most important source of regulatory toxicity values for use across EPA's programs and is also widely used across State programs and internationally.

Historically and currently, the focus of IRIS toxicity assessments has been on the potential health effects of long-term (chronic) exposure to chemicals. According to OMB, EPA is the only federal agency that develops qualitative and quantitative assessments of both cancer and non-cancer risks of exposure to chemicals, and EPA does so largely under the IRIS program. Other federal agencies develop quantitative estimates of non-cancer effects or qualitative cancer assessments of exposure to chemicals in the environment. While these latter assessments provide information on the effects of long-term exposures to chemicals, they provide only qualitative assessments of cancer risks (known human carcinogen, likely human carcinogen, etc.) and not quantitative estimates of cancer potency, which are required to conduct quantitative risk assessments.

EPA's IRIS assessment process has undergone a number of formal and informal changes during the past several years. While the process used to develop IRIS chemical assessments includes numerous individual steps or activities, major assessment steps include (1) a review of the scientific literature; (2) preparation of a draft IRIS assessment; (3) internal EPA reviews of draft assessments; (4) two OMB/interagency reviews, managed by OMB, that provide input from OMB as well as from other federal agencies, including those that may be affected by the IRIS assessments if they lead to regulatory or other actions; (5) an independent peer review conducted by a panel of experts; and (6) the completion of a final assessment that is posted to the IRIS web site.

Unlike many other EPA programs that have statutory requirements, including specific time frames for completing mandated tasks, the IRIS program is not subject to statutory requirements or timeframes. In contrast, the Department of Human Health and Services' Agency for Toxic Substances and Disease Registry (ATSDR),

[2] GAO–08–440 (Washington, D.C.: Mar. 7, 2008).

which develops quantitative estimates of the non-cancer effects of exposures to chemicals in the environment, is statutorily required to complete its assessments within certain timeframes.

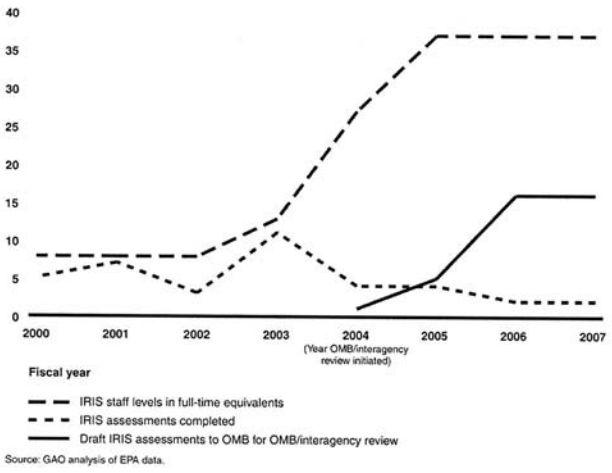
Findings and Recommendations from Our March 2008 Report on the Productivity and Credibility of EPA's Integrated Risk Information System

The IRIS database is at serious risk of becoming obsolete because the agency has not been able to routinely complete timely, credible assessments or decrease a backlog of 70 ongoing assessments. Specifically, although EPA has taken important steps to improve the IRIS program and productivity since 2000 and has developed a number of draft assessments for external review, its efforts to finalize the assessments have been thwarted by a combination of factors including the imposition of external requirements, the growing complexity and scope of risk assessments, and certain EPA management decisions. In addition, the changes to the IRIS assessment process that EPA was considering at the time of our review would have added to the already unacceptable level of delays in completing IRIS assessments and further limited the credibility of the assessments.

EPA's Efforts to Improve the IRIS Assessment Program Have Not Produced the Desired Results

EPA has taken a number of steps to help ensure that IRIS contains current, credible chemical risk information; to address its backlog of ongoing assessments; and to respond to new OMB requirements. However, to date, these changes—including increasing funding, centralizing staff conducting assessments, and revising the assessment process—have not enabled EPA to routinely complete credible IRIS assessments or decrease the backlog. That is, although EPA sent 32 draft assessments for external review in fiscal years 2006 and 2007, the agency finalized only four IRIS assessments during this time (see Fig. 2).

Figure 2: Number of Completed IRIS Assessments, Draft Assessments to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007



Source: GAO analysis of EPA data.

Several key factors have contributed to EPA's inability to achieve a level of productivity that is needed to sustain the IRIS program and database: new OMB-required reviews of IRIS assessments by OMB and other federal agencies; the growing complexity and scope of risk assessments; certain EPA management decisions and issues, including delaying completion of some assessments to await new research or to develop enhanced analyses of uncertainty in the assessments; and the compounding effect of delays. Regarding the last factor, even a single delay in the

assessment process can lead to the need to essentially repeat the assessment process to take into account changes in science and methodologies.

A variety of delays have impacted the majority of the 70 assessments being conducted as of December 2007—48 had been in process for more than five years, and 12 of those for more than nine years. These time frames are problematic because of the substantial rework such cases often require to take into account changing science and methodologies before they can be completed. For example, EPA's assessment of the cancer risks stemming from exposure to naphthalene—a chemical used in jet fuel and in the production of widely used commercial products such as moth balls, dyes, insecticides, and plasticizers—was nearing completion in 2006. However, prior to finalizing this assessment, which had been ongoing for over four years, EPA decided that the existing non-cancer assessment had become outdated and essentially restarted the assessment to include both cancer and non-cancer effects. As a result, six years after the naphthalene assessment began, it is now back at the drafting stage. The assessment now will need to reflect relevant research completed since the draft underwent initial external peer review in 2004, and it will have to undergo all of the IRIS assessment steps again, including the additional internal and external reviews that are now required (see Appendix I).

Further, because EPA staff time continues to be 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 is limited. Importantly, EPA program offices and State and local entities have requested assessments of hundreds of chemicals not yet in IRIS, and EPA data as of 2003 indicated that the assessments of 287 chemicals in the database may be outdated—that is, new information could change the risk estimates currently in IRIS or enable EPA to develop additional risk estimates for chemicals in the database (for example, developing a cancer potency estimate for assessments with only non-cancer estimates). In addition, because EPA's 2003 data are now more than four years old, it is likely that more assessments may be outdated now.

The consequences of not having current, credible IRIS information can be significant. EPA's inability to complete its assessment of formaldehyde, which the agency initiated in 1997 to update information already in IRIS on the chemical, has had a significant impact on EPA's air toxics program. Although in 2003 and 2004, the National Cancer Institute and the National Institute of Occupational Safety and Health (NIOSH) had released updates to major epidemiological studies of industrial workers that showed a relationship between formaldehyde and certain cancers, including leukemia, EPA did not move forward to finalize an IRIS assessment incorporating these important data. Instead, EPA opted to await the results of another update to the National Cancer Institute study. While this additional research was originally estimated to take, at most, 18 months to complete, at the time of our report (more than three years later) the update was not complete. In the absence of this information, EPA's Office of Air and Radiation decided to use risk information developed by an industry-funded organization—the CIIT Centers for Health Research—for a national emissions standard. This decision was a factor in EPA exempting certain facilities with formaldehyde emissions from the national emissions standard. The CIIT risk estimate indicates a potency about 2,400 times lower than the estimate in IRIS that was being re-evaluated and that did not yet consider the 2003 and 2004 National Cancer Institute and NIOSH epidemiological studies. According to an EPA official, an IRIS cancer risk factor based on the 2003 and 2004 National Cancer Institute and NIOSH studies would likely be close to the current IRIS assessment, which EPA has been reevaluating since 1997. The discrepancy between these two risk estimates raises concerns about whether the public health is adequately protected in the absence of current IRIS information. For example, in 1999, EPA published a national assessment that provided information about the types and amounts of air toxics to which people are exposed. The assessment, which also used the CIIT risk estimate for formaldehyde, concluded, for example, that formaldehyde did not contribute significantly to the overall cancer risk in the State of New Jersey. However, in carrying out its own risk assessment on formaldehyde, the New Jersey Department of Environmental Protection opted to use the risk information that is currently in IRIS (dating back to 1991) and found that the contribution from formaldehyde to overall cancer risk in New Jersey is quite significant, second only to diesel particulate matter. (Appendix I provides additional information on EPA's IRIS assessment for formaldehyde.)

One of the factors that has contributed to EPA's inability to complete assessments in a timely manner—the new OMB-directed OMB/interagency review process—also limits the credibility of the assessments because it lacks transparency. Specifically, neither the comments nor the changes EPA makes to the scientific IRIS assessments in response to the comments made by OMB and other federal agencies, in-

cluding those whose workload and resource levels could be affected by the assessments, are disclosed. In addition, the OMB/interagency reviews have hindered EPA's ability to independently manage its IRIS assessments. For example, without communicating its rationale for doing so, OMB directed EPA to terminate five IRIS assessments that for the first time addressed acute, rather than chronic exposure—even though EPA initiated this type of assessment to help it implement the *Clean Air Act.*

The Expansion of Agencies' Roles in IRIS Assessments That EPA Was Considering at the Time of Our Review Would Have Caused Further Delays and Limited the Assessments' Credibility

For our March 2008 report, we reviewed the additional assessment process changes EPA was planning and concluded that they would likely exacerbate delays in completing IRIS assessments and further affect their credibility. Specifically, despite the OMB/interagency review process that OMB required EPA to incorporate into the IRIS assessment process in 2005, certain federal agencies continued to believe they should have greater and more formal roles in EPA's development of IRIS assessments. Consequently, EPA had been working for several years to establish a formal IRIS assessment process that would further expand the role of federal agencies in the process—including agencies such as DOD, which could be affected by the outcome of IRIS assessments. For example, some of these agencies and their contractors could 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. In addition, the agencies could be required to, for example, redesign systems and processes to eliminate hazardous materials; develop material substitutes; and improve personal protective clothing, equipment, and procedures. Under the changes that EPA was planning at the time of our review, these potentially affected agencies would have the opportunity to be involved, or provide some form of input, at almost every step of EPA's IRIS assessment process. Most significantly, the changes would have provided federal agencies, including those facing potential regulatory liability, with several opportunities during the IRIS assessment process to subject particular chemicals of interest to additional process steps. These additional process steps, which would have lengthened assessment times considerably, include:

- giving federal agencies and the public 45 days to identify additional information on a chemical for EPA's consideration in its assessment or to correct any errors on an additional assessment draft that would provide qualitative information;[3]
- giving potentially affected federal agencies 30 days to review the public comments EPA received and initiate a meeting with EPA if they want to discuss a particular set of comments;
- allowing potentially affected federal agencies to have assessments suspended for up to 18 months to fill a data gap or eliminate an uncertainty factor that EPA plans to use in its assessment; and
- allowing other federal agencies to weigh in on (1) the level of independent peer review that would be sought (that is, whether the peer reviews would be conducted by EPA Science Advisory Board panels, National Academies' panels, or panels organized by an EPA contractor); (2) the areas of scientific expertise needed on the panel; and (3) the scope of the peer reviews and the specific issues they would address.

EPA estimated that assessments that undergo these additional process steps would take up to six years to complete. While it is important to ensure that assessments consider the best science, EPA has acknowledged that waiting for new data can result in substantial harm to human health, safety, and the environment. Further, although coordination with other federal agencies about IRIS assessments could enhance their quality,[4] increasing the role of agencies that may be affected

[3] This represents an additional review of a new draft product and comment period that had not existed previously. As shown in Appendix II, the assessment process EPA used at the time of our review included publishing its annual IRIS assessment agenda in the *Federal Register* and soliciting relevant scientific information from the public.

[4] We recommended in our 2006 report on human health risk assessment that EPA consistently involve stakeholders as appropriate to the risk assessment. We made this recommendation in the context of improving the overall quality, consistency, and transparency of risk assessments. GAO, *Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process, but Im-*

Continued

by IRIS assessments in the process itself reduces the credibility of the assessments if that expanded role is not transparent. In this regard, while EPA's proposed changes would have allowed for including federal agencies' comments in the public record, the implementation of this proposal was delayed for a year, in part, because of OMB's view that agencies' comments about IRIS assessments represent internal executive branch communications that may not be made public—a view that is inconsistent with the principle of sound science, which relies on, among other things, transparency. (Appendix II and III provide flow charts of the IRIS process that was in place at the time of our review and EPA's draft proposed process being considered at the time of our review, respectively).

Recommendations Made in Our March 2008 Report

To address the productivity and credibility issues we identified, we recommended that the EPA Administrator require the Office of Research and Development to re-evaluate its draft proposed changes to the IRIS assessment process in light of the issues raised in our report and ensure that any revised process, among other things, clearly defines and documents an IRIS assessment process that will enable the agency to develop the timely chemical risk information it needs to effectively conduct its mission. One of our recommendations—that EPA provide at least two years' notice of IRIS assessments that are planned—would, among other things, provide an efficient alternative to suspending assessments while waiting for new research because interested parties would have the opportunity to conduct research before assessments are started.

In addition, we recommended that the EPA Administrator take steps to better ensure that EPA has the ability to develop transparent, credible IRIS assessments—an ability that relies in large part on EPA's independence in conducting these important assessments. Actions that are key to this ability include ensuring that EPA can (1) determine the types of assessments it needs to support EPA programs and (2) define the appropriate role of external federal agencies in EPA's IRIS assessment process, and (3) manage an interagency review process in a manner that enhances the quality, transparency, timeliness, and credibility of IRIS assessments. In its February 21, 2008, letter providing comments on our draft report, EPA said it would consider each of our recommendations in light of the new IRIS process the agency was developing.

Key Aspects of the Revised IRIS Assessment Process Implemented in April 2008 Which Is Not Responsive to GAO's Recommendations

On April 10, 2008, EPA issued a revised IRIS assessment process, effective immediately. Overall, EPA's revised process is not responsive to the recommendations made in our March 2008 report—it is largely the same as the draft proposed process we evaluated in our March 2008 report (see Appendix III and IV). Moreover, changes EPA did incorporate into the final process are likely to further exacerbate the productivity and credibility issues we identified in our report.

- *We recommended that EPA ensure that, among other things, any revised process clearly defines and documents a streamlined IRIS assessment process that can be conducted within time frames that minimize the need for wasteful rework.*

As discussed in our report, 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. However, EPA's revised process institutionalizes a process that the agency estimates will take up to six years to complete. Further, the estimated time frames do not factor in the time for peer reviews conducted by the National Academies, which can take two years to plan and complete.[5] EPA typically uses reviews by the National Academies for highly controversial chemicals or complex assessments. Therefore, assessments of key chemicals of concern to public health that are reviewed by the National Academies are likely to take at least eight years to complete. These time frames must also be considered in light of OMB's view that health assessment values in IRIS are out of date if they are more than 10 years old and if new scientific information exists that could change the health assessment values. Thus, EPA's new process institutionalizes time frames that could essentially require the agency to start assess-

---

provements Needed in Planning, Data Development, and Training, GAO–06–595 (Washington, D.C.: May 31, 2006).

[5] It is not clear whether the time frames exclude reviews conducted by EPA's Science Advisory Board, which can also add considerably more time than the most basic level of peer review used by the IRIS program—panels organized by an EPA contractor.

ment updates as soon as two years after assessments are finalized in order to keep the IRIS database current. Such time frames are not consistent with our recommendation that EPA develop, clearly define, and document a streamlined IRIS process that can be conducted within time frames that minimize the need for wasteful rework. Further, the agency would need a significant increase in resources to support such an assessment cycle.

In addition, EPA had previously emphasized that, in suspending assessments to allow agencies to fill in data gaps, it would allow no more than 18 months to complete the studies and have them peer reviewed. However, under the new process, EPA states that it *generally* will allow no more than 18 months to complete the studies and have them peer reviewed. As we concluded in our report, we believe the ability to suspend assessments for up to 18 months would add to the already unacceptable level of delays in completing IRIS assessments. Further, we and several agency officials with whom we spoke believe that the time needed to plan, conduct, and complete research that would address significant data gaps, and have it peer reviewed, would likely exceed 18 months. Therefore, the less rigid time frame EPA included in its new process could result in additional delays.

Finally, the new process expands the scope of one of the additional steps that initially was to apply only to chemicals of particular interest to federal agencies.[6] Specifically, under the draft process we reviewed, EPA would have provided an additional review and comment opportunity for federal agencies and the public for what EPA officials said would be a small group of chemicals. However, under EPA's new process, this additional step has been added to the assessment process for all chemicals and, therefore, will add time to the already lengthy assessments of all chemicals.

- *We also recommended that the EPA Administrator take steps to better ensure that EPA has the ability to develop transparent, credible IRIS assessments—an ability that relies in large part on EPA's independence in conducting these important assessments.*

Contrary to our recommendation, EPA has formalized a revised IRIS process that is selectively, rather than fully, transparent, limiting the credibility of the assessments. Specifically, while the draft process we reviewed provided that comments on IRIS assessments from OMB and other federal agencies would be part of the public record, under the recently implemented process, comments from federal agencies are expressly defined as "deliberative" and will not be included in the public record.[7] Given the importance and sensitivity of IRIS assessments, we believe it is critical that input from all parties, particularly agencies that may be affected by the outcome of IRIS assessments, be publicly available. However, under EPA's new process, input from some IRIS assessment reviewers—representatives of federal agencies, including those facing potential regulatory liability, and private stakeholders associated with these agencies—will continue to receive less public scrutiny than comments from all others.

In commenting on a draft of our March 2008 report, and in a recent congressional hearing, EPA's Assistant Administrator, Office of Research and Development, stated that the IRIS process is transparent because all final IRIS assessments must undergo public and external peer review. However, as we stated in our report, the presence of transparency at a later stage of IRIS assessment development does not explain or excuse its absence earlier. Under the new process, neither peer reviewers nor the public are privy to the changes EPA makes in response to the comments OMB and other federal agencies provide to EPA at several stages in the assessment process—changes to draft assessments or to the questions EPA poses to the peer review panels. Importantly, the first IRIS assessment draft that is released to peer reviewers and to the public includes the undisclosed input from federal agencies potentially subject to regulation and therefore with an interest in minimizing the impacts of IRIS assessments on their budgets and operations.

In addition, EPA's revised process does not provide EPA with sufficient independence in developing IRIS assessments to ensure they are credible and transparent. We made several recommendations aimed at restoring EPA's independence. For example, we recommended that the EPA Administrator ensure that EPA has the abil-

[6] The new IRIS assessment process refers to such chemicals as "mission critical." The process defines a mission-critical chemical as one that "is an integral component to the successful and safe conduct of an agency's mission in any or all phases of its operations." According to the process, "impacts on the use of mission-critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints."

[7] Making these comments public would have been a change from the OMB/interagency review process that has been in place since 2004.

ity to, among other things, define the appropriate role of external federal agencies in the IRIS assessment process and determine when interagency issues have been appropriately addressed. However, under the newly implemented IRIS assessment process, OMB continues to inform EPA when EPA has adequately addressed OMB's and interagency comments. This determination must be made both before EPA can provide draft assessments to external peer reviewers and to the public and before EPA can finalize and post assessments on the IRIS database. While EPA officials state that ultimately IRIS assessments reflect EPA decisions, the new process does not support this assertion given the clearances EPA needs to receive from OMB to move forward at key stages. In fact, we believe the new IRIS assessment process may elevate the goal of reaching interagency agreement above achieving IRIS program objectives. Further, as discussed above, because the negotiations over OMB/interagency comments are not disclosed, whether EPA is entirely responsible for the content of information on IRIS is open to question.

In our report, we also emphasized the importance of ensuring that IRIS assessments be based solely on science issues and not policy concerns. However, under the new IRIS assessment process, EPA has further introduced policy considerations into the IRIS assessment process. That is, the newly implemented IRIS assessment process broadens EPA's characterization of IRIS assessments from "the agency's scientific positions on human health effects that may result from exposure to environmental contaminants" to "the agency's science and science policy positions" on such effects. EPA's new, broader characterization of IRIS raises concerns about the agency's stated intent to ensure that scientific assessments are appropriately based on the best available science and that they are not inappropriately impacted by policy issues and considerations. For example, in discussing science and science policy at a recent Senate hearing, EPA's Assistant Administrator of Research and Development described science policy considerations as including decisions about filling knowledge gaps (e.g., whether and to what extent to use default assumptions) and assessing weight-of-the-evidence approaches to make scientific inferences or assumptions. We believe that these are scientific decisions that should reflect the best judgment of EPA scientists who are evaluating the data, using the detailed risk assessment guidance the agency has developed for such purposes. We have concerns about the manner and extent to which other federal agencies, including those that may be affected by the outcome of assessments, are involved in these decisions as well as the lack of transparency of their input. As we highlighted earlier, under the National Academies' risk assessment and risk management paradigm, policy considerations are relevant in the risk management phase—which occurs *after* the risk assessment phase that encompasses IRIS assessments. The National Academies recently addressed this issue as follows: "The committee believes that risk assessors and risk managers should talk with each other; that is, a 'conceptual distinction' does not mean establishing a wall between risk assessors and risk managers. Indeed they should have constant interaction. However, the dialogue should not bias or otherwise color the risk assessment conducted, and the activities should remain distinct; that is, risk assessors should not be performing risk management activities."[8]

Concluding Observations

The new IRIS assessment process that EPA implemented in April 2008 will not allow the agency to routinely and timely complete credible assessments. In fact, it will exacerbate the problems we identified in our March 2008 report and sought to address with our recommendations—all of which were aimed at preserving the viability of this critical database, which is integral to EPA's mission of protecting the public and the environment from exposure to toxic chemicals. Specifically, under the new process, assessment time frames will be significantly lengthened, and the lack of transparency will further limit the credibility of the assessments because input from OMB and other agencies at all stages of the IRIS assessment process is now expressly defined as deliberative and therefore not subject to public disclosure. The position of the Assistant Administrator, Office of Research and Development, that the IRIS process is transparent because all final IRIS assessments must undergo public and external peer review is unconvincing. Transparency at a later stage of the IRIS assessment process—after OMB and other federal agencies have had multiple opportunities to influence the content of the assessment without any disclosure of their input—does not compensate for its absence earlier.

We continue to believe that to effectively maintain IRIS EPA must streamline its lengthy assessment process and adopt transparency practices that provide assur-

[8] National Academies, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget Committee to Review the OMB Risk Assessment Bulletin* (2007).

ance that IRIS assessments are appropriately based on the best available science and that they are not inappropriately biased by policy issues and considerations. As discussed in our April 29, 2008, testimony before the Senate Environment and Public Works Committee, we believe that the Congress should consider requiring EPA to suspend implementation of its new IRIS assessment process and develop a streamlined process that is transparent and otherwise responsive to our recommendations aimed at improving the timeliness and credibility of IRIS assessments.[9] For example, suspending assessments to obtain additional research is inefficient; alternatively, with longer-term planning, EPA could provide agencies and the public with more advance notice of assessments, enabling them to complete relevant research before IRIS assessments are started.

In addition, as discussed in our April 2008 testimony, the Congress should consider requiring EPA to obtain and be responsive to input from the Congress and the public before finalizing a revised IRIS assessment process. We note that while EPA and OMB initially had planned for EPA to release a draft revised IRIS assessment process to the public, hold a public meeting to discuss EPA's proposed changes, and seek and incorporate public input before finalizing the process, EPA released its new assessment process without obtaining public input and made it effective immediately. This was inconsistent with assertions made in OMB's letter commenting on our draft report, which emphasized that EPA had not completed the development of the IRIS assessment process and stated: "Indeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments."

Finally, if EPA is not able to take the steps we have recommended to effectively maintain this critical program, other approaches, including statutory requirements, may need to be explored.

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.

Contacts and Acknowledgments

Contact points for our Congressional Relations and Public Affairs Offices may be found on the last page of this statement. Contributors to this testimony include Christine Fishkin (Assistant Director), Laura Gatz, Richard P. Johnson, and Nancy Crothers.

[9] GA0, *Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals,* GAO–08–743T (Washington, D.C.: April 29, 2008).

Appendix I:

Examples of Key IRIS Assessments That Have Been Delayed

Some key IRIS assessments have been in progress for a number of years, in part because of delays stemming from one or more of the key factors we identified that have hindered EPA's productivity.[10] Examples include the following:

Naphthalene. EPA started the IRIS assessment of cancer risks stemming from the inhalation of naphthalene in 2002. Naphthalene is used in jet fuel and in the production of widely used commercial products such as moth balls, dyes, insecticides, and plasticizers. According to a presentation delivered at the 2007 annual meeting of the Society for Risk Analysis by an Army Corps of Engineers toxicologist,[11] "The changing naphthalene regulatory environment includes a draft EPA risk assessment that if/when finalized, will change naphthalene's status from 'possible' to 'likely' human carcinogen."[12] Thus, according to this presentation, one potential impact of this IRIS assessment on DOD is that DOD would need to provide many employees exposed to naphthalene with equipment measuring their exposure to the chemical. In addition, because many military bases are contaminated with naphthalene, a component of jet fuel (approximately one percent to three percent) used by all DOD services, DOD could face extensive cleanup costs. By 2004, two years after starting the assessment, EPA had drafted a chemical assessment that had completed internal peer reviews and was about to be sent to an external peer review committee. Once it returned from external review, the next step, at that time, would have been a formal review by EPA's IRIS Agency Review Committee. If approved, the assessment would have been completed and released. However, in part because of concerns raised by DOD, OMB asked to review the assessment and conducted an interagency review of the draft. In their 2004 reviews of the draft IRIS assessment, both OMB and DOD raised a number of concerns about the assessment and suggested to EPA that it be suspended until additional research could be completed to address what they considered to be significant uncertainties associated with the assessment. Although all of the issues raised by OMB and DOD were not resolved, EPA continued with its assessment by submitting the draft for external peer review, which was completed in September 2004.[13] However, according to EPA, OMB continued to object to the draft IRIS assessment and directed EPA to convene an additional expert review panel on genotoxicity to obtain recommendations about short-term tests that OMB thought could be done quickly.[14] According to EPA, this added six months to the process, and the panel, which met in April 2005, concluded that the research that OMB was proposing could not be conducted in the short-term. Nonetheless, EPA officials said that the second expert panel review did not eliminate OMB's concerns regarding the assessment, which they described as reaching a stalemate. In September 2006, EPA decided, however, to proceed with developing the assessment. By this time, the naphthalene assessment had been in progress for over four years; EPA decided that the IRIS non-cancer assessment, issued in 1998, was outdated and needed to be revisited. Thus, EPA expanded the IRIS naphthalene assessment to include both non-cancer and cancer assessments. As a result, six years after the naphthalene assessment began, it is now back at the drafting stage. The assessment now will need to reflect relevant research completed since the draft underwent ini-

---

[10] The factors we identified that have hindered EPA's efforts to improve productivity are the OMB/interagency review process managed by OMB, the growing complexity and scope of risk assessments, certain management decisions and issues regarding the IRIS program, congressional action that has delayed some assessments with potentially significant economic effects, and the compounding effect of delays.

[11] Presentations at the Society for Risk Analysis meeting reflect the views of the authors and "do not necessarily reflect the views of any other organization or agency."

[12] Using its 1996 Proposed Guidelines for Carcinogen Risk Assessment, EPA concluded in the 1998 IRIS assessment of naphthalene that its human carcinogenic potential could not be determined at that time, but noted that there was suggestive evidence of potential human carcinogenicity. (EPA also noted that under its 1986 cancer guidelines, EPA classified naphthalene as a possible human carcinogen.) Subsequently, in 2002, the International Agency for Research on Cancer (IARC), part of the World Health Organization, concluded that naphthalene is possibly carcinogenic to humans; in 2004, the Department of Human Health and Services' National Toxicology Program concluded that naphthalene can reasonably be anticipated to be a human carcinogen. EPA's current assessment will be subject to the agency's 2005 cancer guidelines.

[13] According to DOD, EPA did not specifically ask the peer reviewers to address some of the technical questions DOD had raised and wanted the peer review to address.

[14] Genotoxic substances are a type of carcinogen, specifically those capable of causing genetic mutation and of contributing to the development of tumors. This includes both certain chemical compounds and certain types of radiation.

tial external peer review in 2004, and it will have to undergo all of the IRIS assessment steps again, including additional internal and external reviews that are now required. This series of delays has limited EPA's ability to conduct its mission. For example, the Office of Air and Radiation has identified the naphthalene assessment as one of its highest-priority needs for its air toxics program. In addition, the Office of Solid Waste and Emergency Response considers the naphthalene assessment a high priority for the Superfund program—naphthalene has been found in at least 654 of Superfund's current or former National Priorities List sites.[15] Although EPA currently estimates that it will complete the assessment in 2009, meeting this revised estimate will be challenging, given all of the steps that are yet to be completed and the extensive external scrutiny to which it will continue to be subjected.

Royal Demolition Explosive. This chemical, also called RDX or hexahydro-1,3,5-trinitrotriazine, is a highly powerful explosive used by the U.S. military in thousands of munitions. Currently classified by EPA as a possible human carcinogen, this chemical is known to leach from soil to groundwater. Royal Demolition Explosive can cause seizures in humans and animals when large amounts are inhaled or ingested, but the effects of long-term, low-level exposure on the nervous system are unknown. As is the case with naphthalene, the IRIS assessment could potentially require DOD to undertake a number of actions, including steps to protect its employees from the effects of this chemical and to clean up many contaminated sites. Although EPA started an IRIS assessment of Royal Demolition Explosive in 2000, it has made minimal progress on the assessment because EPA agreed to a request by DOD to wait for the results of DOD-sponsored research on this chemical. In 2007, EPA began to actively work on this assessment, although some of the DOD-sponsored research is still outstanding.

Formaldehyde. EPA began an IRIS assessment of formaldehyde in 1997 because the existing assessment was determined to be outdated.[16] Formaldehyde is a colorless, flammable, strong-smelling gas used to manufacture building materials, such as pressed wood products, and used in many household products, including paper, pharmaceuticals, and leather goods. While EPA currently classifies formaldehyde as a probable human carcinogen, the International Agency for Research on Cancer (IARC), part of the World Health Organization, classifies formaldehyde as a known human carcinogen. Since 1986, studies of industrial of workers have suggested that formaldehyde exposure is associated with nasopharyngeal cancer, and possibly with leukemia. For example, in 2003 and 2004, the National Cancer Institute (NCI) and the National Institute of Occupational Safety and Health (NIOSH) released epidemiological studies following up on earlier studies tracking about 26,000 and 11,000 industrial workers, respectively, exposed to formaldehyde; the updates showed exposure to formaldehyde might also cause leukemia in humans, in addition to the cancer types previously identified. According to NCI officials, the key findings in their follow-up study were an increase in leukemia deaths and, more significantly, an exposure/response relationship between formaldehyde and leukemia—as exposure increased, the incidence of leukemia also rose. As with the earlier study, NCI found more cases of a rare form of cancer, nasopharyngeal cancer, than would usually be expected. The studies from NCI and NIOSH were published in 2003 and 2004,[17] around the time that EPA was still drafting its IRIS assessment. In November 2004, the Chairman of the Senate Environment and Public Works Committee requested that EPA delay completion of its IRIS assessment until an update to the just-released NCI study could be conducted, indicating that the effort would take, at most, 18 months. EPA agreed to wait—and more than three years later, the NCI update is not yet complete. As of December 2007, NCI estimates that the study will be completed in two stages, one in mid-2008 and the second one later that year. An NCI

[15] The National Priorities List is EPA's list of seriously contaminated sites.

[16] The cancer portion of the formaldehyde assessment was originally issued in 1989 and updated in 1991; the non-cancer assessment was added in 1990.

[17] NCI published the results of its study in two publications. The first study, published in November 2003, focused on the association between formaldehyde exposure and leukemia. M. Hauptmann, J.H. Lubin, P.A. Stewart, R.B. Hayes, A. Blair, "Mortality from Lymphohematopoietic Malignancies among Workers in Formaldehyde Industries," *Journal of the National Cancer Institute* (2003). The second study, published in June 2004, evaluated the association between formaldehyde exposure and other cancers—including nasopharyngeal cancer. M. Hauptmann, J.H. Lubin, P.A. Stewart, R.B. Hayes, A. Blair, "Mortality from Solid Cancers among Workers in Formaldehyde Industries," *American Journal of Epidemiology* (2004). The results of the NIOSH study were described in one publication, dated March 2004, which assessed mortality from all causes and all cancers. L.E. Pinkerton, M.J. Hein, L.T. Stayner, "Mortality among a Cohort of Garment Workers Exposed to Formaldehyde: an Update," *Occupational and Environmental Medicine* (2004).

official said that the additional leukemia deaths identified in the update provide "greater power" to detect associations between exposure to formaldehyde and cancer. EPA's inability to complete the IRIS assessment it started more than 10 years ago in a timely manner has had a significant impact on EPA's air toxics program. Specifically, when EPA promulgated a national emissions standard for hazardous air pollutants covering facilities in the plywood and composite wood industries in 2004, EPA's Office of Air and Radiation took the unusual step of not using the existing IRIS estimate but rather decided to use a cancer risk estimate developed by an industry-funded organization, the CIIT Centers for Health Research (formerly, the Chemical Industry Institute of Toxicology) that had been used by the Canadian health protection agency. The IRIS cancer risk factor had been subject to criticism because it was last revised in 1991 and was based on data from the 1980s. In its final rule, EPA stated that "the dose-response value in IRIS is based on a 1987 study, and no longer represents the best available science in the peer-reviewed literature." The CIIT quantitative cancer risk estimate that EPA used in its health risk assessment in the plywood and composite wood national emissions standard indicates a potency about 2,400 times lower than the estimate in IRIS that was being re-evaluated and that did not yet consider the 2003 and 2004 NCI and NIOSH epidemiological studies. According to an EPA official, an IRIS cancer risk factor based on the 2003 and 2004 NCI and NIOSH studies would likely be close to the current IRIS assessment, which EPA has been attempting to update since 1997. The decision to use the CIIT assessment in the plywood national emissions standard was controversial, and officials in EPA's National Center for Environmental Assessment said the center identified numerous problems with the CIIT estimate. Nonetheless, the Office of Air and Radiation used the CIIT value, and that decision was a factor in EPA exempting certain facilities with formaldehyde emissions from the national emissions standard. In June 2007, a federal appellate court struck down the rule, holding that EPA's decision to exempt certain facilities that EPA asserted presented a low health risk exceeded the agency's authority under the *Clean Air Act.*[18] Further, the continued delays of the IRIS assessment of formaldehyde—currently estimated to be completed in 2010 but after almost 11 years still in the draft development stage—will impact the quality of other EPA regulatory actions, including other air toxics rules and requirements.

Trichloroethylene. Also known as TCE, this chemical is a solvent widely used as a degreasing agent in industrial and manufacturing settings; it is a common environmental contaminant in air, soil, surface water, and groundwater. TCE has been linked to cancer, including childhood cancer, and other significant health hazards, such as birth defects. TCE is the most frequently reported organic contaminant in groundwater, and contaminated drinking water has been found at Camp Lejeune, a large Marine Corps base in North Carolina. TCE has also been found at Superfund sites and at many industrial and government facilities, including aircraft and spacecraft manufacturing operations. In 1995, the International Agency for Research on Cancer classified TCE as a probable human carcinogen, and in 2000, the Department of Health and Human Services' National Toxicology Program concluded that it is reasonably anticipated to be a human carcinogen. Because of questions raised by peer reviewers about the IRIS cancer assessment for TCE, EPA withdrew it from IRIS in 1989 but did not initiate a new TCE cancer assessment until 1998. In 2001, EPA issued a draft IRIS assessment for TCE that proposed a range of toxicity values indicating a higher potency than in the prior IRIS values and characterizing TCE as "highly likely to produce cancer in humans." The draft assessment, which became controversial, was peer reviewed by EPA's Scientific Advisory Board and released for public comment. A number of scientific issues were raised during the course of these reviews, including how EPA had applied emerging risk assessment methods—such as assessing cumulative effects (of TCE and its metabolites) and using a physiologically based pharmacokinetic model—and the uncertainty associated with the new methods themselves.[19] To help address these issues, EPA, DOD, DOE, and NASA sponsored a National Academies review to provide guidance. The National Academies report, which was issued in 2006, concluded that the weight of evidence of cancer and other health risks from TCE exposure had strengthened since 2001 and recommended that the risk assessment be finalized

[18] *Natural Resources Defense Council v. E.P.A.,* 489 F.3d 1364, 1372–73 (D.C. Cir, 2007). The court did not specifically address EPA's reliance on the CIIT study, holding instead that the *Clean Air Act* prohibited establishment of the exemptions at issue.

[19] Physiologically based pharmacokinetic models are a class of dosimetry models that are useful for predicting internal doses to target organs. With the appropriate data, these models can be used to extrapolate across species and exposure scenarios and address various sources of uncertainty in risk assessments.

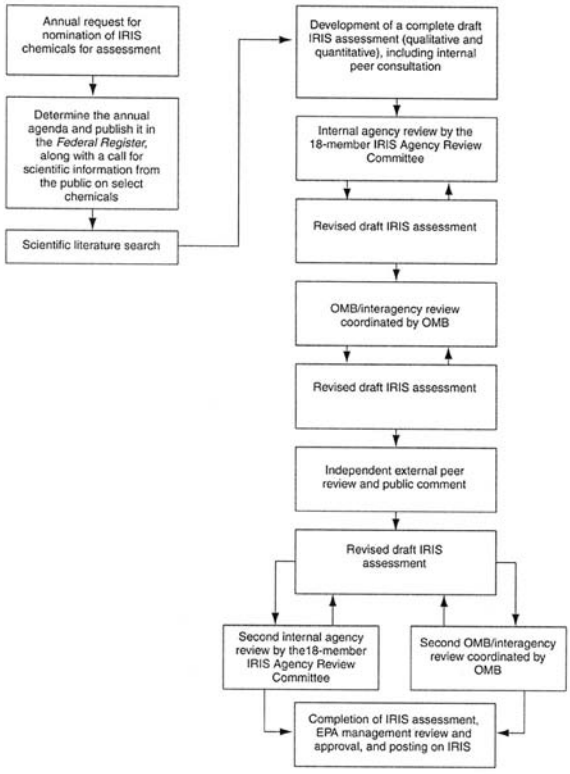
with currently available data so that risk management decisions could be made expeditiously. The report specifically noted that while some additional information would allow for more precise estimates of risk, this information was not necessary for developing a credible risk assessment. Nonetheless, 10 years after EPA started its IRIS assessment, the TCE assessment is back at the draft development stage. EPA estimates this assessment will be finalized in 2010. More in line with the National Academies' recommendation to act expeditiously, five senators introduced a bill in August 2007 that, among other things, would require EPA to both establish IRIS values for TCE and issue final drinking water standards for this contaminant within 18 months.

Tetrachloroethylene. EPA started an IRIS assessment of tetrachloroethylene—also called perchloroethylene or "perc"—in 1998. Tetrachloroethylene is a manufactured chemical widely used for dry cleaning of fabrics, metal degreasing, and making some consumer products and other chemicals. Tetrachloroethylene is a widespread groundwater contaminant, and the Department of Health and Human Services' National Toxicology Program has determined that it is reasonably anticipated to be a carcinogen. The IRIS database currently contains a 1988 non-cancer assessment based on oral exposure that will be updated in the ongoing assessment. Importantly, the ongoing assessment will also provide a non-cancer inhalation risk and a cancer assessment. The IRIS agency review of the draft assessment was completed in February 2005, the draft assessment was sent to OMB for OMB/interagency review in September 2005, and the OMB/interagency review was completed in March 2006. EPA had determined to have the next step, external peer review, conducted by the National Academies—the peer review choice reserved for chemical assessments that are particularly significant or controversial. EPA contracted with the National Academies for a review by an expert panel, and the review was scheduled to start in June 2006 and be completed in 15 months. However, as of December 2007, the draft assessment had not yet been provided to the National Academies. After verbally agreeing with both the non-cancer and cancer assessments following briefings on the assessments, the Assistant Administrator, Office of Research and Development, subsequently requested that additional uncertainty analyses—including some quantitative analyses—be conducted and included in the assessment before the draft was released to the National Academies for peer review. As discussed in our March 2008 report on IRIS (GAO–08–440), quantitative uncertainty analysis is a risk assessment tool that is currently being developed, and although the agency is working on developing policies and procedures for uncertainty analysis, such guidance currently does not exist. The draft tetrachloroethylene assessment has been delayed since early 2006 as EPA staff have gone back and forth with the Assistant Administrator trying to reach agreement on key issues such as whether a linear or nonlinear model is most appropriate for the cancer assessment and how uncertainty should be qualitatively and quantitatively characterized. EPA officials and staff noted that some of the most experienced staff are being used for these efforts, limiting their ability to work on other IRIS assessments. In addition, the significant delay has impacted the planned National Academies peer review because the current contract, which has already been extended once, cannot be extended beyond December 2008. The peer review was initially estimated to take 15 months. As a result, a new contract and the appointment of another panel may be required.

Dioxin. The dioxin assessment is an example of an IRIS assessment that has been, and will likely continue to be, a political as well as a scientific issue. Often the byproducts of combustion and other industrial processes, complex mixtures of dioxins enter the food chain and human diet through emissions into the air that settle on soil, plants, and water. EPA's initial dioxin assessment, published in 1985, focused on the dioxin TCDD (2,3,7,8-tetrachlorodibenzo-p-dioxin) because animal studies in the 1970s showed it to be the most potent cancer-causing chemical studied to date. Several years later, EPA decided to conduct a reassessment of dioxin because of major advances that had occurred in the scientific understanding of dioxin toxicity and significant new studies on dioxins' potential adverse health effects. Initially started in 1991, this assessment has involved repeated literature searches and peer reviews. For example, a draft of the updated assessment was reviewed by a scientific peer review panel in 1995, and three panels reviewed key segments of later versions of the draft in 1997 and 2000. In 2002, EPA officials said that the assessment would conclude that dioxin may adversely affect human health at lower exposure levels than had previously been thought and that most exposure to dioxins occurs from eating such American dietary staples as meats, fish, and dairy products, which contain minute traces of dioxins. These foods contain dioxins because animals eat plants and commercial feed and drink water contaminated with dioxins, which then accumulate in animals' fatty tissue. It is clear that EPA's dioxin risk assess-

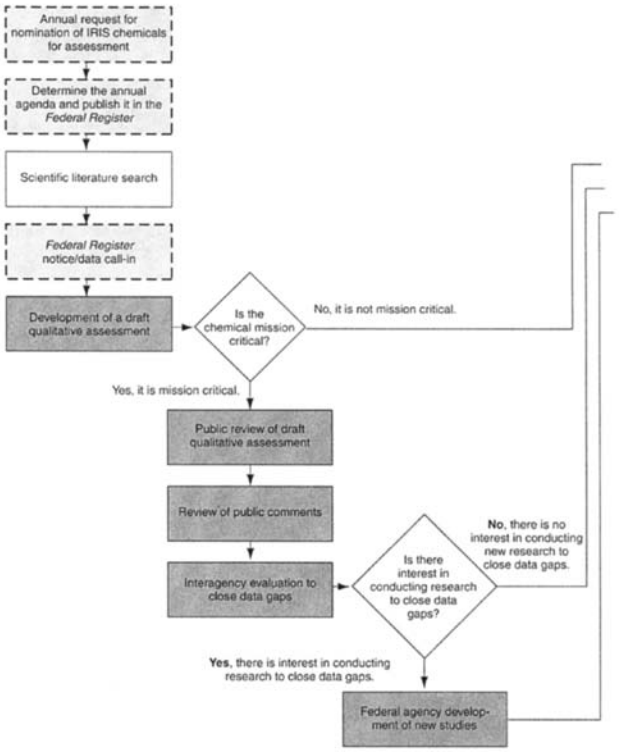
ment could have a potentially significant impact on consumers and on the food and agriculture industries. As EPA moved closer to finalizing the assessment, in 2003 the agency was directed in a congressional appropriations conference committee report to not issue the assessment until it had been reviewed by the National Academies. The National Academies provided EPA with a report in July 2006. In developing a response to the report, which the agency is currently doing, EPA must include new studies and risk assessment approaches that did not exist when the assessment was drafted. EPA officials said the assessment will be subject to the IRIS review process once its response to the National Academies' report is drafted. As of 2008, EPA has been developing the dioxin assessment, which has potentially significant health implications for all Americans, for 17 years.

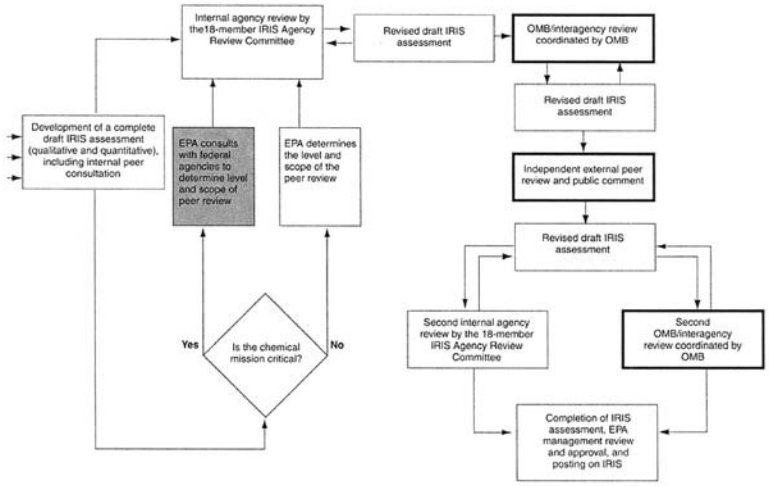
Appendix II: EPA's IRIS Assessment Process Being Implemented at the Time of Our Review (Includes OMB Requirements as of 2005)



Source: GAO analysis of EPA information.

Appendix III: EPA's Draft Proposed IRIS Assessment Process Being Considered at the Time of Our Review (Dated March 2007)





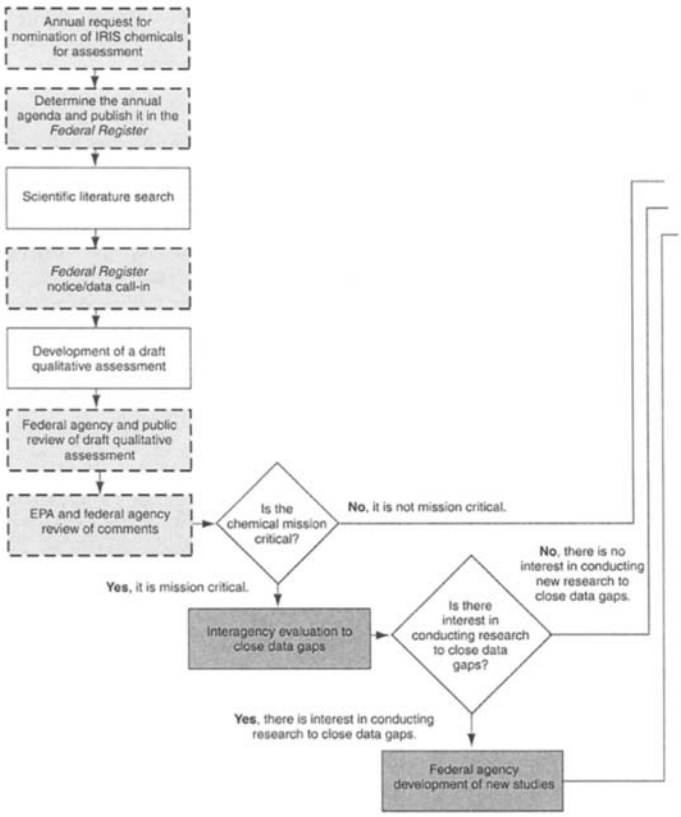
Darker shaded boxes with heavy lines are additional steps, under EPA's planned changes, to its assessment process and indicate steps where EPA has provided additional opportunity for input from potentially affected federal agencies for mission-critical chemicals.

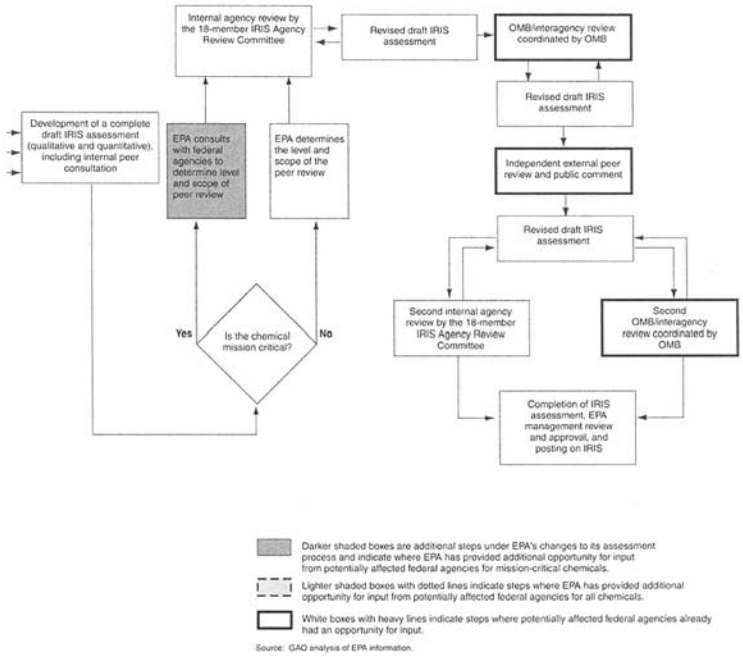
Lighter shaded boxes with heavy lines indicate steps where EPA has provided additional opportunity for input from potentially affected federal agencies for all chemicals.

White boxes with heavy lines indicate steps where potentially affected federal agencies already had an opportunity for input.

Source: GAO analysis of EPA information.

Appendix IV: EPA's IRIS Assessment Process as of April 10, 2008





BIOGRAPHY FOR JOHN B. STEPHENSON

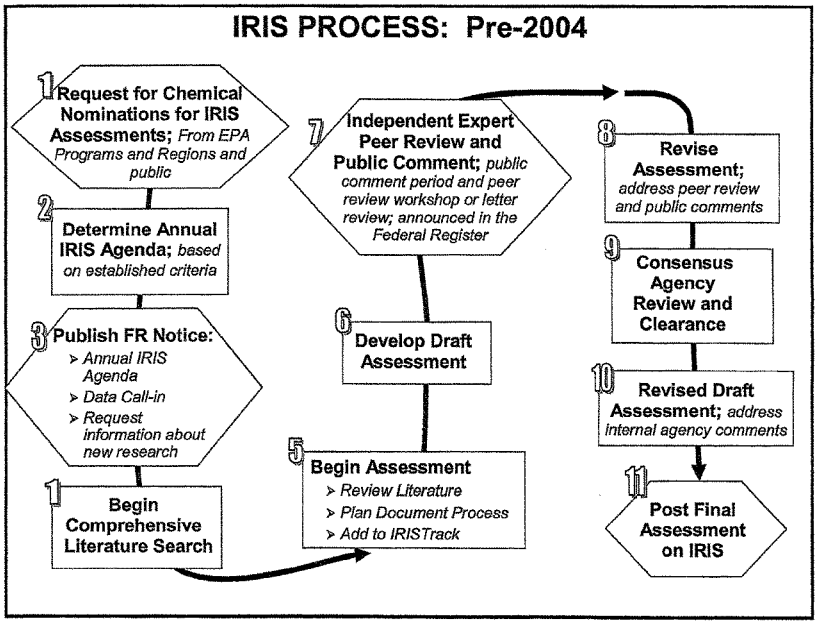
John Stephenson has been the Director of Environmental Protection Issues within GAO's Natural Resources and Environment team since October 2000. He began his GAO career with the Dayton Field Office (formerly Cincinnati Regional Office) where he focused primarily on acquisition management, defense capabilities, and information technology issues. In 1987, he transferred to Headquarters as an Assistant Director in the Accounting and Information Management Division (the forerunner of the IT, SI, and FMA teams). In that capacity he directed numerous projects, assisted in several testimonies, and issued over 100 reports on information technology issues. From April 1998–February 2000, he was detailed to the Senate Special Committee on the Year 2000 Technology Problem where he was the Deputy Staff Director. In that capacity, he ran the day-to-day operations of the Committee including establishing strategy and agendas, managing the staff, overseeing investigations, conducting over 35 hearings, and representing the Chairman (Senator Bennett, R–UT) and the Vice Chairman (Senator Dodd, D–CT) in a variety of forums. He was appointed to GAO's Executive Candidate Program in June 1999. From March–October 2000, he worked in the Office of the Comptroller General and directed GAO's mission support reorganization and realignment project for the Chief Mission Support Officer. John 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.

DISCUSSION

THE REVISED IRIS PROCESS

Chairman MILLER. Thank you. At this point, we will have our first round of questions. The Chair now recognizes himself for five minutes.

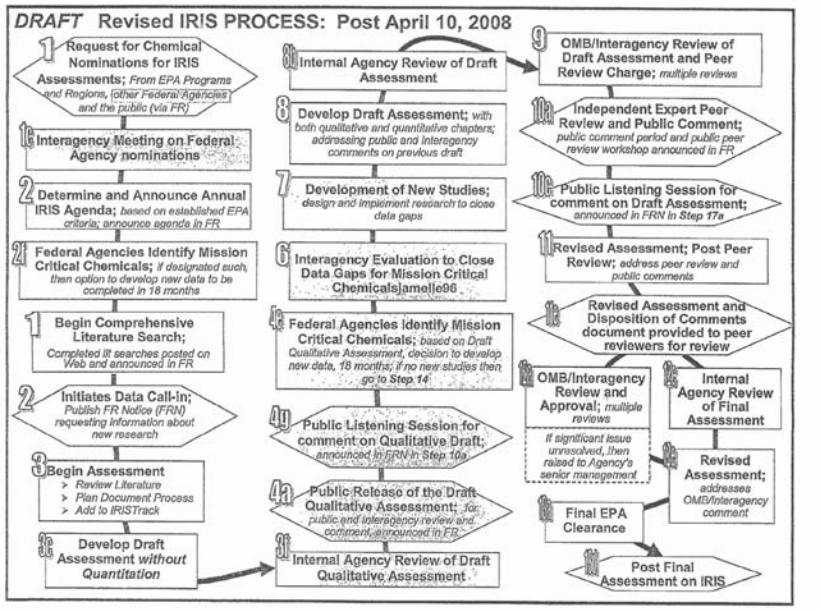
I would like to ask Mr. Whittaker to display a chart, Figure 1, if you would, please.



Chairman MILLER. Mr. Stephenson, displayed there is I believe an EPA-prepared chart that describes the IRIS process that existed before 2004. Is that—before OMB made helpful changes, helpful suggestions, about what the process should be instead. Is that correct?

Mr. STEPHENSON. That looks like a reasonable representation. We have a little bit different one in our testimony but——

Chairman MILLER. Okay. Now, if Mr. Whittaker could then display Figure 3.



Chairman MILLER. All right. Is that the current process? That also is an EPA-prepared document to show their process.

Mr. STEPHENSON. Yes. That looks like some of the new steps that have been inserted in the new process.

Chairman MILLER. Okay. It will be the testimony of the later witnesses today that that process is the streamlined version of the earlier process and that we should not believe our own lying eyes that this really is more streamlined than the previous process. Is it your testimony or your belief that it is in fact a more complicated, convoluted process, not a streamlined process?

Mr. STEPHENSON. It appears to be more complicated, but if you put the individual timeframes associated with each of those steps, we didn't invent the six to eight years, it is based on adding up the amount of time that could be taken for each of those steps and two years additional for any chemical that is deemed mission critical.

Chairman MILLER. But just if our eyes tell us that this looks a lot more complicated, our eyes did not lie?

Mr. STEPHENSON. Not in our opinion.

DID OMB REVIEW EPA'S GAO EXIT CONFERENCE COMMENTS?

Chairman MILLER. All right. Thank you. Mr. Stephenson, one of your findings was that the EPA needed to be more independent and that the lack of independence was undermining the credibility of IRIS assessments. Is it your typical procedure to show proposed findings to the agency that you have been examining?

Mr. STEPHENSON. Yes, there is a two-step process. Whenever GAO completes a review, we hold what we call an exit conference

with the affected agency, usually at the program level; and it is really a fact check, if you will, to make sure that we have characterized the facts correctly. We did that and then when we go back and consider those comments, and we publish a draft report which we then pass by the agency for official review. In this case, we passed the final report by both EPA and OMB since both were affected.

Chairman MILLER. And what was the result of that review?

Mr. STEPHENSON. Well, the first process is not considered official agency comments because it isn't blessed all the way up the chain. Nevertheless, it represents the views of the program office people who run IRIS, and in that case they felt like the interagency review process that was being levied on them was indeed adding time to the process. And not only that, they felt like they could not move forward without an OMB blessing at several points along the way when they had adequately responded to concerns of the other agencies and OMB.

So in that sense, this science agency that, as you mentioned, is set up in statute to be a science agency was kind of, in our view, being obstructed by other agencies that don't have that as their primary mission.

Chairman MILLER. And in their own view based on what they said to you.

Mr. STEPHENSON. Yes. I mean, OMB will tell you that EPA owns the IRIS process, but it depends upon which part of OMB you talk to. The management agenda part of OMB says that EPA loses control of the process when they send a draft assessment to OMB, yet the OIRA part of OMB will tell you that EPA still owns the process, and they are only serving to coordinate the federal family of comments.

Chairman MILLER. Have they stuck with that initial response to the GAO's facts?

Mr. STEPHENSON. They asked that we not consider the exit conference comments of the program office officials and instead consider the official agency comments which no longer considered the interagency process as obstructive or taking additional time, rather that the real thing that took time was the complexity of IRIS assessments.

Chairman MILLER. Okay. So OMB told them that they were in fact independent? They misapprehended the facts when they said that they were not independent, OMB advised them that they were, and now it is their view that they are?

Mr. STEPHENSON. They are the decision-makers according to OMB.

Chairman MILLER. My time is almost expired, but I have two documents that have been provided to the Minority which I believe are the initial response of the staff of IRIS, and then the official response. And I now enter both of these into the record.

[The information follows:]

From IRIS PROGRAM MGT 12/19/04
(Director, NCEA; Deputy Dir, NCEA; Chief of IRIS Program Managers)

Overall Comments to the Statement of Facts for GAO's Review of EPA's IRIS Program:

We thank the GAO for allowing us to review the Statements of Facts, and offer here a few general comments. In addition we are providing a 'marked-up-text' that includes many more detailed comments.

In general, we appreciate the effort that GAO has made to understand the IRIS Program, including its shortcomings and accomplishments. We share with the GAO the goal of making continual improvements, having the IRIS database be credible, scientifically excellent, timely and up-to-date. Our comments follow:

1. In general, a very negative picture is painted of the IRIS Program that is largely based on past history, and gives insufficient attention to the many positive changes that have occurred over the past four years.
    a. Many of the recent changes are viewed negatively rather than seeing them in light of the positive things that are occurring as a result.
    b. Trivial examples are commingled with major issues, so that the important issues really do not stand out. For example, changing the peer reviews from letter reviews to face-to-face reviews delays the IRIS process slightly, but has very large benefits in terms of open discussion and consideration of other viewpoints. The delays are minor, but there is an extended discussion in the document, nevertheless, that paints this as an important source of delays and hence more of a problem than a benefit. This misconstrues this change, as an example of a negative influence rather than an improvement.
    c. Many of the "sins of the past" are due to having an IRIS Program that was based on volunteer efforts by staff in the Program and Regional Offices, who undertook IRIS assessments as "other duties as assigned", and often did not have time to work on the assessments. Recent changes will prevent such situations from occurring in the future.

2. One major recent development of considering IRIS assessments as guidance documents that must be reviewed by OMB, and approved by OMB, is given too little attention. Also missing is a discussion of the implications of this conclusion by OMB, which is extremely important i.e., that the IRIS program cannot release the draft for public comment prior to external peer review, and again cannot release the final draft following peer review, until OMB agrees with EPA's revisions in response to OMB comments, comments which can be very extensive and troubling to address. The addition of this interagency review process, and approval steps, has added tremendously to the time it takes to release drafts at each of these two stages. It seems GAO could determine the additional time this total process addition imposed by OMB on IRIS has taken, in addition to the troubling policy issue it raises e.g., that science is being commented on by an

OMB analyst and that such comments are not in the public arena.

3. Resources are mentioned only in passing. IRIS needs to complete more than 50 assessments a year in order to ensure that no assessment is more than 10 years old, and in order to accommodate the EPA's need for new assessments. This is critical for an IRIS database to be useful and up-to-date. Significant additional resources (FTE and dollars) would be needed to reach this level.

4. IRIS productivity has increased exponentially for the parts of the process that EPA has control over. In FY 2006 and in FY 2007, 16 IRIS assessments per year were sent for interagency review. This level of productivity and accomplishment is a quantum change from previous accomplishments. Consequently, we suggest that graphs in the statement of facts be changed to include these recent accomplishments and indicate the level of productivity and accomplishment planned for the next few years until the program arrives at "steady state".

AA ORD's Revised Comments to GAO subsequent to our OMB exit mtg 1-25-08

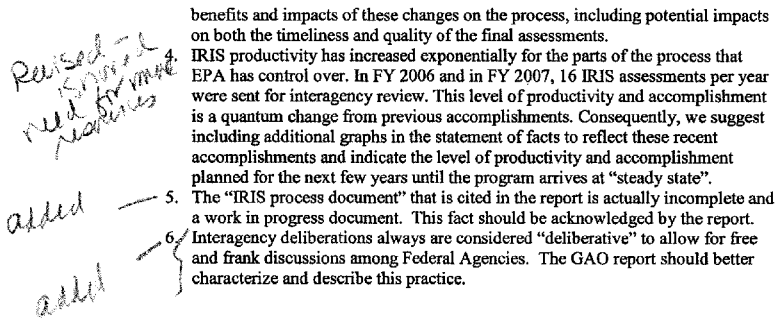
Overall Comments to the Statement of Facts On GAO's Review of EPA's IRIS Program

Thank you for allowing us to review the Statement of Facts. The Agency's general comments are written below. The handwritten "mark-up" of the Statement of Facts and the draft of these comments that we sent earlier were provided as a follow-up to the exit interview but had not yet been reviewed by the Agency's senior management.

We appreciate the effort that GAO has made to understand the IRIS Program, including its shortcomings and accomplishments. We share with GAO the goal of continually improving the IRIS database to be credible, scientifically excellent, timely and up-to-date.

1. In general, there should be more emphasis on the positive changes that have occurred in the past four years and less emphasis on older history. Many of the recent changes are characterized negatively rather than described in the context of the positive activities that are occurring.
    a. Major and minor issues are commingled, so that the important issues are not emphasized. For example, changing the peer reviews from letter reviews to face-to-face reviews delays the IRIS process slightly, but has enormous benefits in terms of open discussion and consideration of other viewpoints. The delays are minor, but there is an extended discussion in the document, nevertheless, that paints this as an important source of delays and hence more of a problem than a benefit. This misconstrues this change, as an example of a negative influence rather than an improvement.
    b. Many "sins of the past" were due to an IRIS Program that relied on volunteer efforts by staff in the program and regional offices, who undertook IRIS assessments as "other duties as assigned," and often did not have time to work on the assessments. Recent changes will prevent similar situations from occurring in the future.
2. More attention should be given to the increased complexity of assessments, which requires more staff effort and a greater level of peer review. This is the largest source of time delays. new
3. One recent development that should be highlighted is the importance and impact of revising the process for collecting and responding to external feedback on the IRIS assessments. The addition of an interagency review process (which includes OMB) has added additional time to the release of assessments. The role of other Federal Agencies in the IRIS process is promoting communication, sharing information, and teaming with EPA at key points throughout the nomination and assessment activities. The enhanced transparency brought about by teaming Agencies with EPA will help identify scientific issues early and unify scientific thought, which will ultimately help streamline the IRIS process. EPA is working diligently with OMB on the content of the new process, and expects that it will speed the release of future assessments. It would be helpful for GAO to assess the

Tommy revised



Chairman MILLER. My time is now expired. Mr. Reichert for five minutes.

THE IRIS PROCESS

Mr. REICHERT. Thank you, Mr. Chairman. Thank you for being here with us this morning, sir. I have a question about balancing priorities. How do you balance the competing priorities of timeliness and thoroughness?

Mr. STEPHENSON. In science, that is always an issue. As I said in my statement, the science is never going to be absolutely certain on a given chemical, but in the judgment of the scientific community, they have to decide when protecting human health should be undertaken. You have to get into a cycle of risk assessments that takes about two to four years. To have it take 10 years, you will never finish anything. Chemicals should be reassessed after 10 years, so it is obvious that you won't make any progress at two per year. You need more like 50 a year.

Mr. REICHERT. But to follow up on that, until this new process was released, were there any schedules imposed at any point in this process?

Mr. STEPHENSON. That was part of the problem. There were no schedules imposed. So now there is a schedule imposed on that complex flow chart you just saw, and if you add all those up, the minimum you can complete an assessment in is six years. In other words, that is an unacceptable schedule.

Mr. REICHERT. Mr. Chairman, I will yield back.

Chairman MILLER. Thank you. Mr. Baird for five minutes.

DELAYED RISK ASSESSMENTS

Mr. BAIRD. Have you got any insights into what the costs of the current situation is in terms of the relatively slow pace and some bias of information?

Mr. STEPHENSON. Well, I mean, if you don't have a credible risk assessment, you can't move from the risk assessment process to the

risk management process. The risk management process is where you start determining what regulatory options are appropriate. So the cost and lack of protection to human health, I don't know how you would measure that, but it has got to be enormous if you are not getting these risk assessments completed in time. Now, you know, they can use other sources of science. They don't have to use IRIS, and they have in some cases done that. Nevertheless, IRIS was put in place to streamline the scientific process so that we get on with the business of determining which regulatory options were appropriate for a given chemical.

Mr. BAIRD. You know, I have witnessed a pattern in the past. I spent a fair bit of time doing research on the area of risk analysis, and a rhetorical pattern which is, well, of course we need to protect the public, but we must make that protection based on the best available science. And if the corollary is that you make interventions to slow down or obstruct or obfuscate the best available science, you then allow the prior argument to occur. Is there any of that going on where people are saying, well, we can't regulate because we don't have the information but then obstructing the access to the information?

Mr. STEPHENSON. I mean, we are not trying to say that there is intentional obstruction going on. We didn't try to find that. But that is why we do believe transparency in the entire process is so critical. It removes the perception of a conflict of interest. We encourage DOD and DOE and any agency to provide comments on risk assessments, but it should be in the sunlight, it should be available to the scientific community for scrutiny, the same as any other comments from any other organization is.

Mr. BAIRD. What recourse exists? If you are a scientist working for an agency, and you have in your best scientific judgment made a case in a certain direction, and it heads to another entity and comes back in some way different than what you had put forward, what options exist right now?

Mr. STEPHENSON. Well, I mean, that is why independence of EPA is so important. They have to own the process. You have to hope that the credibility of the science will rule and that they will consider legitimate comments appropriately and address those kinds of concerns appropriately. But to keep all that from public view is not a good thing.

Mr. BAIRD. Yeah, that is my question. So do we believe it has happened that someone has put forward a report that went to a different entity, let us say OMB, the scientific judgment in the initial report is in some way altered, influenced, undermined, blocked, and then it comes back and is disseminated in a fashion different than the initial input?

Mr. STEPHENSON. I don't know that, but OMB, DOD, anybody can challenge the assumptions within the assessment, the uncertainty analysis, exposure characteristics. And so they can ask for additional research if they think there are gaps in the research which can take up to two years. There is a certain amount of ad hocness to the whole process that is secretive right now, and you just can't tell what is going on. And to say again that there is transparency in the final assessment does not excuse its absence

early in the process when you need to see what is going on with these decisions.

Mr. BAIRD. Right. And let me ask this question. If someone were to ask for—in the IRIS process, if someone says, okay, so this is our best available science at the present moment regarding risk of exposure at certain levels——

Mr. STEPHENSON. Right.

Mr. BAIRD.—we don't ever expect to have the final answer on all these chemicals. What IRIS I thought was to get the best available evidence out there.

Mr. STEPHENSON. That is what we are suggesting, that you should take available research, do the best assessment you can, put it into the database, and the intention is to revisit it at least every 10 years or when new science becomes available. So it should be a moving database that is the repository for the best available science on any chemical.

Mr. BAIRD. If that is the case then, requests for additional information that are delaying should not necessarily delay publication of a position, they should be included as a corollary opinion or a statement, an explicit statement; but here is a question that is unresolved, but you don't necessarily delay moving forward with the information, right?

Mr. STEPHENSON. But all of that rationale for moving forward or considering that science later and the next reassessment of that chemical should be open to the science community for scrutiny.

Mr. BAIRD. Right. Right. I think that is right. But I think there is a difference between saying we are not going to move forward with something——

Mr. STEPHENSON. Right.

Mr. BAIRD.—until we get the additional information versus move forward with what you have got with the caveat explicitly stated that while we put this forward, there are these additional questions. What you are saying right now is that the additional questions can block moving forward.

Mr. STEPHENSON. Exactly. If you wait until the science is perfect, you will never regulate, you will never complete a toxicity assessment. So it is always a judgment call, and it is only the first step to deciding whether you need to regulate or not. It doesn't mean anything. It is just the best available science on that chemical at the time.

Mr. BAIRD. Thank you.

Chairman MILLER. Thank you, Mr. Baird. Mr. Rohrabacher for five minutes.

COMPARING RISK ASSESSMENTS: EPA VS. FDA

Mr. ROHRABACHER. I have been trying to put into perspective the discussions on this particular issue compared to some of the other issues that we face. You seem to be telling us we need to speed up assessments in the process. Certainly I wouldn't disagree with the concept about transparency and openness. In terms of speed, now let me note that in other areas where we have people taking the——

Chairman MILLER. Mr. Rohrabacher, it is very hard to hear you. Your mic——

Mr. ROHRABACHER. Excuse me. I will get a little—have to lean down a little closer. The assessment time that, for example, that the FDA takes in approving a new drug or approving a new medical process that could be sold on the market, would you think that we should be speeding up those type of assessments?

Mr. STEPHENSON. Well, I think they should all be made efficient. This is entirely different. This is toxic chemicals. They are not things that you consume, not things that you eat.

Mr. ROHRABACHER. Well, but——

Mr. STEPHENSON. And we——

Mr. ROHRABACHER. Actually it is something you consume.

Mr. STEPHENSON. Well, IRIS——

Mr. ROHRABACHER. Something that will affect people's health and it will affect in a big way whether or not certain people live or die, and frankly with the FDA approval, we have the same situation. There are people who wait for years and are told, oh, boy, the FDA has approved this and it is going to save 100,000 people a year but it has taken them 10 years to get it on the market, and it hasn't changed a bit in 10 years. And so we have to assume that 100,000 people a year have been negatively affected by not having it available to them. So why is there a dichotomy then between speeding up the assessment now but not wanting to speed up the FDA assessments?

Mr. STEPHENSON. Let me just say that IRIS, you don't start from scratch in researching the chemical. It is based on a body of research that is already available. So you are not starting from ground zero. It is not a new drug that has been introduced, it is not consumed. You may be exposed to it in a variety of ways, airborne ways. You are not ingesting it like a food product or a drug. So the standards are completely different. Speeding up to me means you start with the available assignments right now and you create a system where you can complete the synopsis of a summary of that scientific information on a given chemical in about two years. Then you are going to revisit it as new research becomes available. But if you never finish the risk assessment in the first place, then EPA can't move to the next step of determining what is appropriate in terms of regulating or not a given chemical. This is the first step to regulating or deciding what you need to regulate a dangerous chemical. This is deciding how dangerous it is. It is based on existing research, not new research necessarily.

Mr. ROHRABACHER. Well, I think in both situations you have people's lives at stake or at least their health at stake. And it seems to me that there is a sort of predetermined reaction with certain people that some are trying to basically protect the public to the point that the public is sometimes damaged by that and sometimes it is not. Sometimes you can be overly protected and find that the person who is trying to actually end up helping you is doing something that prevents you from improving your situation.

Mr. STEPHENSON. In your example, you are denying a drug that may save lives in the future. In my example, you are not moving forward with regulations on a chemical that may protect human health until you wait for the science to be perfect. It is a judgment call in both cases. You are absolutely right. But we are suggesting that if you wait until the science is perfect, then there is many

more years of a potentially dangerous chemical that could affect public health.

Mr. ROHRABACHER. As could public health be affected by people who take too long in assessing something that could have a dramatic impact on cancer or some other malady.

Thank you very much. I appreciate your testimony.

RISK ASSESSMENT VS. RISK MANAGEMENT

Chairman MILLER. Thank you. Mr. Stephenson, if I could get Mr. Whittaker again to put up the streamlined process, Figure 3.

While it is coming up, Mr. Stephenson, quickly, explain again in a sentence or two the difference between risk assessment and risk management.

Mr. STEPHENSON. Risk assessment is when you are really synthesizing the best available research on a given chemical to determine the toxicity of that chemical.

Chairman MILLER. What danger does this chemical pose.

Mr. STEPHENSON. What danger does it potentially pose.

Chairman MILLER. What is risk management?

Mr. STEPHENSON. Risk management is when you take that information and you decide how serious it is, how many people are affected, what regulatory options might be available, what would be the cost benefit of instituting those regulations, and it is a whole separate process that starts after the risk assessment is complete.

Chairman MILLER. Mr. Rohrabacher talked about some people—I thought he was probably calling my name—who thought we should be doing, you know, a good deal more to protect people from risk. Is that not risk management rather than risk assessment?

Mr. STEPHENSON. It is.

Chairman MILLER. Okay. So this is simply trying to decide what danger to the public health and to the environment a chemical may pose.

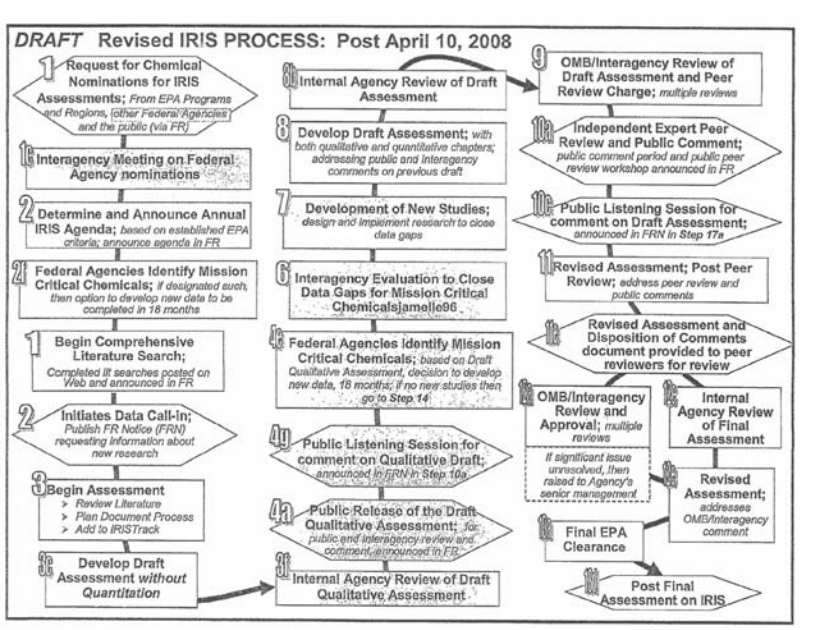
Mr. STEPHENSON. And until you know that you don't know what——

Chairman MILLER. You don't know what to do about it.

Mr. STEPHENSON. Right.

Chairman MILLER. Or whether you need to do anything about it.

Mr. STEPHENSON. That is right.



Chairman MILLER. Or how to proceed with any kind of risk or cost benefit analysis, is that correct? Okay. Now, you talked about transparency. Again, looking at Figure 3, and I assume that you have got it before you which may be easier on your neck to look down, but could you kind of walk through the various steps where there is no public participation, there is no transparency?

Mr. STEPHENSON. I don't have it in front of me unfortunately but——

Chairman MILLER. Can you turn so you can see it?

Mr. STEPHENSON. Where there is no public participation is when EPA is starting its draft assessment process and other agencies can comment on the approach and on what things should be considered on, if they have research they can bring it forward. With glasses on I can't see that.

Chairman MILLER. This is the Science Committee, and the Science and Technology Committee doesn't mean that we are all adept at technology.

Mr. STEPHENSON. Well, I think it is probably, it is hard to tell. I mean, this is a very confusing process, but in general, it is the part where they look at the draft assessment, determine if additional research is needed, what default assumptions might be appropriate, what toxicity assessments might be appropriate.

Chairman MILLER. And the agencies that are using the chemical presumably would have a chance to comment at that point?

Mr. STEPHENSON. Exactly. Like I say, I disagree with this in your risk assessment. You may need to do this additional research or you need to consider that.

Chairman MILLER. We are using again the example of TCE. Is it your impression that the DOD's toxicologist would be participating or someone else or do you know?

Mr. STEPHENSON. I don't know.

Chairman MILLER. Just someone at Department of Defense would presumably be participating. How about TCE manufacturers?

Mr. STEPHENSON. I don't know.

Chairman MILLER. You don't know if they would be given an opportunity to comment privately or publicly? Well, we know they could comment publicly.

Mr. STEPHENSON. TCE is a degreaser that is widely used in motor pools and in gas stations across the country. It is used everywhere.

Chairman MILLER. If the Department of Defense's point is, we really need to use this or our stuff isn't going to work right, that is really more risk management than risk assessment?

Mr. STEPHENSON. It is. If they have concerns about the cost of cleaning up TCE based on a given standard, that is all risk management decisions.

Chairman MILLER. And if they are saying this TCE is just not going to hurt you, it doesn't pose any kind of environmental risk, it doesn't pose any kind of health risk, that is risk assessment.

Mr. STEPHENSON. Exactly.

Chairman MILLER. Okay. And wouldn't you expect scientists to be involved in risk assessment?

Mr. STEPHENSON. That is our assertion.

Chairman MILLER. Is there any reason that if their toxicologists are participating in this it wouldn't be an open, transparent process, it wouldn't be peer reviewed, it wouldn't be an open, transparent discussion, argument, disputation, asserting facts in public for them to be questioned by other scientists, other peers, expert in the field? Is there any reason that kind of debate should be private?

Mr. STEPHENSON. We can't imagine a scientific concern that shouldn't be made public.

Chairman MILLER. All right. And what expertise in science does OMB have?

Mr. STEPHENSON. I don't know.

Chairman MILLER. Is that part of their mission to your knowledge?

Mr. STEPHENSON. There is no "s" in OMB so I don't know.

Chairman MILLER. There is no public health, there is no environment, it is all management and budget. Okay. Mr. Baird, four or five minutes.

GAO RECOMMENDATIONS

Mr. BAIRD. Mr. Stephenson, if there would be an "s" it would be OMBS.

Mr. STEPHENSON. You said that, I didn't.

Chairman MILLER. That is the line of questioning I was pursuing earlier. Can you talk a little bit about what it would take to change the current situation. Is this something we need to deal with statu-

torily or do we need to just say to those who would meddle inappropriately, knock it off or what do we do?

Mr. STEPHENSON. Again, we had eight specific recommendations that EPA said it would consider in our report, and it did not. Other than loosely assigning some timeframes to this cumbersome process, I can't imagine what recommendations they did consider. So that is why we suggest in our testimony—you have got to remember that the report was written before this new process was unveiled on April the 10th. Our report was in March. And so we were frankly very surprised when this process came out, and we mentioned there may be a need for legislation. Certainly we would recommend stopping this process, but there may be—if EPA is unable to make the changes we suggest in our report, then legislative action may be needed to establish timeframes and establish a process for them. That is not the desired approach, but I am not sure what else can be done.

Mr. BAIRD. And you don't seem to have seen much evidence that they are going to follow these recommendations?

Mr. STEPHENSON. To the contrary. I think this process is worse than the draft we reviewed because of the transparency issue, because of the many bites at the apple that agencies with a conflict of interest like DOD have that is now secretive and not public. And all this is new from the draft proposal. But we are encouraging agencies to participate in the process early, it just should be done in the sunlight and with better planning and advanced notice of when you are going to do assessment. There is no reason why this process can't be shortened and still be very, very credible.

Mr. BAIRD. Have any cogent arguments been made or what are the arguments that are made for keeping the shades drawn and not letting the sunlight in?

Mr. STEPHENSON. The only thing that came up was the quality of the assessments. If you take 10 years, the quality doesn't make much difference because it is obsolete the day it is finished. So there have been no good arguments that I can see why this process can't be streamlined and improved, and it is so, so critical to the protection of human health that we just have to get it fixed.

Mr. BAIRD. In science there are some occasions where things are confidential, identity of peer reviewers and peer review. I think it is actually an error to do that myself. But certainly the data are supposed to be made available.

Mr. STEPHENSON. The data, the assumptions, the process——

Mr. BAIRD. Methodology.

Mr. STEPHENSON.—the methodology. Everything should be totally open. How are you going to assure that the best science is considered and is in there if it is not an open process?

Mr. BAIRD. This is admittedly a little bit extreme but under the current situation, risk analysis, risk assessment could be sent up. Somebody with OMB or some other agency could say, yes, but you haven't studied this impact in the strain of Norwegian rats R24A6. You haven't done this with R24A2, and we won't let you go forward until you do R24A6 and just sort of throw that out there, whether or not it is relevant but nevertheless results in a significant delay. Is that——

Mr. STEPHENSON. It could happen. I mean, we have no evidence of that, but if it is not open to scrutiny by the scientific community, things like that could happen. It could be continually be assessed. If it is continually assessed, it is never regulated.

Mr. BAIRD. But if it were made available, then people would have transparency and say possibly, thank goodness for this agency doing their job. It turns out that the assessment had not looked at something important, and then the people who asked that more be looked at were doing a good job and a good public service. Or conversely, the publicity or the transparency could lead some to say they are asking tangential, ridiculous, and unjustified questions which are not scientifically defensible. It could go either way, right?

Mr. STEPHENSON. Exactly. Very well said.

Mr. BAIRD. Thank you. I would yield back.

Chairman MILLER. Mr. Rohrabacher for five minutes.

MORE ON RISK ASSESSMENT VS. RISK MANAGEMENT

Mr. ROHRABACHER. Yes, I am not sure if I agree with the Chairman on his emphasis of differentiating risk management from risk assessment. Obviously, we live in a real world. What we have to do is make sure the activities that are being conducted relate to exactly what the impacts will be and not just state theoretical standard not associated with the way things happen in our lives. Is it possible for the OMB to come in earlier? Scientists, I have a great deal of respect for scientists, but I also know that sometimes scientists become too focused and do not fully appreciate the magnitude of what they are doing to other people and other things outside of the laboratory. And sometimes perhaps—and I am a journalist by profession, by the way. So I realize that I do not know this much about anything but I do know this much about that much. And sometimes it helps science authorities to have their perspective come in and talk to them about putting their science in perspective, rather than having it be a purely scientific laboratory endeavor, does it not?

Mr. STEPHENSON. Well, yes, but I mean the toxicity of a chemical is the toxicity of a chemical. It is not subject to the implications of whatever that assessment shows. That is risk management. That is when you decide whether it needs to be regulated or not.

Mr. ROHRABACHER. But there are certain——

Mr. STEPHENSON. Is it a big risk?

Mr. ROHRABACHER. Yeah, but there are certain areas that—for example, if a certain chemical is needed to complete a mission that is important for the security or safety or even health of the public, that should be taken into consideration in terms of the risks that people take in order to achieve that other goal.

Mr. STEPHENSON. Under either risk management phase. That is when cost becomes an option. Toxicity should have no bearing on the cost of that toxicity assessment.

Mr. ROHRABACHER. But the importance of that should not be part of a determinant factor by those scientists at all?

Mr. STEPHENSON. I mean, we are not suggesting that——

Mr. ROHRABACHER. That should——

Mr. STEPHENSON. We are not suggesting that the EPA scientists go into a vacuum in a closed room and do their analysis. We are

suggesting that everybody should have an opportunity to comment on that. We just think that all the comments should be treated openly, that the whole science community——

Mr. ROHRABACHER. There is no question about whatever communication happens, and I would certainly look into that, within government, people should be held accountable and it should be transparent. I mean I certainly am not suggesting that. I am suggesting that maybe what you are suggesting is that it be a lack of communication.

Mr. STEPHENSON. No. No. The cost of cleaning up a given chemical—let us use TCE again. Let us say that it is determined and it has been by the National Academy and EPA and everybody else who has looked at it to be a very toxic chemical that likely causes cancer. Now we should move to the risk management phase and decide—that is when we decide, okay, DOD uses a lot of this stuff and if we set the cleanup standard at this level, it is going to cost them hundreds of millions of dollars to clean it up. That is a risk management decision. Those factors, those cost benefit analysis of the regulation——

Mr. ROHRABACHER. Or let me put——

Mr. STEPHENSON.—are appropriate but not in the scientific phase.

Mr. ROHRABACHER. Let me put it in a different way. You have got a chemical that is an important part of a process that is used to save lives rather than just put things at risk. Maybe there is a chemical that is needed in the process of a certain kind of food that is necessary to prevent starvation or to take care of certain types of diseases in Africa or such. Yeah, we need to know that that is important——

Mr. STEPHENSON. I agree.

Mr. ROHRABACHER.—that if there is going to be no way to control the mosquitoes in Africa if this decision goes the wrong way.

Mr. STEPHENSON. I agree, and those decisions are made all the time. When you consider how expensive it would be for the regulated community to impose a regulation, all those are fair game and appropriate discussions, but they are part of the risk management phase, not the scientifically based risk assessment phase of a chemical.

Mr. ROHRABACHER. I am thinking that what we are talking about is—again, you are much more an expert. That is why you are testifying and I am listening. But it just seems to me that we have—the process isn't as defined as all of these boxes that we have seen and that people realize that within a period of time perhaps more science examination can come into the process rather than in the first box it could also come in the last box unless we have a totally closed system. Does that make sense?

Mr. STEPHENSON. Yeah, and we are not suggesting a closed system. We are suggesting that it is appropriate for all commenters to comment on a scientific risk assessment.

Mr. ROHRABACHER. I am certainly not in favor of anything that would hinder transparency or making people accountable.

Mr. STEPHENSON. Nor are we.

Mr. ROHRABACHER. Thank you very much.

Chairman MILLER. That was the last round of questions. I would, just to summarize, if I understand correctly your testimony in response to Mr. Rohrabacher's question, you see no virtue in consciously not knowing and not consciously not learning the potential risk to public health or to the environment of a chemical?

Mr. STEPHENSON. None whatsoever.

Chairman MILLER. Okay. Thank you very much. If we will now have a short break, and the next set of witnesses, the next panel.

[Recess.]

Chairman MILLER. Welcome back. We do have a couple of housekeeping matters that I neglected earlier. One is I now ask unanimous consent that all Members have two weeks to enter statements for the record. Without objection.

I also ask unanimous consent to enter materials in the record. All the materials have been shared with the Minority already. Again, without objection.

Panel II:

I would now like introduce our second panel. Dr. George Gray is the Assistant Administrator for Research and Development of the United States Environmental Protection Agency. Ms. Susan Dudley is the Administrator for the Office of Information and Regulatory Affairs of the Office of Management and Budget, OIRA. As our witnesses should know, taking testimony is limited to five minutes after which the Members of the Committee will have five minutes to ask questions in at least one round and perhaps a series of rounds. It is the practice of the Subcommittee to take testimony under oath. Do either of you have any objections to being sworn in? The Committee also provides that you may be represented by counsel. Are either of you represented by counsel today? You are not? Okay. If you would please stand and raise your right hand? Do you swear to tell the truth and nothing but the truth? Let the record reflect that both the witnesses answered yes that they do so swear.

At this point, we will now open our first—I am sorry. Dr. Gray, you may begin.

STATEMENT OF DR. GEORGE M. GRAY, ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT, U.S. ENVIRONMENTAL PROTECTION AGENCY

Dr. GRAY. Thank you, Chairman Miller, Members of the Committee. Thank you for the opportunity to appear before this subcommittee to discuss EPA's highly regarded IRIS, Integrated Risk Information System. As you know, IRIS is a repository of information on potential adverse effects of long-term exposure to over 540 potential environmental contaminants.

The IRIS program began in the mid-1980s. At that time, it was clear that the toxicity values that were being used and developed by EPA were not internally consistent across the Agency, even when based on the same data. That was due to different assumptions, different science, different choices of defaults. IRIS was therefore formed as an internal database in response to the critical need to have Agency-wide toxicity values in one place.

Word quickly spread about the existence of IRIS, and State and local, public health and environmental agencies as well as the regulated community asked us to make it publicly available. So in the late 1980's IRIS was made available to the public. I have actually been interested in and using IRIS for many years as part of my research and my teaching at the Harvard School of Public Health. I have had a very longstanding interest in IRIS.

Now the IRIS website gets more than 20,000 hits a day with inquiries coming from over 100 countries. The IRIS assessments contain only part of the information that is needed to characterize public health risks of chemical substances in support of risk management decisions.

It is important to understand not only how risk assessment differs from risk management but also to recognize that risk assessments, including our IRIS assessments, include both science and science policy components. This is often a source of confusion.

Now like all living processes, the IRIS process has evolved over time. For example, efforts have been made to enhance our peer review process and to address the longstanding issue of the timeliness of our IRIS reviews. Because it began as an internal EPA resource, the agenda for developing IRIS assessments first focused on those chemical assessments that were needed for EPA. But now each year EPA develops an annual agenda for the IRIS program and announces the new assessments under review in the *Federal Register*. In recent years the IRIS program has also sought nominations for IRIS chemical reviews from the public and from other federal agencies.

Some of these recent changes in the IRIS process include: development of our IRIS track web system so people can see the status of a chemical; new opportunities for the public and other agencies to review and comment on IRIS assessments; and enhanced independent external peer review of our draft IRIS assessments.

In 2005, a formal process for documenting all the existing steps in the IRIS process, including formalizing some of these and some new recent changes to the process, was initiated. And on April 10, 2008, this revised IRIS process was announced by EPA.

The release of this is noteworthy because this is the first time that the IRIS process has been transparently documented and made available to the public. The new IRIS process has been designed to provide greater transparency, objectivity, balance, rigor, and predictability in our IRIS assessments. For example, improvements in the IRIS process helped define critical and appropriate roles for public and interagency comments and for interactions that promote greater communication, sharing information, between all interested parties in EPA. Yearly involvement of various stakeholders is consistent with recommendations we received from our own science advisory board and from the GAO. Remember that along with the increased opportunities for public and other agency involvement, all draft IRIS toxicological reviews will ultimately undergo independent external peer review, and all final decisions on IRIS content remain with EPA.

It is worth noting that the revised IRIS process also meets many of the recommendations of the recently-issued 2008 GAO report. Specifically, we believe that the new process clearly defines and

documents a streamlined IRIS process, it defines the critical and appropriate roles for the public and other agencies, and importantly, it sets time limits for all parties including EPA. So though the revised process is expected to improve the timeliness of IRIS assessments, it is important to recognize that many assessments today are more complex than ever, and some assessments will take longer than others to complete.

For example, recent NAS and Science Advisory Board reviewers have recommended EPA do a better job of incorporating quantitative uncertainty analysis in IRIS assessments.

Right now, EPA needs time to implement and evaluate this new process, recognizing that additional changes to the process may be needed in the future because it really is intended to be a living database and a living process.

So thank you, Chairman Miller and Members of the Subcommittee for the opportunity to describe the scope, the purpose, and the future of EPA's IRIS program. I look forward to answering any questions you may have.

[The prepared statement of Dr. Gray follows:]

PREPARED STATEMENT OF GEORGE M. GRAY

Good morning, Chairman Miller and Members of the Committee. My name is Dr. George Gray, and I am the Assistant Administrator for Research and Development (ORD) at the U.S. Environmental Protection Agency (EPA). I also serve as the Agency's Science Advisor. Thank you for this opportunity to appear before the Subcommittee to discuss EPA's highly regarded Integrated Risk Information System (IRIS), which is managed by EPA's National Center for Environmental Assessment (NCEA) within ORD.

As you may know, IRIS is a repository of human health risk information on the potential adverse effects of long-term, or chronic, exposure to over 540 potential environmental contaminants. The risk information in IRIS can include quantitative risk estimates for both non-cancer and cancer effects, as well as a detailed narrative that accompanies the risk estimates. The narratives, or qualitative risk information, include a full discussion of the peer reviewed scientific literature used in the assessment, the EPA confidence in the IRIS risk estimates, and an explanation of the judgments (including application of default approaches and uncertainty factors) that the Agency must make in the face of inadequate data.

A significant part of EPA's efforts to fulfill its mission to protect public health and the environment is to regulate, when necessary, the release of contaminants into the Nation's air, water, and soil. As first outlined by the National Academy of Sciences (NAS) in its seminal 1983 report (*"Risk Assessment in the Federal Government: Managing the Process,"* National Academies Press, ISBN:0309033497, commonly called the "Red Book"), there are two distinct steps that should be used in the Federal Government to assess and manage risks. These steps are called *risk assessment* and *risk management.* Risk assessment, as defined by the NAS, is "the characterization of the potential adverse health effects of human exposures to environmental hazards" (p. 18). Risk assessments can entail either quantitative or qualitative expressions of risk, and should include characterization of the uncertainties inherent in the process of inferring risk. The risk assessment process has four components: hazard identification, dose-response evaluation, exposure assessment, and risk characterization. Risk management is defined by the NAS as "the process of evaluating alternative regulatory options and selecting among them" (p. 18). A risk assessment may serve as one of the bases of risk management.

IRIS assessments fall into the first step (risk assessment); however they only include information on hazard identification and dose-response evaluation. Combined with exposure information, government and private entities use IRIS to help characterize the public health risks of chemical substances and thereby support risk management decisions. Thus, it is important to note that an IRIS health assessment is not a complete risk assessment. It provides part of the foundation for EPA's decision-making and regulatory processes. In addition, risk managers consider other important factors in a risk management decision such as exposures, statutory and

legal considerations, social considerations, public health considerations, economic factors, and political considerations.

It is important to recognize that although risk assessment is distinct from risk management, the risk assessment process consists of both "science" and "science policy" components. That is, although there are some instances at EPA where "pure science" is involved (e.g., conducting bench or lab research on animals in toxicity studies), much of the work done at EPA (including IRIS assessments) involves both science and science policy. For example, due to the uncertainty in IRIS assessments, judgments and choices must be made about the most appropriate assumptions, data sets, health endpoints, models, etc. to use in deriving toxicity values. These are science policy choices because the science is not precise enough to provide definitive answers. For this reason, guidance documents such as EPA's "Guidelines for Carcinogen Risk Assessment" were developed and approved through the Agency's Science Policy Council to inform the many choices in the risk assessment process. This is an important distinction that is often overlooked or confused by the public, yet the NAS Red Book (1983) recognized and commented on this issue in the very first chapter and its section on "Scientific and Policy Judgments in Risk Assessment" (p. 28).

The IRIS program began in the mid-1980s. At that time, it was clear that the toxicity values that were being developed by EPA were not internally consistent across the Agency. For example, EPA's Program Offices were publishing toxicity values for a particular chemical in their rule-makings and in other policy documents that were based on the same set of available scientific data—but these values could be orders of magnitude different and based on different human health endpoints or default uncertainty factors. This example illustrates how important it is to acknowledge where the science stops and science policy begins, as credible scientists can (and often do) reach different conclusions based on their interpretation of the science or make different choices when confronted with several scientifically plausible options. IRIS was therefore formed in response to a critical need to have Agency-wide toxicity values in one place—including accompanying narratives detailing the supporting studies, key assumptions and choices, and text on confidence—that were developed through reviews by Agency health scientists.

IRIS was originally intended to be an internal system that provided EPA risk assessors and managers with an EPA consensus position on the potential human health hazard and dose-response information for environmental contaminants of interest to Agency programs and regions. Word spread quickly about the existence of IRIS and many asked to make it a publicly available system. State and local public health and environmental agencies, as well as the regulated community, requested access to the IRIS information. Therefore, in the late 1980's, IRIS access was made available to the public. EPA was pleased to share this information resource with a large, external user community. IRIS first became available on a dial-up service and later through the National Library of Medicine's TOXNET family of information resources, and then on the Internet. The IRIS web site is accessed over 20,000 times per day with inquiries coming from well over 100 other countries.

The IRIS process has evolved over time including in areas such as setting the annual IRIS agenda, level of independent external peer review, and opportunities for public and other federal agency review and comments. Because IRIS began as an internal EPA resource, the agenda for developing IRIS assessments focused on those chemical assessments of interest to EPA's program offices and regions. It was an informal process where only Agency needs were addressed. Now each year, EPA develops an annual agenda for the IRIS program and announces new assessments under review in the *Federal Register*. EPA uses five general criteria to determine which new chemicals to assess: (1) potential public health impact; (2) EPA statutory, regulatory, or program/regional-specific implementation needs; (3) availability of new scientific information or methodology that might significantly change the current IRIS information; (4) interest to other governmental agencies or the public; and (5) availability of other scientific assessment documents that could serve as a basis for an IRIS assessment.

In recent years, the IRIS Program has also sought nominations for IRIS chemical reviews from the public and other federal agencies. The list of new or updated assessments chosen for potential development is published in the *Federal Register* (FR) as part of the IRIS annual agenda. The Agency is also working to improve the prioritization process to more appropriately capture relative priorities of individual chemical assessments under development. For each of the assessments added to the IRIS agenda, an initial literature search is conducted. As literature searches are completed, the results are posted on the IRIS web site (*www.epa.gov/iris*) and the public and other agencies are invited to review the literature search results and submit additional information to EPA. Other recent changes to the IRIS process in-

clude creation of a chemical assessment tracking system (IRISTrack) on the IRIS web site to inform the public and stakeholders of the status of the IRIS assessments that are underway, new opportunities for the public and other agencies to review and comment on the qualitative and draft IRIS assessments (including the ability to participate in "listening sessions" held during the public comment period), and enhanced independent external peer reviews of draft IRIS assessments. The IRIS program has also experienced an expansion of scientific staff and a significantly increased budget over the last few years. For example, based on the enacted FY 2003 resources, EPA has since nearly tripled the number of IRIS staff and have quadrupled the IRIS budget through the FY 2009 request to 37.0 FTE and $9.4 million, respectively.

In 2005, a formal process for documenting all of the existing steps in the IRIS process, including formalizing recent changes to the process, was initiated, and on April 10, 2008, the revised IRIS process was announced by EPA. The public release of the revised IRIS process is especially noteworthy because the IRIS process has never before been transparently documented and made available to the public. Consequently, the IRIS process had often been viewed as a "black box" both within and outside of the Agency, as it was unclear what steps comprised the process, what the timing was for each step, or where opportunities existed for internal and external Agency involvement. The new IRIS process has been designed to provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. Specifically, improvements to the IRIS process help define critical and appropriate roles for public and interagency comments and interactions, and promote greater communication and sharing of information between all interested parties and EPA. The outcome of these improvements are expected to result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor.

Delays in the completion of IRIS assessments have been a long-standing problem at EPA. For example, prior IRIS assessments took an average of five years to complete, and EPA has been working on some assessments for a decade or longer. The revised process was designed to help address these delays, in part, by allowing for input from various stakeholders (e.g., EPA program and regional offices, other agencies, scientific organizations, NGOs, and the public) early in the process and providing clear descriptions and timeframes for each step. The early involvement of various stakeholders is consistent with recommendations from EPA's Science Advisory Board (SAB) as well as a prior report by the General Accounting Office (GAO). For example, in a September 26, 2000, letter from EPA's SAB to Administrator Carol Browner, it was noted that "critical data" were often missing from IRIS risk assessment discussions and it was suggested that one way to enhance the quality of toxicologic evaluations was to "make the IRIS process open to public stakeholder review in a more formal manner." A 2006 report by GAO (GAO–06–595) entitled *"Human Health Risk Assessment: EPA Has Taken Steps to Strengthen Its Process but Improvements Needed in Planning, Data Development, and Training"* also noted that ". . . several experts said that increased involvement with a broad range of stakeholders early in the planning process would help identify alternative methods and models and obtain stakeholder concurrence with the agency's approach." The new process therefore allows the EPA access to a wide range of scientific data, expertise, and knowledge that can be used to produce timely and high quality IRIS assessments. However, it should be noted that all draft IRIS assessments are peer reviewed by outside experts, and all final decisions on IRIS content remain with EPA.

It is important to recognize that many of the assessments today are more complex than ever before. For example, some chemicals have extensive toxicity testing data that must be reviewed and analyzed, new data are now available for assessing the mode of action of many chemicals, and more sophisticated statistical and modeling techniques (e.g., physiologically-based pharmacokinetic or PBPK models) are now available for evaluating intra-species and inter-species differences. Recent peer reviews of IRIS assessments by the NAS and EPA's SAB have also recommended that EPA do a better job of incorporating quantitative uncertainty analyses into IRIS assessments. The timelines in the new IRIS process balance the need for careful consideration of science and science policy in assessments with the Agency's need for information.

An important aspect of the revised process includes "mission critical" chemicals that will be determined by a sponsoring agency together with EPA. A "mission critical" chemical is one that is an integral component to the successful and safe conduct of an agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints. Agencies must identify to ORD

those chemicals on the IRIS Program Annual Agenda that they determine meet this definition, and generate a detailed report documenting what types of new research will address significant data gaps and whether such research can be conducted within the allotted time frame (but it is ultimately up to EPA to agree to allow new research to be conducted). Although we do not anticipate that many chemicals will receive this designation each year or that additional studies will be requested for all mission critical chemicals, any such new studies will help fill important data gaps to ensure assessments of the highest quality.

Independent external peer reviews are also a hallmark of EPA's commitment to ensuring we have high-quality science that has been vetted by a panel of outside experts. Consistent with past practices, the revised process specifies that all draft IRIS Toxicological Reviews will undergo independent external peer review. Most reviews will be conducted by external peer review panels at public meetings, although a small number of complex or high profile chemicals may undergo more in-depth SAB or NAS peer reviews. As part of the revised IRIS process, external peer reviewers will also for the first time have an opportunity to review the revised IRIS Toxicological Review and comment on ORD's responses to the peer reviewers and public comments. This is an important step that is consistent with other peer review practices, such as publishing in the peer-reviewed literature, to ensure that peer reviewer comments are adequately addressed or sufficient rationale is provided for not addressing such comments.

It is noteworthy that the revised IRIS process meets many of the recommendations of the recently issued 2008 GAO report entitled *"Toxic Chemicals: EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals"* (GAO–08–743T). Specifically, the revised process (1) clearly defines and documents a streamlined IRIS assessment process; (2) sets time limits for all parties, including OMB and other federal agencies, to provide comments to EPA on draft IRIS assessments; (3) defines the appropriate role of external federal agencies in EPA's IRIS assessment process; and (4) determines the types of IRIS assessments to conduct on the basis of the needs of EPA's program offices and other users. The GAO (2008) report also lacks an appropriate characterization of several key issues. For example, the GAO report erroneously suggests that only pure science is involved in the risk assessment process. In reality, all risk assessments (including IRIS assessments) have always included a mix of science and science policy, as acknowledged in the NAS (1983) Red Book. The GAO report also mischaracterizes the interagency review process at EPA. Specifically, to ensure that scientists and policymakers are able to have full and frank discussions without being concerned about how these discussions may be viewed or misrepresented, all internal EPA comments and interagency comments and disposition documents on draft IRIS assessments are considered "deliberative" and do not become a part of the public record. This is not a new or unique process, as this protection is the same as that afforded any other policy-making setting at EPA (and other federal agencies follow similar processes). Additionally, once EPA comes to a conclusion and releases its external review draft, there is a transparent public comment and external peer review process. The GAO report also incorrectly suggests that EPA will not have the final say on the content of IRIS assessments under the revised process. However, despite increased opportunities for public and other agency involvement, the revised process makes it clear that all final decisions on content will remain within EPA.

EPA now needs time to implement and evaluate the new process, recognizing that additional changes to the process may be needed in the future (i.e., it is intended to be a "living" document). Because the revised process attempts to streamline and set specific time frames for each step, it is expected to reduce the amount of time to complete future IRIS assessments.

Thank you, Chairman Miller and Members of the Subcommittee for this opportunity to describe the scope, the purpose and the future of EPA's IRIS program. I look forward to answering any questions you may have.

BIOGRAPHY FOR GEORGE M. GRAY

On November 1, 2005, Dr. Gray was sworn in to serve as the Assistant Administrator for the Office of Research and Development, which is the 1,900-person, $600 million science and technology arm of the Environmental Protection Agency. Dr. Gray was appointed to this position by President George W. Bush and confirmed—by unanimous consent—by the U.S. Senate.

Prior to joining EPA, Dr. Gray was Executive Director of the Harvard Center for Risk Analysis and a Lecturer in Risk Analysis at the Harvard School of Public Health (HSPH). In 16 years at HSPH, his research focused on scientific bases of human health risk assessment and its application to risk policy with a focus on

tradeoffs in risk management. Dr. Gray taught toxicology and risk assessment to both graduate students and participants in the School's Continuing Professional Education program.

Dr. Gray holds a B.S. degree in biology from the University of Michigan, and M.S. and Ph.D. degrees in toxicology from the University of Rochester. He and his wife, Ann, and their two children make their home in McLean, Virginia.

Chairman MILLER. Thank you, Dr. Gray. Ms. Dudley for five minutes.

STATEMENT OF MS. SUSAN E. DUDLEY, ADMINISTRATOR, OFFICE OF INFORMATION AND REGULATORY AFFAIRS (OIRA), OFFICE OF MANAGEMENT AND BUDGET

Ms. DUDLEY. Thank you, Chairman Miller and distinguished Members of the Committee. As administrator of the Office of Information and Regulatory Affairs, or OIRA, I am pleased to be here today to talk with you about OIRA's role in ensuring that the highest quality of information, including scientific information, is used and disseminated by federal agencies.

OIRA was created as part of the Office of Management and Budget by the Paperwork Reduction Act of 1980. Staffed almost exclusively by career civil servants, OIRA has served Administrations, both Democratic and Republican, for decades by providing centralized oversight and interagency coordination of federal information, as well as regulatory and statistical policy.

In recognition of the increasing importance of science-based regulation at federal agencies, OIRA's staffing has evolved over the last 8 years to include scientific and engineering expertise to accompany a well-established team of economists, statisticians, lawyers, and information policy specialists. This more diversified pool of expertise enables us to engage with federal experts throughout the government on issues relevant to policy development.

Since the fall of 2005, OMB has coordinated interagency review of the Environmental Protection Agency's IRIS. IRIS is an important online database containing science and science policy information on chronic human health effects. It supports risk-based decision-making not only by EPA but by other federal agencies, State and local environmental programs, international regulatory bodies, academia, industry and others.

Interagency coordination allows EPA to take advantage of the broad scientific expertise that exists throughout the government. The science in IRIS assessments is growing more and more complex, and vigorous discussion among a diverse set of governmental experts helps EPA ensure that the IRIS assessments reflect the consensus on the best science and science policy judgments. OMB has continually supported changes that will improve the quality and efficiency of the IRIS program.

Since 2000, OMB has supported funding increases of over 450 percent, and IRIS's program budget has increased from $1.7 million in fiscal year 2000 to $9.6 million in fiscal year 2007. Despite this increased funding, concerns remain with the pace of development of IRIS assessments. EPA observes that assessments take an average of five years to complete, with some taking as long as 10 years. 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. The new process is expected to reduce the time to complete an IRIS assessment from the historical average of over five years down to three to four and one-half years. EPA expects these changes will result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor.

So in conclusion, let me reiterate a few key points. EPA's IRIS database is a highly regarded database of potential chronic effects of environmental contaminants on human health. It is widely used within EPA, by other federal, State, and local agencies and elsewhere to support policies to protect human health. It includes science policies as well as pure science, quantitative risk estimates, and qualitative narratives. Scientists at other federal agencies and the public have an appropriate role in the development of IRIS assessments. EPA's recent clarifications to the process for developing IRIS assessments should improve both the quality and efficiency of assessments by engaging the public as well as experts within and outside the government earlier in the process and providing streamlined opportunity for review and comment.

I have a few seconds left on my clock. I would like to correct a misimpression that may have been left from the last panel. OMB did not review EPA's response to the GAO report as was suggested.

Thank you.

[The prepared statement of Ms. Dudley follows:]

PREPARED STATEMENT OF SUSAN E. DUDLEY

Chairman Miller, Ranking Member Sensenbrenner, and distinguished Members of the Committee, thank you for inviting me to testify at today's hearing about the Environmental Protection Agency's Integrated Risk Information System (IRIS) database policy.

As the Administrator of the Office of Information and Regulatory Affairs (OIRA), I am pleased to be here today to talk with you about OIRA's role in ensuring that the highest quality of information, including scientific information, is used and disseminated by federal agencies.

OIRA was created as part of the Office of Management and Budget (OMB) by the *Paperwork Reduction Act of 1980*. Staffed almost exclusively by career civil servants, OIRA has served Administrations, both Democratic and Republican, for decades by providing centralized oversight and interagency coordination of federal information, as well as regulatory and statistical policy.

Over the last 27 years, OIRA's interagency coordination role has been an integral part of government accountability—a non-partisan tool for understanding the likely effects of government policy. In recognition of the increasing importance of science-based regulation at federal agencies, OIRA's staffing has evolved over the last eight years to include scientific and engineering expertise to accompany a well established team of economists, statisticians, and information technology specialists. This more diversified pool of expertise enables us to engage with experts throughout the Federal Government on issues relevant to policy development.

EPA's Updated IRIS Process

The Environmental Protection Agency (EPA)'s Integrated Risk Information System (IRIS) is an online database prepared and maintained by the EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD). IRIS contains science and science policy information on chronic human health effects.[1] The hazard identification and dose-response assessment information in IRIS can be used in combination with exposure information to charac-

[1] See EPA, "Revised IRIS Process Q&A's," (EPA Q&A) question 1, available at *http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=472643*

terize the public health risks of a given substance in a given situation. These risk characterizations can form the basis for risk-based decision-making, regulatory activities, and other risk management decisions designed to characterize and protect public health. The IRIS database supports risk-based decision-making not only by EPA, but by other federal agencies, State and local environmental programs, international regulatory bodies, academia, industry, and others. According to EPA, national and international users access the IRIS database approximately nine million times a year.[2]

OMB recognizes the importance of IRIS assessments for making sound, science-based decisions across the government, throughout the country, and internationally as well. OMB has continually supported changes that will improve the quality and efficiency of the IRIS program.

Since 2000, OMB has supported funding increases for the IRIS program of over 450 percent; as evidenced in the President's annual budgets, the funding requested has increased from $1.7 million in FY 2000 to $9.6 million in FY 2007.[3]

Despite these funding increases, concerns remain with the pace of development of IRIS assessments. EPA observes that prior assessments took an average of five years to complete, with some taking as long as 10 years.[4] In response to concerns both with delays in completion of IRIS assessments, and lack of transparency in the IRIS process, EPA has recently revised the process to provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. The revised process clarifies the role of the public and interagency reviewers, and promotes greater communication and sharing of information between all interested parties and EPA. EPA expects these changes to result in a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor.[5]

The nomination process for chemicals to be included in IRIS is transparent and open. ORD initiates the process through a *Federal Register* notice which invites nominations from the public and at the same time reaches out to the EPA Program and Regional Offices and other agencies for their nominations. After receiving the nominations and discussing them with other agencies and EPA Program and Regional Offices, EPA determines its IRIS agenda for the coming year, and publishes that in the *Federal Register.* EPA's determination is based on its published selection criteria, as well as its available work force and areas of expertise.

EPA then begins the process of developing chemical health assessments that ultimately are posted to the IRIS database.[6] This assessment process consists of 13 steps:

1. A scientific literature search for each chemical;
2. A *Federal Register* notice seeking scientific information on selected chemical substances;
3. EPA development of draft qualitative IRIS health assessment;
4. Review of the draft qualitative assessment within EPA, by other agencies, and by the public, announced in the *Federal Register*;
5. EPA review of public and agency comments;
6. EPA evaluation of interagency interest in closing data gaps for mission critical chemicals;[7]
7. Design and implementation of new studies for mission critical chemicals, if needed;
8. EPA completion of its draft IRIS review, including quantitative values;
9. EPA initiation of interagency review (and revision of draft assessment documents as appropriate);

---

[2] See U.S. Government Accountability Office, Report to Chairman, Committee on Environment and Public Works, U.S. Senate, "Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System," (March 2008), p. 6.

[3] *Id.* at 14.

[4] See EPA Q&A, supra note 1, at question 13.

[5] Memorandum from EPA Deputy Administrator Marcus Peacock to EPA Assistant Administrator George Gray (Peacock Memo), "Implementation of Revised IRIS Process," (April 10, 2008), available at *http://oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=472651*

[6] *Id.*

[7] EPA defines a "mission critical chemical" as one that is an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operation. *Id.* at n. 1.

10. EPA initiation of independent external peer review and release of the draft IRIS assessment to the public;
11. EPA revision to the IRIS assessment and development of an IRIS summary based on expert review and public comment;
12. EPA initiation of final intra-agency and interagency review; and
13. EPA completion of the IRIS assessment and IRIS summary and posting of completed IRIS assessments on to the database.

OMB Role in the IRIS Process

Since the fall of 2005, OMB has coordinated review of IRIS assessments (steps 9 and 12 in the new process). Interagency coordination allows EPA to take advantage of the broad scientific expertise that exists throughout the government. The science in IRIS assessments is growing more and more complex, and vigorous discussion that involves a diverse set of governmental experts helps EPA ensure that the IRIS assessments represent the consensus opinions of the government's leading scientists. In addition, risk assessment involves science policy judgments which help to shape the risk assessment process. As many accepted 'default' positions are based on scientific consensus opinions, a frank and broad discussion among interagency experts helps to inform EPA's choices.[8] The agencies involved in any interagency review process will vary depending on the chemical in question, agencies' expertise, and agencies' interest in it. The interagency group may consist of representatives from the following offices and departments:

- Office of Management and Budget (OMB),
- Office of Science and Technology Policy (OSTP),
- Council on Environmental Quality,
- Department of Health and Human Services (HHS) [including representation from the Agency for Toxic Substances and Disease Registry (ATSDR), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), National Institute for Environmental Health Sciences (NIEHS), National Institute for Occupational Safety and Health (NIOSH) and Food and Drug Administration (FDA)],
- Department of Defense (DOD),
- Department of the Interior (DOI),
- Department of Labor (DOL),
- National Air and Space Administration (NASA),
- Department of Energy (DOE),
- Department of Transportation (DOT),
- Department of Agriculture (USDA), and
- the Consumer Product Safety Commission (CPSC).

In step 9 noted above, EPA provides OMB the draft health assessment and the draft charge to the external peer reviewers. OMB distributes these draft documents to the others in the interagency group for review and comment. EPA then revises the draft health assessment and charge, as appropriate, to respond to the interagency comments. After completing interagency review, EPA publishes the draft assessment in the *Federal Register* for public comment and begins independent peer review. After revising the IRIS assessment based on peer review and public comment, EPA again shares the assessment with OMB and other federal agencies (step 12 listed above).

Under EPA's revised system, OMB will continue to coordinate interagency review to help assure timely responses from agencies within designated review periods. For step 9, interagency review comments are due within 30 to 60 days, depending on the complexity of draft assessment documents.[9] EPA will respond, as appropriate, in 15–30 days.[10] At step 12, interagency and intra-agency review comments are provided to ORD within 30 days[11] and ORD addresses any remaining issues within 15

[8] See EPA, Office of the Science Advisor, Staff Paper, "Risk Assessment Principles and Practices," (March 2004), available at http://www.epa.gov/OSA/pdfs/ratf-final.pdf. Sections 2.1.3 and 4.1.2 discuss the science policy used in risk assessment and in determining default assumptions.
[9] See Peacock Memo, *supra* note 5, at step 9(C)(a).
[10] *Id.* at step 9(E).
[11] *Id.* at step 12(D)(a).

days.[12] In addition, the EPA web page allows the public to track the progress of each chemical as it moves through the IRIS assessment process.[13]

OMB supports the new EPA IRIS process and EPA's efforts to provide greater transparency, and opportunities for the public to share information and comment on EPA's assessment. For example, the public has an opportunity to comment on EPA's initial literature review and to present additional information on a chemical. The public can also comment on the draft qualitative assessment and participate in an EPA-sponsored "listening session." This "listening session" will allow for broad public participation earlier in the assessment process. The new process also defines appropriate roles for the public and interagency interactions with ORD and also allows the interagency group, as well as the EPA Program and Regional Offices, in addition to the public, opportunities to share information and comment on EPA's draft assessments.[14] All of these steps will also help to ensure the high quality of IRIS assessments. OMB also believes that the new process will increase efficiencies in the IRIS program. EPA estimates that the new process will reduce the time to complete an IRIS assessment from the historical average of over five years to three to four and one-half years, with perhaps an additional one to two and one-half years for the smaller number of mission critical chemicals.[15] Thus this revised process not only allows for earlier public and agency involvement, but also streamlines the process such that EPA will be able to release IRIS assessments in a more timely manner.

Conclusion

Thank you for the opportunity to testify in today's hearing. EPA's IRIS database is highly regarded and widely used. EPA's recent clarifications to the process for developing IRIS assessments should improve both the quality and efficiency of the assessments by engaging the public as well as experts within and outside the government earlier in the process and providing streamlined opportunity for review. I would be happy to answer any questions you may have.

BIOGRAPHY FOR SUSAN E. DUDLEY

Susan Dudley was nominated by the President on July 31, 2006, and appointed on April 4, 2007, to serve as the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget.

Prior to her service at OIRA, from 1998 through January 2007, Ms. Dudley served at the non-profit Mercatus Center at George Mason University, where she directed the Regulatory Studies Program from 2003 to 2006. As an Adjunct professor at the George Mason University School of Law from 2002 to 2006, she designed and taught courses on regulations and led regulatory clinics.

Earlier in her career, Ms. Dudley served as a career civil servant, working as a policy analyst at the Environmental Protection Agency (1984–1985), an economist at OIRA (1985–1989), and an economist advisor to the Commodity Futures Trading Commission (1989–1991). From 1991 until 1998, she was a consultant to government and private clients at Economists Incorporated.

Ms. Dudley has authored more than 25 scholarly publications on regulatory matters ranging from e-rule-making, to electricity, health care, the environment, and occupational safety. Before joining the Administration, she served on the boards of the Association of Private Enterprise Education and the International Foundation for Research in Experimental Economics, which was founded by Nobel Prize winning economist Vernon Smith. She has also served as a citizen member of several committees and boards in the Commonwealth of Virginia, including the Virginia Environmental Education Advisory Committee (2000–2002), the Administrative Law Advisory Committee (2000–2003), and the Virginia Waste Management Board (1996–2001).

Ms. Dudley holds a Master of Science degree from the Sloan School of Management at the Massachusetts Institute of Technology (1981) and a Bachelor of Science degree (*summa cum laude*) in Resource Economics from the University of Massachusetts, Amherst (1977). She lives in Virginia with her husband and two sons.

---

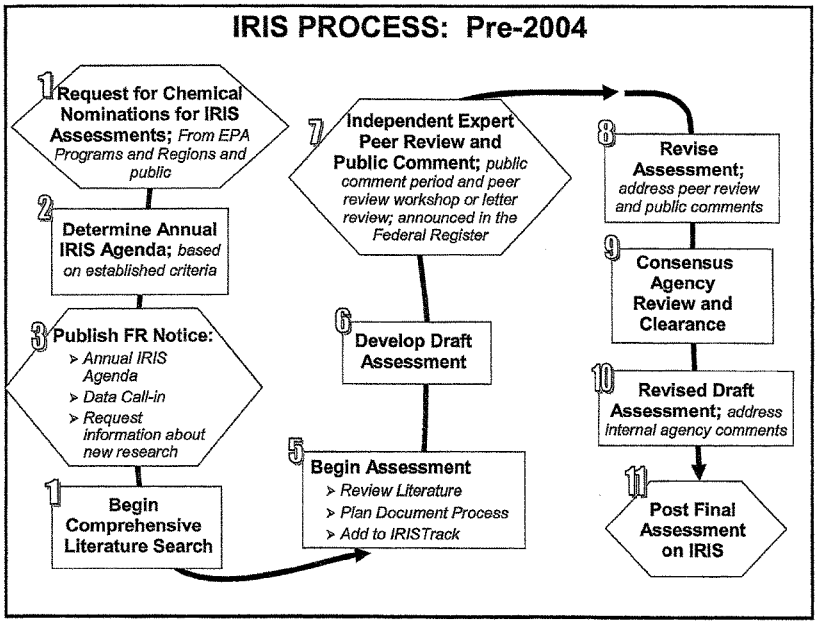
[12] *Id.* at step 12(E).
[13] See *www.epa.gov/iris*
[14] See EPA Q&A, supra note 4, at questions 6 and 12.
[15] *Id.* at question 13.

DISCUSSION

Chairman MILLER. Thank you, Ms. Dudley. There are only three witnesses today. Mr. Stephenson, would you mind rejoining the panel so you might be able to respond to questions that were directed to all of us because your testimony has been very different from the testimony of that we have heard from others today.

Mr. STEPHENSON. Yes, it has.

Chairman MILLER. Again, if Mr. Whittaker could put up Figure 1.



Mr. ROHRABACHER. Mr. Chairman, I might note that we didn't have these witnesses available to comment on his testimony——

Chairman MILLER. Well, they certainly——

Mr. ROHRABACHER.—to have the time when he was testifying. It seems to be not quite a balanced decision on your part.

MORE ON EPA'S GAO EXIT CONFERENCE COMMENTS

Chairman MILLER. Dr. Gray, do you have anything to say in response to anything Mr. Stephenson said?

Dr. GRAY. There are areas where I think there is some misperceptions in some of Mr. Stephenson's testimony.

Chairman MILLER. Perhaps we can elaborate on those as we go along. Ms. Dudley? Okay, could you——

Ms. DUDLEY. Yes, I do, too.

Chairman MILLER. Can you just tell me the topics quickly and perhaps we can try to hit those as we ask questions, Mr. Rohrabacher and I.

Ms. DUDLEY. I don't have notes on all the topics. One was the notion that OMB reviewed EPA's response to the GAO report, which is not true. OMB did not review that.

Chairman MILLER. You have already said that that was simply not true.

Ms. DUDLEY. Just the——

Chairman MILLER. Is there anything that you want to elaborate besides that it is not true?

Ms. DUDLEY. Yeah, the suggestion that OMB doesn't have scientific expertise. You know, Mr. Stephenson's response was that there is no "s" in OMB but there is no "s" in GAO, either.

Chairman MILLER. Okay.

Mr. STEPHENSON. Or EPA.

Ms. DUDLEY. That is right. So I don't think whether there is an "s" in the title of an agency qualifies.

Mr. STEPHENSON. Well, I didn't mean that literally.

OMB'S ROLE IN RISK ASSESSMENTS

Chairman MILLER. Well, we haven't really begun our line—well, I guess I will now recognize myself for five minutes. Following that, Ms. Dudley, do you think it is part of the role of OMB or allow it 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?

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. So at the——

Chairman MILLER. Do you take advantage of expertise outside of the Federal Government?

Ms. DUDLEY. No, as a rule, OIRA does not do that. Our role is coordinating within the government.

MORE ON THE IRIS PROCESS

Chairman MILLER. Okay. If we could turn back our attention to Figure 1. This is the IRIS process that existed before OMB, OIRA, made helpful suggestions to make sure, to try to make this a more productive transparent system, is that correct?

Ms. DUDLEY. I have to defer to Dr. Gray on that.

Dr. GRAY. The first thing I would have to say is that these diagrams, I don't necessarily—I am not able to endorse these because I was not involved in preparing them. In fact, I will say——

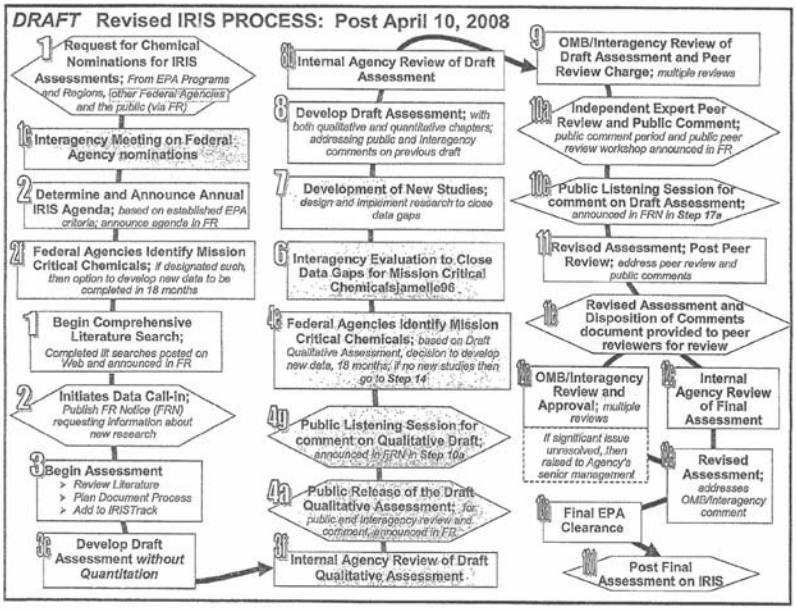
Chairman MILLER. Actually it says—these are not diagrams prepared by critics of OMB——

Dr. GRAY. No.

Chairman MILLER.—or EPA to belittle or make a mockery of the complexity of the process. These are actually EPA documents.

Dr. GRAY. Yes, they are. And the only reason I am unable to completely verify things is that the process that we use in IRIS prior to April 10th was never written down and made publicly available.

Chairman MILLER. Okay. But if we could now look at Figure 3.



Ms. DUDLEY. May I ask, do you have hard copies of those? It is hard for us to see them on the screens.

Chairman MILLER. Okay. Is your need now satisfied? Okay. This is the streamlined version, the streamlined transparent version of the earlier, slow, opaque process, is that correct?

Dr. GRAY. This is——

Chairman MILLER. This is what is recently adopted.

Dr. GRAY. This is our process, yes, that is how to find many of those enhancements that I had mentioned that have been going on in the IRIS process for many years. They are designed to enhance the transparency and the timeliness of the process and in fact putting timelines on this, which are not on this diagram I notice, is very helpful in that it reminds both EPA of its responsibilities and the others who are involved in the responsibilities. It also indicates all of the various places where the EPA, its regions and program

offices, the public, non-governmental organizations, anyone in the scientific community, and other agencies can come together to provide input to our process.

Chairman MILLER. That is a yes. Let me ask the same question that I asked of Mr. Stephenson to clarify or to summarize his testimony response to Mr. Rohrabacher's questions. Do either of you see a virtue in consciously not knowing and consciously not learning the environmental or public health risk posed by a chemical? That is a yes or no answer.

Ms. DUDLEY. No.

Dr. GRAY. Not at all. Not at all.

Chairman MILLER. None. And the purpose of IRIS is that, to assess what the risk is.

Dr. GRAY. IRIS is an input to the risk assessment process. It is not a complete risk assessment.

Chairman MILLER. Okay. But it is not risk management?

Dr. GRAY. That is correct.

Chairman MILLER. Ms. Dudley, it is not risk management, correct?

Ms. DUDLEY. IRIS is not risk management. It is a component of the risk——

Chairman MILLER. If there is a later decision about what to do about it, if a chemical poses a risk but the IRIS decision, the IRIS listing is the best available science at the time of what risk a chemical poses, isn't that right?

Ms. DUDLEY. It is science and science policy because science doesn't give you the full answer, so there are policy judgments involved.

Chairman MILLER. Well, the policy is what scientific assumptions to make if the data is incomplete.

Ms. DUDLEY. That is correct. It deals with uncertainty.

Chairman MILLER. It is still science. A policy might be, do we really need to use TCE, even if it is toxic, because our machines, our Bradley fighting vehicles, work better, and it is important that our Bradley fighting vehicles work better. That is policy, right?

Dr. GRAY. Sir, could I make a statement? I know——

Chairman MILLER. That is risk management.

Dr. GRAY. That is management. Risk policy—I notice there is a copy of the NAS Red Book next to you. Chapter 1, the very first thing after defining terminology says science and policy and risk assessment. That is the kind of policy we are talking about.

Chairman MILLER. All right. Well, my time is expired. There will be other opportunities. Mr. Rohrabacher for five minutes.

Mr. ROHRABACHER. Thank you very much, Mr. Chairman. So, Dr. Gray, you were mentioning these charts that have been shown a number of times in this hearing. So you are suggesting that the chart that has been given to us during this hearing is not an officially approved chart from your agency?

Dr. GRAY. I am just saying that I was not involved in drafting them, and it is—there are questions about defining the previous versions of the process simply because they were not written down in the same way as we have now done.

Mr. ROHRABACHER. I am not quite understanding the answer, whether that was—it seems that you are saying that this chart

then was developed by somebody in your agency, that it was not officially entitled to have the final word on what the flow chart would——

Dr. GRAY. No, I don't think that is quite it. It is my understanding that those were put together in an effort for our staff to come up here and brief the Committee, and we use those to brief some other committees. What I am saying is I didn't—I was not involved in putting those together. The only one of those that I can say accurately, to the best of my knowledge, completely and accurately reflects the way things are done is the last one that does reflect the new process that we have released.

Mr. ROHRABACHER. So the complicated flow chart that we see does not reflect or does reflect——

Dr. GRAY. It does reflect the process as it is currently defined.

Mr. ROHRABACHER. And what is your disagreement then with the Chairman on the flow chart? I was not quite understanding why——

Dr. GRAY. Oh, simply——

Mr. ROHRABACHER.—you brought up that point.

Dr. GRAY. Well, because it is very difficult I think to accurately compare these because in the past this process has not been written down as explicitly and transparently as it is now so that knowing exactly what the process was in each of those steps is a little harder.

Mr. ROHRABACHER. So, the other flow chart, the original one that has been presented to us as the formerly streamlined process now has been made more complicated actually does not reflect the complication of what it was before?

Dr. GRAY. Well, to me, complication is not what this is about. This is about making sure we are doing the right science. Those processes that we were looking at in, I believe it was Chart 1 and maybe Chart 2, are the ones that have us in the place today where we have assessments that are taking over 10 years to do. That is not what I want, that is not what EPA needs. The new process is designed with timelines and milestones to help us move that process along, and actually though it may look more complicated, I believe it is both more streamlined and will be more efficient.

Mr. ROHRABACHER. Okay. So what you are suggesting then is that because something looks more complicated, it doesn't necessarily mean that it is more time consuming and complicated?

Dr. GRAY. No, I would—that is exactly true.

Mr. ROHRABACHER. Well, I think that is a disagreement you have with our Chairman, but I will follow through on that.

Dr. GRAY. Thank you.

Mr. ROHRABACHER. I think that sometimes, yes, I really understand that you sometimes cannot believe your eyes. Thank you.

Chairman MILLER. Well, as I said in the opening that we should—apparently it is you testimony that we should not believe our lying eyes, that the flow chart that was prepared by IRIS staff—I am advised by our Committee staff that all the charts were prepared by IRIS committee staff and prepared to our staff as part of our preparation for this hearing. Isn't that correct?

Dr. GRAY. I believe that is what I said.

Chairman MILLER. You may not have done it, but it was IRIS staff that prepared the charts that describe the process as it has existed along the way before 2004, before OMB and OIRA began making helpful suggestions about how it might be different, how it existed from 2004 to April 2008 and how it exists since April 10, 2008, isn't that right?

Dr. GRAY. That is correct.

HOW TRANSPARENT IS THE NEW IRIS PROCESS?

Chairman MILLER. All right. There has been discussion of transparency. Well, it is not really possible to describe how many steps there are because there are so many kind of sub-numbers. But say for instance looking at 2F, Step 2F, federal agencies identify mission critical chemicals. Is that step transparent? Does the public know what the agencies have had to say about what chemicals are mission critical?

Dr. GRAY. The designation mission critical is something we expect to happen very, very infrequently. When it does, it happens in consultation with and with the agreement of the EPA. If that in fact is something that is—if that designation is made and agreed to by the Agency, it would be certainly made known publicly.

Chairman MILLER. The final decision or the viewpoints that went into the decision?

Dr. GRAY. The decision that this has been chosen to be mission critical and that the Agency had agreed that in fact there were specific areas of research that could be conducted in a short amount of time that would provide additional information to improve the——

Chairman MILLER. How about Step 8B, internal Agency review of draft assessment?

Dr. GRAY. It has always been the practice that our discussions that we have within our Agency where I can tell you there is rarely scientific agreement, those are always kept deliberative within the Agency.

Chairman MILLER. So if it was a chemical that was being used by the Department of Defense, the Department of Defense—that would be the step at which, or a step at which the Department of Defense would say whatever they had to say about TCE being on the IRIS list? Now, whether it should be on the list of chemicals that we know something about the risk—what we know about the risk, is that right?

Dr. GRAY. I am sorry, could you—I wasn't sure what your question was.

Chairman MILLER. 8B. Internal agency review. Is that all your agency or is that——

Dr. GRAY. Yeah, no, that is EPA. As I said, our remarks in EPA have always been kept deliberative, if it is something that—and are not released publicly.

Chairman MILLER. All right. How about nine? OMB interagency review of draft assessment and peer review charge? Is that public?

Dr. GRAY. No, that is interagency.

Chairman MILLER. Okay. And what would happen at that step?

Dr. GRAY. This is when the Office of Management and Budget would coordinate a review of the document by other federal agen-

cies. Comments would come in to EPA, they would be combined with our comments that we had from within our agency and would be considered in ultimately revising the document that would then go very importantly to step 10A, external peer review, so that any scientific choices, any scientific decisions that are made in that document have to pass independent external peer review.

Chairman MILLER. Well, who would be commenting at that point? Would the Department of Defense—if you are talking about a chemical used by the Department of Defense, would the Department of Defense, would that be where they would have something to say?

Dr. GRAY. This process opens up the ability for comment much more broadly for the——

Chairman MILLER. Was that a yes?

Dr. GRAY.—for the agencies, for the public, and other interested parties.

Chairman MILLER. I am talking about nine, interagency review of draft assessment peer. Is that where the Department of Defense would have something to say?

Dr. GRAY. 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.

Chairman MILLER. And that would be——

Dr. GRAY. And as the GAO has recognized—we often get very useful comments back from that interagency process.

Chairman MILLER. Okay. And that is public or private?

Dr. GRAY. Those are deliberative, within the executive branch.

Chairman MILLER. That means it is not public.

Dr. GRAY. That is correct.

Chairman MILLER. Okay. Now, if this is all about what risk a chemical poses, not what to do about it, what risk it poses, isn't that entirely a scientific decision?

Dr. GRAY. No——

Chairman MILLER. Are toxicologists at DOD commenting? Who are you getting from DOD?

Dr. GRAY. I don't know who all of the commenters are, but again, as GAO has recognized, EPA says those comments that come in are useful. But again, they can be comments on science and on the science policy decisions and choices that are made——

Chairman MILLER. Which is also science. Which is also science.

Dr. GRAY. No, we have——

Chairman MILLER. Of course it is.

Dr. GRAY. We have a separate process in our Agency for example for dealing with science policy. We develop guidelines for those choices. They are vetted through our Science Policy Council.

Chairman MILLER. What would be the——

Dr. GRAY. We keep these two things separate.

Chairman MILLER. What would be the purpose of having this be a deliberative process, rather than open, transparent, having everyone who had anything to say, say it right out loud in front of God and everybody? So everybody else who has expertise can comment on what they had to say, whether their factual assumptions are correct, whether their analysis is correct or flawed, whatever. Isn't

that the whole nature of peer review? Isn't scientific analysis open? Ms. Dudley?

Ms. DUDLEY. Mind if I comment on that? I think the purpose is that healthy skepticism and frank discussions or candid discussions among scientists throughout the government actually makes for better results. And let me just read to you from the National Academies—they frequently ask questions. "Deliberative portions of meetings"—and this is the National Academy of Sciences—"deliberative portions of meetings are closed to allow the discussions and consensus process to proceed frankly and without public posturing so that Committee Members are free to change their positions in the face of evidence or argument." That is the same nature, the same reason as Dr. Gray said the discussions among EPA scientists who don't always agree, the discussions among interagency scientists. Providing that opportunity for candid, frank discussion is valuable.

Chairman MILLER. Mr. Stephenson, do you have anything to say on this point?

Mr. STEPHENSON. Well, any time you want to question a risk assessment, whether it is what Dr. Gray is referring to as science policy or not, I still see no problem with the toxicologist at DOD suggesting that you don't have a good enough uncertainty analysis. Why can't that be made public, the basis for that statement? It is not to say that individual scientists within DOD statements would be available, but at least the DOD position on that particular risk assessment or why they are concerned with the science would be publicly available. I can't understand the scenario in which deliberative—if it encourages more frank and open conversations with the federal family, why doesn't it encourage more frank and open conversations with other public commenters? I mean, the logic defies me.

Chairman MILLER. I now recognize myself for another—well, do you wish, Dr. Gray, before I recognize myself for another five minutes, do you wish to comment on what Mr. Stephenson had to say?

Dr. GRAY. I did want to say that I think it is important for these discussions to take place. One of the new enhancements in the IRIS process that is here is something that we call listening sessions in which we open up and invite scientists from the public, from industry, from environmental organizations to all come in and to have a discussion about the science of a particular assessment at two different points here to make sure that we are hearing a wide range of views and we are getting that kind of input. We think that is very important.

Chairman MILLER. Now I recognize myself for five more minutes. Is there any stage at which a TCE manufacturer would have a say? Would a TCE manufacturer be able to talk to OMB? Would a TCE manufacturer fit in any of these boxes? Would someone outside a Federal Government agency have any chance to comment other than the public comment?

Dr. GRAY. Can I say right here, this goes back to my previous point of these listening sessions. Previously, there are contacts that come from various affected parties. It may be an industry or a manufacturer or use——

Chairman MILLER. Right. You have to have public comment.

Dr. GRAY. No.

Chairman MILLER. That is not public, that is private.

Dr. GRAY. Now in the new process, that will be happening in these open public listening sessions.

Chairman MILLER. Okay. Is there an opportunity for a manufacturer other than a public open listening sessions to have a say? Do they fit in any of these boxes or do they talk to OMB, to OIRA?

Dr. GRAY. I cannot speak for that. In our case, the intention now is to have these listening sessions which are open, publicly available as the——

Chairman MILLER. Right.

Dr. GRAY.—way that anyone who wants to bring——

Chairman MILLER. Any chance——

Dr. GRAY.—information brings it in.

Chairman MILLER. Any chance to do it in a deliberative way, not a public way, but deliberative way?

Dr. GRAY. No.

Chairman MILLER. Okay.

Mr. STEPHENSON. Mr. Chairman——

Chairman MILLER. Ms. Dudley, is there any opportunity for deliberative——

Ms. DUDLEY. No, not to my knowledge.

Chairman MILLER. OMB doesn't talk to manufacturers or no——

Ms. DUDLEY. We talk to other federal scientists. Our role is coordinating scientific dialogue between scientists within the Federal Government.

Mr. STEPHENSON. Mr. Chairman, could I add a comment here?

Chairman MILLER. Mr. Stephenson.

Mr. STEPHENSON. In the course of doing our work and having discussions with DOD, DOE, and NASA, none of them really had objections to their comments on the scientific risk assessment being made public. So I am not sure where this need for deliberation comes from.

Chairman MILLER. All right. I am sorry, Dr. Gray and Ms. Dudley, you are both testifying that there is no step in this whole process, there is no procedure by which a private party, not a government agency, a private party can participate formally or informally in a deliberative way, not in a public way, but privately? Ms. Dudley, is that correct?

Ms. DUDLEY. I am not familiar with the entire process. I know that the two steps that OMB manages—interagency review—that is not an opportunity for people outside the government to weigh in.

Chairman MILLER. Okay. Now, both the EPA and OMB have recently asserted in Congressional testimony and refused to answer questions based upon the deliberative process privilege, that internal government discussions are not subject to—I don't agree with it, I am stating that—the assertion the privilege that EPA and OMB has asserted. Do you contend that if there were private conversations with those outside of government that they would be subject to any privilege?

Ms. DUDLEY. I am not a lawyer. I know that our process is that in our regulatory review as well as the IRIS review, we do not talk to people outside the government. In our regulatory review, we op-

erate under Executive Order 12866, and under that when we have a regulation under review, if we are to meet with people outside the government, we post that on our website, we post the attendees to that meeting and we also invite the agency.

There is a balance to be struck, and I understand where you are going. There is a balance to be struck between a deliberative process to allow for that frank and candid discussion and also for the public's need for transparency and need to know. And I think we try to strike that balance. In the IRIS process, it is through this new procedure, and in the regulatory process it is through our transparent posting of meetings with people outside the government.

Chairman MILLER. Dr. Gray, the head of your agency asserted that privilege yesterday and refused to answer a direct question in another committee.

Ms. DUDLEY. Actually, if I could just quickly correct that. I was sitting next to him, and he did not assert that privilege.

Chairman MILLER. I am sorry. He didn't actually say those words, he just said he wasn't going to answer. So do you intend, assert that I-don't-feel-like-telling-you privilege?

Ms. DUDLEY. Only the President can assert Executive Privilege, and to my knowledge he has not done that in the issue of the testimony yesterday nor today.

Chairman MILLER. Do you have any idea of the nature of the privilege upon which the head of the EPA was lying in refusing to answer direct questions in a committee?

Ms. DUDLEY. Are we discussing yesterday or on IRIS?

Chairman MILLER. Well, I am trying to figure out which one of these is going to be available to a Congressional oversight committee.

Ms. DUDLEY. On this issue, actually, Dr. Gray is probably better to answer. But after the assessments have gone through interagency review, they are available for public peer review, and all the information on which those assessments rely is available for scientists outside the government or the general public outside the government to evaluate.

Chairman MILLER. Okay. Dr. Gray, did you have an answer to that question?

Dr. GRAY. I would agree completely with what Ms. Dudley has just said. No, there is—here the only things—there is a deliberative process with the discussions that we have within the EPA and the discussions that we have with the other federal agencies. When the ultimate decisions are made, the choices, the data, the endpoints in an IRIS assessment, those are put forth in a transparent way and go out for independent, external peer review to make sure that the science choices, the science assumptions, the data choices we have made are scientifically appropriate.

Chairman MILLER. Dr. Gray, Mr. Stephenson said a minute ago that—he listed three agencies, NASA and who else?

Mr. STEPHENSON. DOE and DOD.

Chairman MILLER. They say they don't mind commenting right out loud in front of God and everybody. They don't need for it to be privileged or private, deliberative. They are willing to say what

they have to say publicly. Are there agencies that have objected to having their comments be public?

Dr. GRAY. The deliberative steps here were decisions that were taken by the EPA to make these steps deliberative as they have been in the past and as is done with other kinds of reviews that we have.

Ms. DUDLEY. Excuse me sir, do you mind if I comment on that?

Chairman MILLER. Sure.

Ms. DUDLEY. Any agency that wants to make that information public certainly can do that during the comment period. So there is nothing in this process that would bar them from making that information public.

TIMELINES FOR IRIS ASSESSMENTS

Chairman MILLER. I understand this has only been in effect since April 10, 2008, and it is designed to streamline the process so that it would be more productive and that more chemicals will be assessed. We won't still be waiting 11 years after formaldehyde was submitted for re-evaluation, and formaldehyde is—we have had another Subcommittee hearing on formaldehyde. It would have been nice to have for the EPA and FEMA and for the Centers for Disease Control to have a picture of formaldehyde's likely toxicity, likely risk, based on the current science. But it still hasn't happened. When are we going to know that this is actually producing more assessments? Four in the last two years does not seem like the changes made in 2004 resulted in a leap in productivity. When are we doing to know if this is now going to fix whatever errors there are? Mr. Stephenson thinks that it will not but it will make it worse. When are we going to decide who is correct?

Dr. GRAY. Well, I would say that we agree, that there are real issues with the development of IRIS assessments and their timeliness. These delays have been a longstanding issue, and it is very clear the fact that we have a significant number that have taken 10 years or more, that a lot of the delays predate any changes in this process. Our goal is to have a process that will increase the rigor and the timeliness with these timelines that will provide strict milestones for EPA and for the other parties in this entire process to move this along. I think what we need now is time to implement this process, to evaluate it. It is intended to be a living document, recognizing it may need future revisions, but I think that the process that we have been using certainly hasn't gotten us to the place we want to be.

Chairman MILLER. Ms. Dudley.

Ms. DUDLEY. You know, I wasn't involved in developing the new IRIS process, but the fact that it has timelines for every step along the way, including interagency comment and EPA response to that, I think will both streamline the process and improve the quality and rigor of the resulting assessments.

Chairman MILLER. What are the consequences of not meeting the timelines?

Ms. DUDLEY. I don't know that there are any consequences.

Dr. GRAY. No, but these are intended as part of a management system that we are implementing so that people know on our side how we expect them to do their work and when we expect them

to do their work when we deal with the other agencies how things go. For example, one of the things that is commonly done is to suggest to an agency, if we don't hear from you in some amount of time, we assume you have no comments. Those sorts of things may well be the way in which this would work to help make sure that things keep to the timelines.

Chairman MILLER. Mr. Stephenson, when do you have a sense of how well this is working?

Mr. STEPHENSON. If you look at the timeframes that are missing from your chart with this system, we already know that it is not going to work.

Chairman MILLER. And how is that?

Mr. STEPHENSON. All we did was add up the timeframes which, as you just heard, may or may not have consequences. We added them up through this flow chart, and they total six years. And if it is a mission critical system, the DOD commenter or whomever, has the ability to ask for additional research, which can take up to 18 more months. It is already broken.

Dr. GRAY. I would like to suggest that in fact this process I believe can help us get done in less time than our current five and one-half year per assessment average; if you add up the timelines and remove those small fraction of chemicals that might be considered mission critical, this is something that will take less time than our current process and will be more responsive, more rigorous, and more transparent.

Mr. STEPHENSON. We are not thrilled with the current process.

Chairman MILLER. Are there no milestones at all in the current process, in the previous process?

Dr. GRAY. There are none that are written down and publicly available.

Chairman MILLER. Okay.

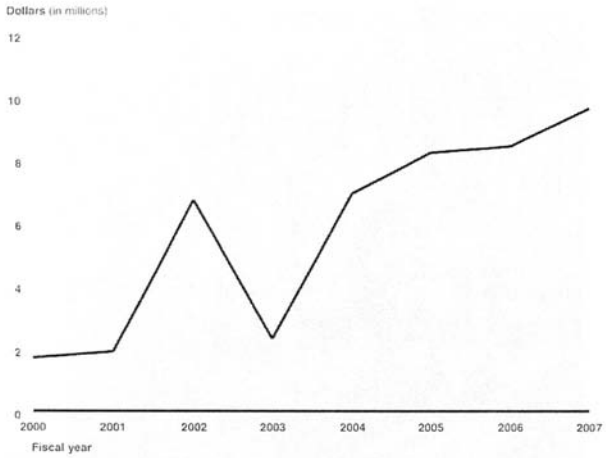
Mr. STEPHENSON. That is the improvement. It is no longer ad hoc. Now you know what the process is.

Ms. DUDLEY. Sir, I actually have a chart that I don't know—did you get this just before the hearing? I am sorry that we don't have it so that you can put it up.

Chairman MILLER. I haven't seen it but perhaps the staff has.

Ms. DUDLEY. What it does is it takes a look—EPA has data on the number of IRIS assessments completed going back to 1997. The GAO reports—I am not sure what day it starts, but it doesn't go back as far as we have data. And that suggests that there are increases—that you see increases and decreases in the assessments but that on average in the last three years of the previous administration, there were four assessments per year, whereas the average between 2000 and 2007 has been 4.6. So I think we all agree that the process, that it is too slow and we need to speed that up, but I think it is not fair to characterize the previous way as the golden age and the future as a slowing of the process.

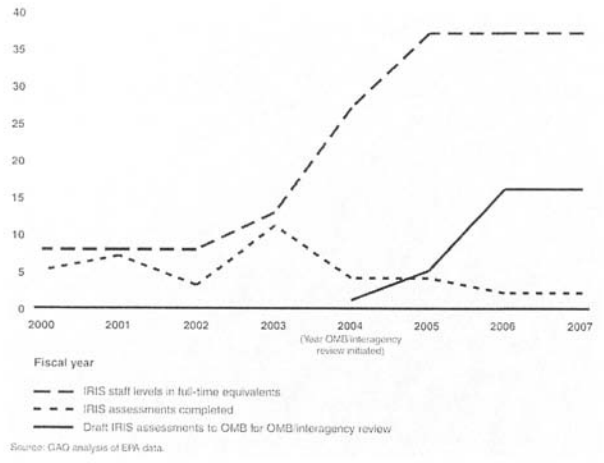
Figure 2: Funding for the IRIS Program, Fiscal Years 2000-2007



Source: GAO analysis of EPA data.

Note: In fiscal year 2002, a congressional appropriations conference committee designated $5 million to accelerate the development of new IRIS values and to update current IRIS values. According to EPA officials, this funding was provided to various EPA program offices to support the IRIS assessments that program offices were leading at that time. In addition, EPA has reprogrammed funds from some of its other programs to expand the IRIS program to support the development of IRIS assessments, especially high-priority chemicals.

Figure 3: Number of Completed IRIS Assessments, Draft Assessments to OMB, and IRIS Staff in Full-Time Equivalents, Fiscal Years 2000-2007



Produced by GAO

Mr. STEPHENSON. I agree with that.

Chairman MILLER. I am advised by our staff that we do have this but we got it 15 minutes before the hearing. So there has not exactly been an ample opportunity to look at it closely.

That is the end of the hearing today. Thank you all for appearing. We did have an earlier hearing on the issue of formaldehyde in trailers provided by FEMA. And an effort began in 1997 to update the listing for formaldehyde. The equivalent agencies through the EPA and other developed countries list formaldehyde as a known carcinogen. It is still listed as a suspected carcinogen, and since 1997, there has not been a completed revision of formaldehyde's risk to the public, risk to health, risk to the environment. There were hundreds and thousands of people who were living in trailers provided by FEMA that used particle board made with formaldehyde with high levels of formaldehyde in the air inside the trailers, with families who were displaced by Katrina and by Rita breathing that air every day. It would have been nice to have a current assessment of the health consequences for formaldehyde that FEMA could have relied upon, that the Centers for Disease Control could have relied upon, and that the Agency for Toxic Substances and Disease Registry, ATSDR, could have relied upon instead of saying, well, just open the windows and doors. If in fact formaldehyde is a substantially greater health risk than the now more than decade old assessment, that is a current science. There is no virtue—and I agree with all of the witnesses today—there is no virtue in not knowing. There is no virtue in not finding out. This is not a process about—ours is not intended to be health or

risk management. It is not what to do about the fact that there is a risk, it is what is the risk? And there is no virtue in not knowing. But it is hard to look at EPA's performance and not conclude that we are not doing a sufficient job in determining which of the 80,000 chemicals present a hazard and what the hazard is.

So I thank all of you for appearing today, and we will pursue this further. Thank you. The hearing is adjourned.

[Whereupon, at 12:50 p.m., the Subcommittee was adjourned.]

Appendix:

Additional Material for the Record

DoD Interests in Emerging Contaminants

Tom Morehouse
Program Advisor, Emerging Contaminants
Office of Deputy Under Secretary of Defense
(Installations & Environment)
October 26, 2006

Imagine
if the largest industrial complex in the nation could...

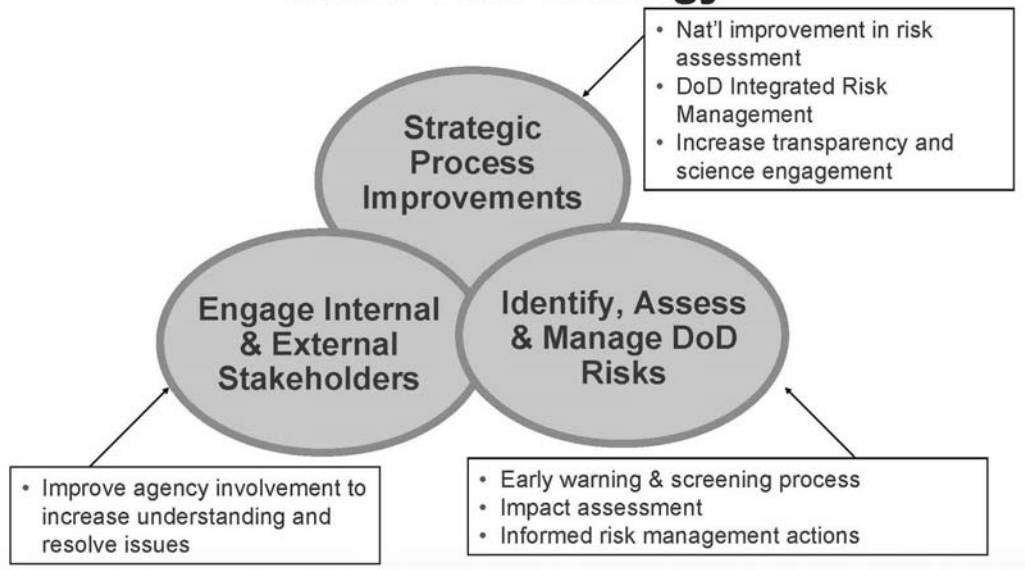
- **Predict** which chemicals it used were most likely to pose human health and environmental challenges and be regulated in the future.
- **Develop** a consensus evaluation of risks posed to the sustainability of its mission.
- **Disseminate** rapidly new useful information on scientific and technical implications and options.
- **Leverage and strategically focus** intellectual capital and other resources on highest priority issues.

DEPARTMENT OF DEFENSE
MERIT
Materials of Evolving Regulatory Interest Team

DoD Strategic Vision for ECs

- **Protect People & Enhance Readiness**
  - Ensure application of sound, thorough science in risk assessments
  - Make processes transparent and inclusive
  - Make sound risk management decisions on emerging contaminants

Three Part Strategy



DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

Materials/EC Tracking Process

Over-the-Horizon Scanning

May be of interest

Watch List

Probable mission or budget impacts

Action List

Review literature, periodicals, regulatory communications, etc.

Monitor events; conduct rough impact analysis

Detailed impact analysis; launch risk management actions, including pollution prevention

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

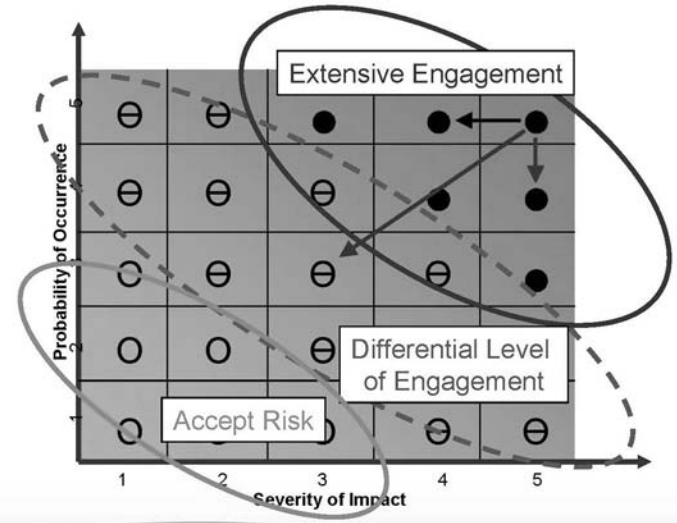
Phase I EC Impact Assessment

Probability of Regulation/Re-regulation				
Impact on DoD Functional Categories				
Environment Safety & Health	Readiness & Training	Acquisition	O&M of DoD Assets	Cleanup
H	H	H	H	H
M	M	M	M	M
L	L	L	L	L

Material and process decisions span functional areas 3 and 4

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

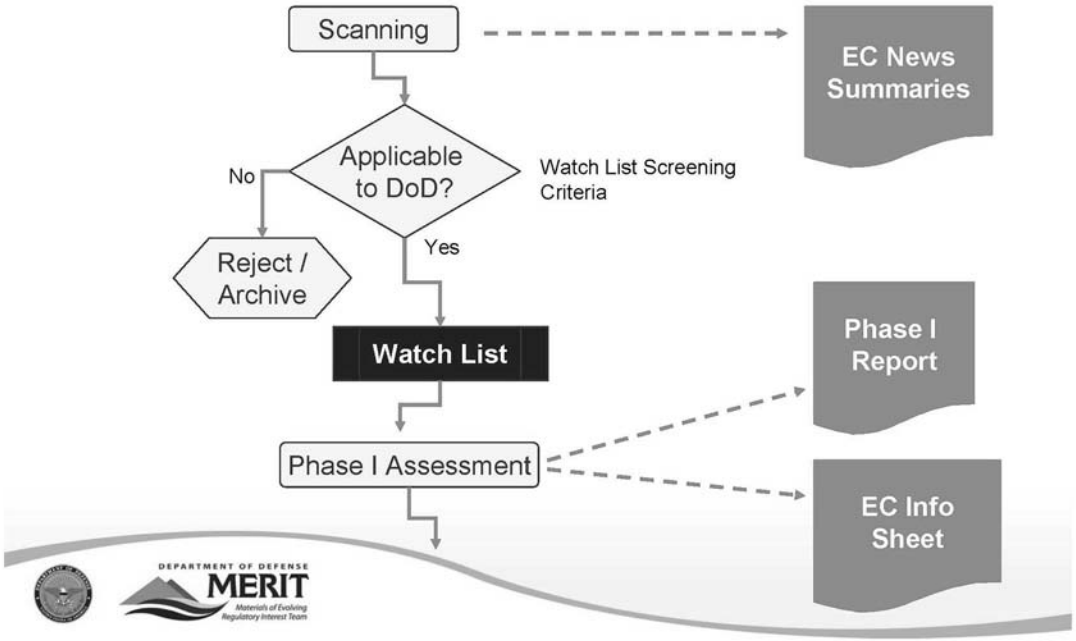
Integrated Risk Management Actions



- Risk Assessment
  - Fill science gaps
  - Exposure assessment
  - Benchmark with Industry
- Risk Management
  - Material substitution
  - Process changes
  - RDT&E
  - Acquisition changes
  - Benchmark with industry
  - Stockpile material
  - Increase compliance monitoring
  - Additional training
- Risk communication

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

EC Assessment Process - Part 1

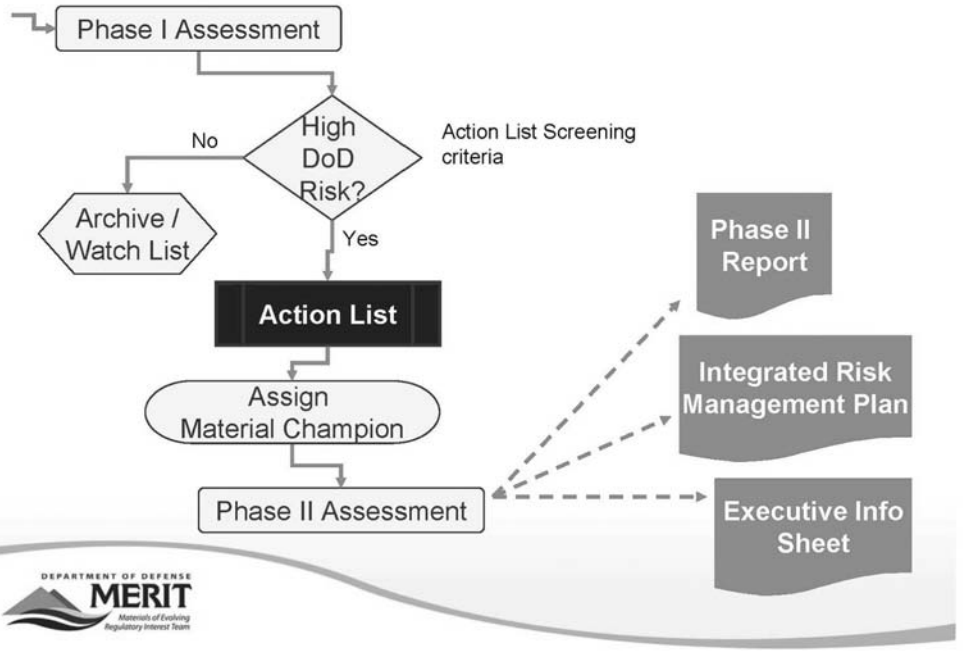


What is a Phase I Assessment?

- **An initial assessment of the likelihood that new regulations will be enacted, and the impacts those new regulations will have on DoD.**
- **What's required to conduct a Phase I Assessment**
  - An understanding of the reasons for regulatory change and their probability.
  - An understanding of where, why, how and how much of the materials subject to regulatory change; and the impacts the proposed regulations will have on our operations.
- **Working with the regulatory community to understand the reasons and risk of regulation is often easier than understanding the impacts proposed regulations will have on DOD.**
- **To make sound investment decisions, this situation must change.**
- **We need your help.**

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

Assessment Process - Part 2



What is a Phase II Assessment?

- The same as a Phase I assessment, but much more detailed.
- Monetary estimates and operational assessments sufficiently detailed to support multi-million to billion+ dollar investment decisions in mitigation efforts.
- Mitigation efforts can include RDT&E, material substitution, process changes, protective equipment, new handling procedures, etc
- We need your help.

Current Processes Inadequate

- **Data on material purchase and use scattered across DoD and its suppliers**
- **Databases do not communicate with each other**
  - Formats differ
  - Information collected is not consistent
  - Single point access not possible
- **Manual data calls notoriously inaccurate and incomplete**

Making it Better: EC Industrial Base Working Group

- **Potential Membership**
  - DoD industrial policy
  - Service acquisition commands
    - » Systems Engineering
    - » ESOH specialists
  - DoD industrial facilities
  - Defense Logistics Agency
  - Other DoD material database resources
  - Cognizant military authorities
  - OEMs
  - Providers of material management services
- **Task**
  - Collect and synthesize comprehensive information about material uses and alternatives to support informed decision making

Differences - Watch & Action List

Watch List

- May impact DoD
- Limited analysis of impact – more qualitative
- Monitor external actions
- Updated regularly
- Short info sheets developed
- Minimal resources expended

Action List

- Likely to impact DoD
- Detailed analysis of impact – more quantitative
- Take RM actions
- Executive info sheets developed
- Significant resources may be expended
- "Material champion" assigned

Integrated Risk Management Plan

- **Engaging with regulators**
  - Agreement on uncertainty factors, toxicity and levels
  - Understanding on efforts needed to achieve mitigation
- **Mitigation Options**
  - Identifying measures available to comply
  - Identifying research needed to develop new materials, processes or handling procedures
  - Estimating time and resources needed to comply
- **Communications**
  - Clear consistent message from DoD
  - May be the same as other users, may differ
- **Decision – best path forward**
  - Invest in science to reduce uncertainty?
  - Invest in mitigation?
  - Combination of the two?

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

EC Watch List

- Tungsten & alloys
- Tetrachloroethylene
- Dioxin
- N-nitrosodimethylamine (NDMA)
- 1,4-dioxane
- 1,2,3-trichloropropane (TCP)
- Nanomaterials
- Dichlorobenzenes
- Beryllium
- Polybrominated biphenyl ethers (PBDEs) and polybrominated biphenyls (PBBs)
- Di-nitrotoluenes (DNT)
- PFOS/PFOAs
- Lead

EC Action List

- Perchlorate
- Royal Demolition eXplosive (RDX)
  - Cyclotrimethylenetrinitramine
- Trichloroethylene (TCE)
- Chromium VI
- Naphthalene

Imagine: Hexavalent Chromium

- **OSHA PEL reduced by factor of 10 -- At Navy facilities alone, affects 3200 workers**
  - Medical surveillance, Hazard communication, Recordkeeping
  - Protective work clothing and equipment. Respiratory protection
  - Separate hygiene areas and practices
- **If EC Directorate had been in place five years ago:**
  - Earlier engagement with regulators to reconcile dispute over proposed exposure limits
  - Earlier and more accurate assessment of impacts of proposed rule
  - Earlier and better funded R&D projects to improve knowledge of health risks to workers
  - Earlier and better funded R&D on alternative materials and processes

Imagine: Nickel-Cadmium

- **Used by military to plate jet engine compressor propeller blades**
  - Cd leached into wash water during standard maintenance
  - Wash water allowed to flow onto tarmac
  - Once environmental impact realized, wash water captured
  - Long-term solution: replace all coated blades with Al blades over 10 years

- **If EC Directorate had been in place when engine was first designed:**
  - Earlier understanding of Ni-Cd coating issues
  - Earlier and better funded R&D on alternatives to Ni-Cd
  - Environmental implications and costly retrofits could have been avoided

Imagine a future where...

- Information is shared
- Perspectives exchanged
- Common definitions and processes exist
- Science priorities agreed upon and coordinated research conducted
- Environmental and public health liabilities are avoided

Summary

- **EC management requires new thinking**
  - Proactive vice reactive
  - Investments before regulatory action

- **Potential large payback**
  - Protects people, mission and assets
  - Sustainable

DoD Emerging Contaminant Website!

www.DODMeritinfo.net

www.DENIX.osd.mil

DEPARTMENT OF DEFENSE MERIT Materials of Evolving Regulatory Interest Team

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 10

DEPUTY ADMINISTRATOR

MEMORANDUM

FROM: Marcus Peacock

TO: George Gray
Assistant Administrator, ORD

SUBJECT: Implementation of Revised IRIS Process

I understand that the Agency has completed its review of the IRIS process. The revised process is described in the document entitled "*EPA's Integrated Risk Information System: Assessment Development Procedures*" (attached). As you are aware, reforming the IRIS process has been an important goal of the Administrator, as reflected in his Action Plan.

I believe that the revised IRIS process will provide greater transparency, objectivity, balance, rigor and predictability in IRIS assessments. For example, the revised process creates a new step that allows the public to bring forth additional scientific information and to comment on the scope of an assessment early in the IRIS process. New opportunities are also provided for EPA to host a "listening session" during public review and comment periods to allow for broader participation and engagement of interested parties. Additionally, the revised process creates a limited opportunity for other agencies to collect data to fill significant data gaps for "mission critical" chemicals. Although interagency comments on IRIS assessments are considered deliberative in nature (as is the case for all EPA assessments), all conclusions reached by the Agency, including justifications for making science or science policy decisions, are made available to interested parties and the public in the assessment and all IRIS assessments undergo a thorough peer review. Final decisions on the content of IRIS assessments clearly remain with EPA.

These and other improvements to the IRIS process help to define critical and appropriate roles for public and interagency comments and interactions, and promote and foster greater communication and sharing of information between interested parties and EPA. I believe that the outcome of these improvements will be a more predictable, streamlined, and transparent process for conducting IRIS assessments, which will ultimately lead to assessments that are of the highest quality and rigor. The revised process is also expected to result in a much more timely completion of IRIS assessments than has occurred in the past.

The Administrator gave us this task three years ago. Given this and the many advantages the revised process holds relative to past or current practices, the Agency should begin following the steps outlined here as soon as possible. Consequently, I request that you implement the new

IRIS process in all ongoing and future scientific and science-policy assessments, effective immediately. This process, however, should be seen as a "living" document that can be revised and improved as experience is gained and new ideas brought forward. I encourage you to share this process widely and encourage review and comment from interested parties.

The revised IRIS process will yield assessments that are of the highest quality and timeliness, so that they can be used by the Agency, States, the public and various other stakeholders. I look forward to continuing to work with you to advance the Agency's goals through this important process.

Attachment

EPA's Integrated Risk Information System

Assessment Development Procedures

Introduction: The Integrated Risk Information System (IRIS) is a U. S. Environmental Protection Agency (EPA) database that contains the Agency's science and science policy positions on chronic human health effects that may result from exposure to environment contaminants. Through IRIS, EPA provides the highest quality science-based human health assessments to support Agency policymaking activities.

Since the 1980s when IRIS began, EPA has taken many steps to improve the IRIS process that make it more accessible and transparent. In addition, the Agency has worked to enhance the independent expert peer review process to assure high quality human health assessments. In its continuing efforts to improve risk assessment practices, EPA has reviewed its development processes for human health assessments that, once completed, are included on IRIS.

The role of other Federal agencies and the public in the IRIS process is to promote communication, sharing of information, and teaming with EPA at key points throughout the nomination and assessment activities. Agencies may identify chemical substances that are critical to their mission and operation, therefore initiating targeted discussions with EPA in the development of risk assessments for these mission critical chemicals. The public is also offered opportunities to bring forth data and expertise to inform the IRIS process. The enhanced transparency brought about by teaming of other Federal agencies and the public with EPA will help identify scientific issues early, which will ultimately help streamline the IRIS process.

I. Annual Chemical Nomination Process

1. EPA Initiates Annual Nomination Process for IRIS Assessments (75 days)

A. EPA's Office of Research and Development (ORD) issues a *Federal Register* (FR) notice inviting public nominations of chemical substances for ORD to consider for inclusion on the IRIS Program annual agenda (Agenda). Nominations could include chemical substances to consider for the development of new assessments as well as the revision of assessments already on IRIS for which critical new information is available. Nominations must be submitted within 60 days of the solicitation.

B. Simultaneously, ORD asks the EPA Program and Regional Offices and other agencies to nominate chemical substance(s) for inclusion on the Agenda.

   a. Agencies include, but are not limited to, HHS, NASA, DOA, DOE, DOT, DOD, OMB, CEQ, and OSTP.

   b. Each interested agency appoints one point of contact (POC) at the organizational level it deems appropriate. Each agency POC is responsible for keeping their management appropriately informed and for coordinating reviews of draft IRIS documents by that agency.

   c. ORD appoints the POC in the IRIS program.

   d. ORD notifies EPA Program and Regional Offices via memorandum to the EPA Deputy Assistant Administrators and Deputy Regional Administrators, with a copy to the intra-Agency IRIS Review Committee (via email), about the request for assessment nominations.

e. ORD notifies the other agencies via memorandum to the agency POCs (via email) about the request for assessment.

f. Other agencies and EPA Program and Regional Offices have 60 days to submit nominations for inclusion on the Agenda; nomination submittals will be considered part of the public record.

g. If an other agency or EPA Program and Regional Office does not respond within 60 days of the solicitation ORD will assume that it did not have any nominations for that year.

h. Other agencies and EPA Program and Regional Offices provide documentation that supports their interest in the chemical(s) and rationale for consideration to ORD.

C. At the end of the nomination period, within 15 days, ORD calls a meeting with other agencies and EPA Program and Regional Offices to discuss their nominations, including:

a. Other agencies' or EPA's Program and Regional Offices' specific questions and concerns about, and recommendations for, adding or updating assessments for the chemical substance(s) that they nominate;

b. The importance that other agencies or EPA Program and Regional Offices place on having the chemical substance(s) that they nominate included on the Agenda, and the basis for the nomination; and

c. Current or planned research and/or assessments by EPA or the other agencies.

2. EPA Determines Annual IRIS Agenda (30 – 60 days)

A. ORD applies its published selection criteria to the slate of nominated chemicals.

B. ORD reviews its available work force and areas of expertise that might be available for new assignments.

C. ORD prepares the IRIS Program Annual Agenda, which lists the chemical substances for which work will be initiated in the upcoming year, including chemicals selected by ORD and consideration of chemicals nominated in response to **Step 1.A** and **Step 1.B**.

D. ORD notifies EPA Program and Regional Offices, other agencies, and the public that the IRIS Program Annual Agenda is available.

a. Notify EPA Program and Regional Offices by memorandum to the EPA Deputy Assistant Administrators and Deputy Regional Administrators, with a copy to the intra-Agency IRIS Review Committee (via email).

b. Notify other agencies by memorandum to agency POCs (via email).

c. Notify public by issuing an FR notice announcing the IRIS Program Annual Agenda (new starts and updates).

E. The other agencies or EPA Program and Regional Offices may decide at this early stage to sponsor or perform research associated with the chemicals selected or proposed to be assessed if they conclude that such work would be beneficial to the assessment or future re-assessments. The results of this research will be considered for inclusion in the IRIS assessment if it is completed within an appropriate time frame as determined by ORD and has undergone independent external peer review (e.g., peer review publications or independent peer review panel evaluations).

F. The other agencies identify to ORD an initial list of the chemical(s) on the IRIS Program Annual Agenda that they have determined meet the definition of mission critical [1].

II. The Assessment Process

1. EPA Conducts Scientific Literature Search (60 – 90 days)

A. ORD appoints a chemical manager(s) for each chemical on the IRIS Program Annual Agenda.

B. The chemical manager(s) direct an EPA contractor to conduct and complete a comprehensive search of the scientific literature for the chemical.

2. EPA Initiates Data Call-In (45 – 60 days)

A. After the literature search has been completed for each chemical, ORD publishes an FR notice that notifies the public that completed literature searches for a set of chemicals are available on the IRIS Internet site, and invites the public and other agencies to submit additional scientific information (studies, reports, other assessments, etc.) on the chemical.

   a. FR notice requests information on new research that may be planned, underway, or in press.

   b. FR notice includes notification that the initial literature review results for each chemical are available on the Internet for review (eliminates submission of information about which EPA is already aware).

   c. FR notice includes information on how and where to submit scientific information.

   d. A minimum of 45 days is provided for submission of information.

B. ORD ensures that EPA Program and Regional Offices and other agencies are aware of the FR notice:

   a. EPA Program and Regional Offices: via email

   b. Other agencies: via email to agency POCs. Each agency POC is responsible for keeping his/her management appropriately informed.

C. Other agencies confirm to ORD whether the chemical is mission critical. It is expected that only a few chemicals will receive this designation.

[1] A mission critical chemical is one that is an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation or degradation of the conduct of the mission and/or unacceptable resource constraints.

3. EPA Begins IRIS Assessment and Develops Draft Qualitative Assessment (180 – 240 days)

A. ORD identifies and assembles an IRIS assessment team.

B. ORD reviews new scientific information submitted in response to the call for information in **Step 2.**

C. ORD assesses the data in the scientific literature and submitted in **Step 2** and develops a draft Qualitative 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. description of approaches being considered for dose-response assessment including default approaches and types of models under consideration;

   e. identification and discussion of potential uncertainty factors; and

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

D. This draft Qualitative Assessment does not include quantification; however, extensive qualitative information including ORD's interpretation of scientific data and description of potential assumptions and approaches will be included.

E. The draft Qualitative Assessment completes internal ORD clearance.

F. The draft Qualitative Assessment completes internal EPA review via the intra-Agency IRIS Review Committee. Intra-Agency comments are deliberative.

4. EPA Initiates Public and Agency Review of Draft Qualitative Assessment (45 – 60 days)

A. ORD issues a FR notice inviting the public and other agencies to comment on the draft Qualitative Assessment.

B. On the publication date of the FR notice, the draft Qualitative Assessment is posted on the IRIS Internet site.

C. ORD ensures that EPA Program and Regional Offices and other agencies are aware of the FR notice.

D. The FR notice includes instructions for submitting comments to ORD. The FR notice also requests that the public and other agencies identify missing types of studies and areas where uncertainties might be reduced, modes of action elucidated, or estimation of dose-response informed through new short-term (12 month) research.

E. Other agencies may identify a chemical as mission critical based on the results of the draft Qualitative Assessment (see Annual Chemical Nomination Process - **Step 2.F**).

F. All public comments received during the official public comment period must be submitted through E-Gov (www.regulations.gov); all public comments will be part of the official record. Other agency comments are deliberative.

G. ORD holds a "listening session" during the public review process to allow all interested parties to comment on the draft Qualitative Assessment.

5. EPA Initiates Review of Public and Agency Comments (30 days)

A. ORD compiles and reviews all public and other agency comments received on the draft Qualitative Assessment, and shares the comments with EPA Program and Regional Offices and other agencies.

B. ORD provides other agencies and EPA Program and Regional Offices with information about any significant changes that might occur in the IRIS assessment as a result of the public or other agency comments and listening session.

C. If another agency or the public wants to discuss with ORD a particular comment or set of comments, they should contact the IRIS POC to arrange a meeting with ORD.

D. If significant alternative science or science policy judgments are raised by the public, EPA Program or Regional Offices, or other agencies, these will be added to the document and brought forward in the charge to the independent external peer review panel.

6. Evaluation of Agency Interest in Closing Data Gaps for Mission Critical Chemicals (90 days)

A. If another agency is interested in filling a significant data gap, it must first document that the chemical is mission critical (see Annual Chemical Nomination Process - **Step 2.F** and The Assessment Process - **Step 4.E**).

B. For mission critical chemicals, the agency interested in addressing data gaps will consider the comments provided in **Steps 4 and 5**, and submit to ORD a research plan that documents how the conduct of new research has the potential to reduce uncertainties, clarify the mode-of-action, or inform the estimation of dose-response. The other agency must also show that the proposed research and peer review can be completed in less than 18 months. If desired, a letter of agreement between ORD and the other agency sponsoring the research can be created articulating the relevance of the proposed research to the risk assessment and how the proposed research may inform the risk assessment. Such a letter would indicate the timeframe for expected research to be completed.

C. The sponsoring agency may decide that an independent 3rd party consultation should be done to evaluate the estimated costs of the proposed research, and the expected benefits of additional research for the assessment. This 3rd party consultation must be completed during this 90 day period.

D. If a sponsoring agency wants to partner with an external party or any other agency to conduct a study, that decision is theirs to make, but ORD and other interested agencies should be informed.

E. If no request for developing new short-term research is received, or if no interest in conducting such research is expressed for mission critical chemicals, proceed to **Step 8.**

7. Design and Implementation of New Studies for Mission Critical Chemicals (365 – 540 Days)

A. If in **Step 6** the consequences and interest in closing data gaps are determined to be critical by ORD, in consultation with the intra-Agency IRIS Review Committee and other interested agencies, the agency can sponsor the new research.

B. ORD will generally allow no more than an 18 month hiatus from the completion of the IRIS assessment to allow for the completion and peer review of studies specified in **Step 6**.

C. The sponsoring agency develops a detailed research plan and solicits comments and recommendations on the research plan from ORD, in consultation with the intra-Agency IRIS Review Committee, and from other agencies. ORD and the other agencies respond to the sponsoring agency within 30 days, focusing on study design and whether the research, if conducted as planned, is likely to reduce uncertainties (e.g., specific uncertainty factor), clarify the mode-of-action, or inform the estimation of dose-response. The study plan and characterization of potential impacts on the assessment is documented in a letter between the sponsoring agency and ORD, as a complement to the letter discussed in **Step 6.B**.

D. The agency sponsoring the research will work expeditiously to complete its planning, protocol design, and study implementation. ORD, in consultation with the intra-Agency IRIS Review Committee, will provide timely reviews and responses of any aspect of this work, if requested by the sponsoring agency.

E. If ORD or the sponsoring agency deems that consultations are warranted, ORD or the sponsoring agency can call meetings and teleconferences to discuss critical issues articulated in correspondence among the agencies. Third-party consultants can be invited by ORD or the other agencies to participate in these meetings and teleconferences.

F. An agency may also sponsor or perform any other research (that is outside the scope of this effort) associated with the chemical being assessed if it concludes that such work might be beneficial to a future IRIS assessment. Agencies will continue to direct their internal research agendas as they see fit.

G. The sponsoring agency provides the study report(s) to ORD and other interested agencies immediately upon completion of the study.

H. Independent External Peer Review (included as part of **Step 7** timeframe):

   a. Upon completion of the study, the sponsoring agency arranges for external peer review of the research report(s) by the scientific community.

   b. The sponsoring agency consults with ORD in determining who will conduct this review, the level of review, and by what means (e.g., panel review).

   c. ORD and the sponsoring Agency provide the studies, peer review comments and disposition of comments report(s) to the public.

   d. If ORD or the sponsoring agency deems that consultation is warranted, ORD or the sponsoring agency may call a meeting to discuss critical issues and significant disagreements about the peer reviews. Third-party consultants may be invited by ORD or the sponsoring agency to participate in this meeting.

I. ORD, in consultation with the intra-Agency IRIS Review Committee, will consider the results of the new studies carefully as it proceeds with the development of the assessment. Discussion of the new study results will be included in the draft assessment.

8. EPA Completes Draft IRIS Toxicological Review (120 – 270 days)

A. ORD completes the draft IRIS Toxicological Review.

a. The draft IRIS Toxicological Review draws upon the previous draft Qualitative Assessment and the comments received in **Steps 4 and 5.**

b. ORD reviews and analyzes any new short-term research completed under **Steps 6 and 7.**

c. The draft IRIS Toxicological Review includes a quantitative assessment, including application of uncertainty factors, mode-of-action information, and dose-response modeling.

B. The draft IRIS Toxicological Review undergoes internal ORD review (30 – 45 days).

C. ORD submits the draft IRIS Toxicological Review for internal review via the intra-Agency IRIS Review Committee and addresses intra-Agency comments (30 – 60 days).

D. Determination of peer review characteristics:

a. For mission critical chemicals, ORD will cooperate with other interested agencies to determine the level of peer review (e.g., National Academy of Science (NAS) review, EPA Science Advisory Board (SAB) review, or contractor-led panel peer review), panel disciplines, and the scope of the review.

b. For other chemicals, ORD determines the level of peer review, panel disciplines, and the scope of the review.

c. ORD develops any contract documentation.

9. EPA Initiates Interagency Review of Draft IRIS Toxicological Review (45 – 105 days)

A. ORD sends the draft IRIS Toxicological Review and draft external peer review charge questions to OMB to initiate interagency review.

B. ORD develops a charge for interagency reviewers. It is anticipated that the interagency review charge will remain similar for each draft IRIS Toxicological Review, with chemical specific text added as appropriate.

C. OMB distributes the draft IRIS Toxicological Review, draft external peer review charge questions, and the interagency review charge to interagency reviewers.

a. Length of review period is 30 – 60 days and depends on complexity of draft assessment documents.

b. OMB facilitates interagency review to help assure timely response within designated review period.

D. OMB compiles and provides all interagency comments to ORD; other agency comments are deliberative.

a. ORD assumes "no comment" from other agencies that do not respond within the designated review period.

b. If another agency requests an extension of the review period, both the IRIS POC and OMB POC should be contacted regarding the request and the justification.

E. ORD addresses the interagency comments and develops a "disposition of comments" document and revises the draft assessment documents, as appropriate, within 15 – 30 days.

F. Within 15 days after the comment period ends, ORD, OMB, or other interested agencies may call a meeting to discuss and resolve critical issues and significant disagreements articulated in the other agencies' comments on the draft assessment documents.

a. OMB serves as the facilitator for the meeting.

b. Areas of disagreement may result in additional charge questions for the external peer review.

10. EPA Initiates Independent External Peer Review and Releases External Draft IRIS Toxicological Review (120 – 280 days[2])

A. ORD provides the draft IRIS Toxicological Review and peer review charge questions to independent external peer reviewers. Peer reviews are public meetings, generally through a face-to-face meeting of panelists, though some may be held via public teleconference.

B. Concurrently, ORD publicly releases the draft IRIS Toxicological Review and charge to peer reviewers for public review and comment on the IRIS Internet site.

a. ORD prepares an FR notice announcing a public comment period of 45 to 60 days.

b. Length of the public comment period depends on the complexity of the draft IRIS Toxicological Review.

c. The draft IRIS Toxicological Review and charge to peer reviewers is released on the IRIS Internet site on the day that the FR is published.

d. Public comment period is open to all stakeholders, including other agencies.

e. ORD insures that other agencies are aware of the FR notice.

C. ORD holds a "listening session" during the public comment process to allow all interested parties to comment on the draft IRIS Toxicological Review.

D. Public comments from Steps B and C are submitted to ORD.

a. All public comments received during the official public comment period will be submitted through E-Gov (www.regulations.gov); all public comments will be part of the official record.

b. Comments received by the close of the public comment period will be provided to the external peer review panel at least 30 days in advance of the peer review meeting.

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

11. EPA Revises IRIS Toxicological Review and Develops IRIS Summary (120 – 150 days)

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

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

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

[2] This time frame does not include reviews conducted by the National Academy of Sciences (NAS).

D. Within 90 – 120 days, ORD develops a disposition of peer reviewer and public comments and provides the disposition of comments document and the revised IRIS Toxicological Review and IRIS Summary to the external peer review panel members for their comment within 30 days.

E. ORD provides the disposition of peer reviewer and public comments document and any additional peer review panel comments from **Step 11.D** as an appendix to the IRIS Toxicological Review.

12. EPA Initiates Final Agency and Interagency Review of the IRIS Toxicological Review and IRIS Summary (30 – 45 days)

A. ORD sends the final IRIS Toxicological Review and IRIS Summary to OMB for distribution to the other agencies.

B. In general, this distribution is intended as a final check-in to address any remaining issues and ensure that public and peer reviewer comments were adequately considered or addressed by ORD.

C. Concurrently, ORD sends the IRIS Toxicological Review and IRIS Summary to the intra-Agency IRIS Review Committee for comment (30 days).

D. OMB compiles and provides all interagency comments to ORD within 30 days.

   a. ORD assumes "no comment" if the other agencies or EPA Program or Regional Offices do not respond within the designated review period.

   b. If another agency or EPA Program or Regional Office requests an extension of the review period, both the IRIS POC and OMB POC should be contacted regarding the request and the justification.

E. ORD addresses and resolves any remaining issues in consultation with OMB and other agency or EPA Program or Regional Office POCs within 15 days. Should resolution of any issue not be achieved in discussions with the POC, the other agency or EPA Program or Regional Office that raised the issue may decide to elevate the discussion to their senior management level to achieve resolution. The final decision on IRIS content remains with EPA.

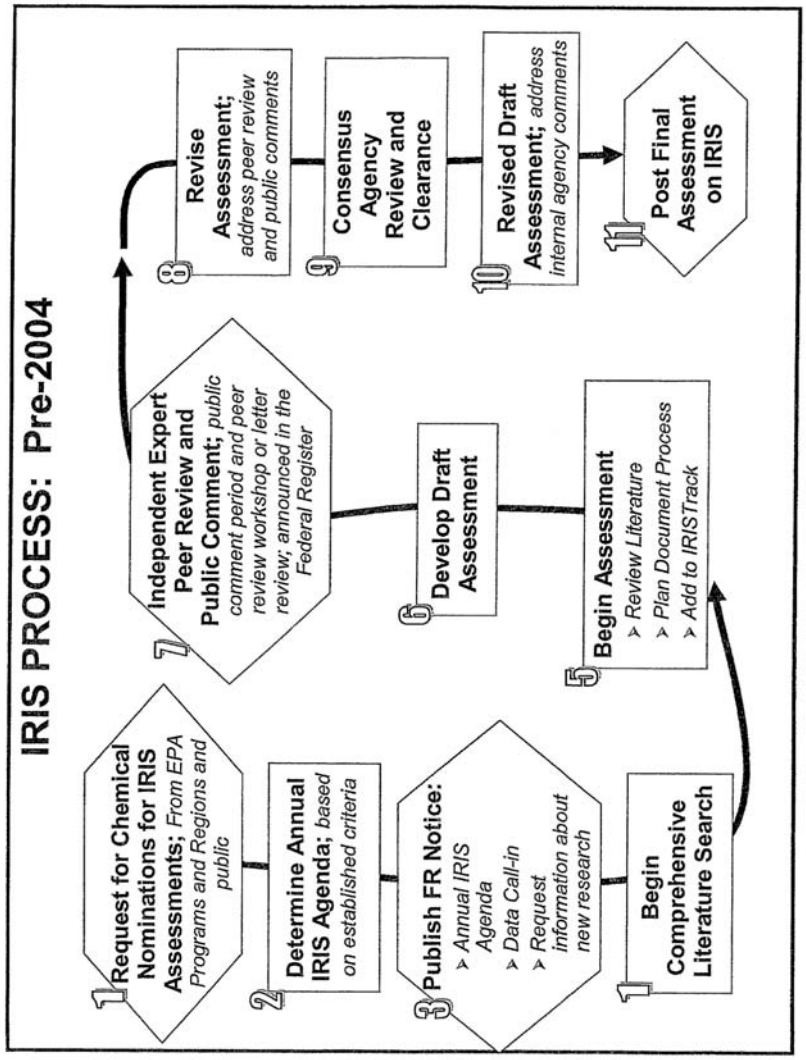
13. EPA Completion of IRIS Toxicological Review and IRIS Summary (60 days)

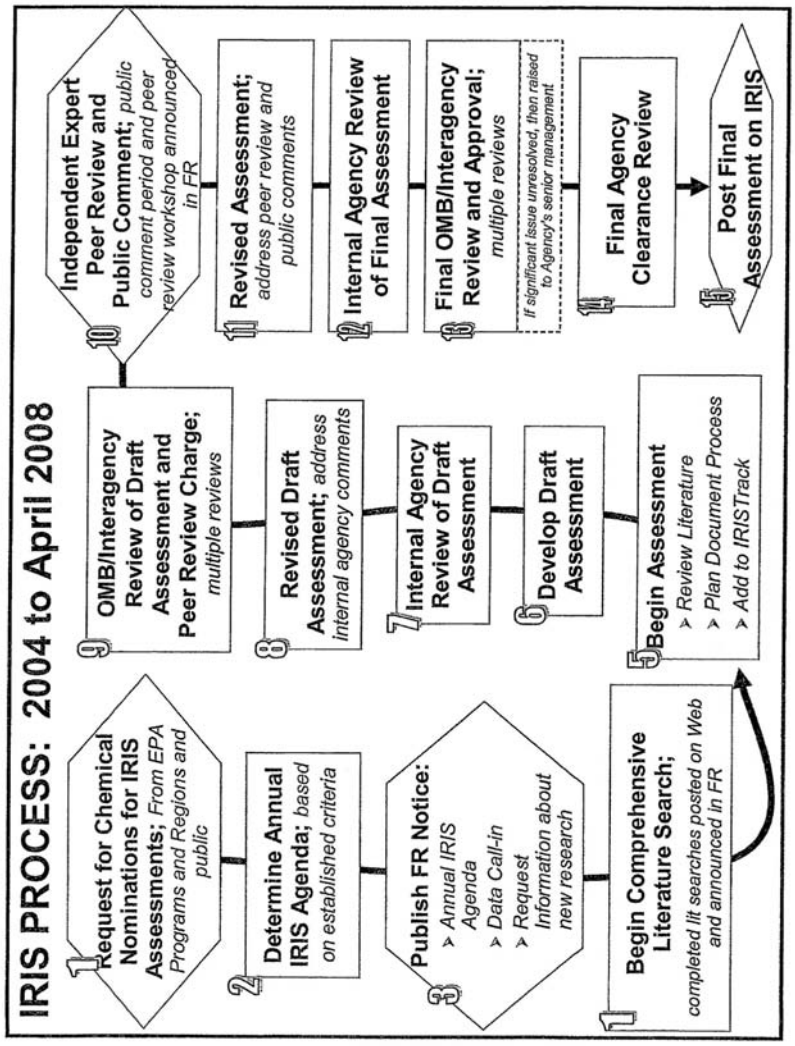
A. ORD completes the IRIS Toxicological Review and IRIS Summary.

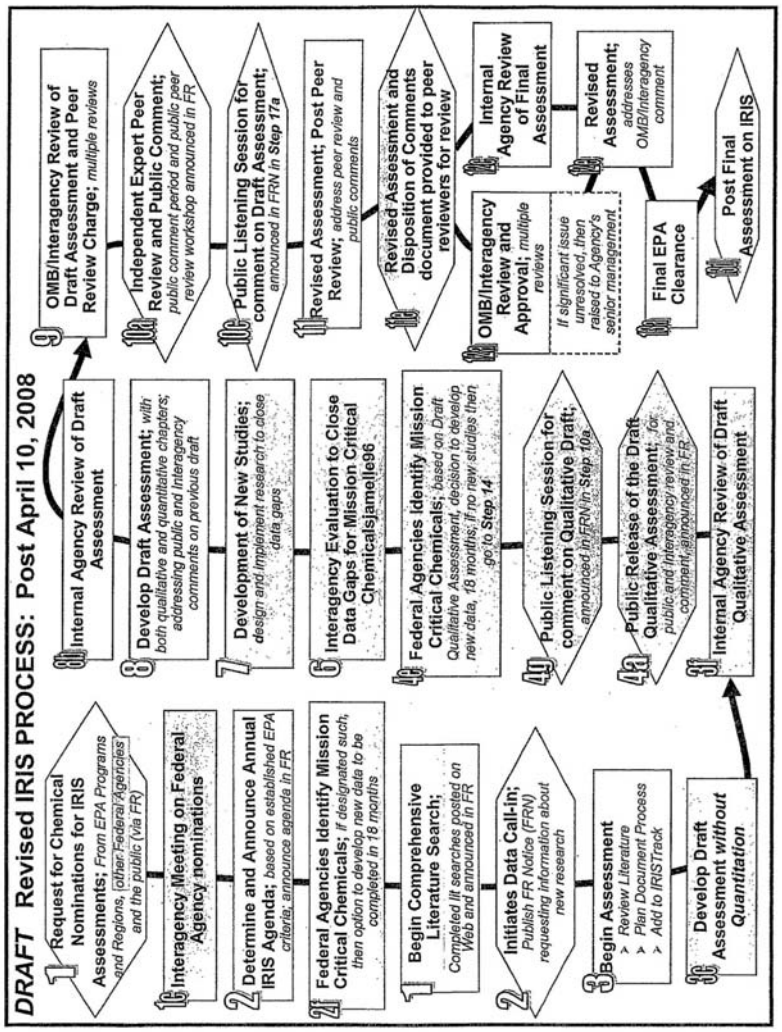
B. ORD prepares the final assessment to post on the IRIS Internet site.

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

D. ORD posts the assessment to the IRIS Internet site. ORD completes and maintains the public record.


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
4 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 Begin Comprehensive Literature Search; completed lit searches posted on Web and announced in FR
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 Request for Chemical Nominations for IRIS Assessments; From EPA Programs and Regions and public
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
8b Internal Agency Review of Draft Assessment
8 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 Chemicalsjamelle96
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
4 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
3a 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
10c 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
12b OMB/Interagency Review and Approval; multiple reviews
If significant issue unresolved, then raised to Agency's senior management
13b Internal Agency Review of Final Assessment
13 Revised Assessment; addresses OMB/Interagency comment
14 Final EPA Clearance
15 Post Final Assessment on IRIS

TOXIC COMMUNITIES: HOW EPA'S IRIS PROGRAM FAILS THE PUBLIC

THURSDAY, JUNE 12, 2008

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

The Subcommittee met, pursuant to call, at 10:00 a.m., in Room 2318 of the Rayburn House Office Building, Hon. Brad Miller [Chairman of the Subcommittee] presiding.

BART GORDON, TENNESSEE
CHAIRMAN

RALPH M. HALL, TEXAS
RANKING MEMBER

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON SCIENCE AND TECHNOLOGY
SUITE 2320 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6301
(202) 225–6375
TTY: (202) 226–4410
http://science.house.gov

Subcommittee on Investigations and Oversight

Hearing on

Toxic Communities: How EPA's IRIS Program Fails the Public

Thursday, June 12, 2008
10:00 a.m. – 12:00 p.m.
2318 Rayburn House Office Building

Witness List

Mr. Jerome Ensminger
Master Sergeant, U.S. Marine Corps (ret).

Mr. Lenny Siegel
Executive Director, the Center for Public Environmental Oversight (CPEO)

Dr. Linda Greer
Director, Health Program, Natural Resources Defense Council

Dr. David Hoel
Distinguished University Professor, Medical University of South Carolina
Charleston, South Carolina

HEARING CHARTER

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

Toxic Communities: How EPA's IRIS Program Fails the Public

THURSDAY, JUNE 12, 2008
10:00 A.M.—12:00 P.M.
2318 RAYBURN HOUSE OFFICE BUILDING

The Subcommittee on Investigations and Oversight will hold the second hearing on the Integrated Risk Information System (IRIS) at the Environmental Protection Agency (EPA).

On May 21, 2008, the Subcommittee heard the Government Accountability Office's (GAO) evaluation of the Administration's new process for reviewing and approving chemical assessments for inclusion in the IRIS database. In their March 2008 review of EPA's IRIS program GAO found that the IRIS database was at serious risk of becoming obsolete because the Agency has not been able to complete credible assessments in a timely manner or to reduce the backlog of 70 assessments that were in the development, review or approval process.[1] In their subsequent examination of the process implemented by the Administration on April 10, 2008, GAO testified that the recent assessment process changes arid the other process changes being implemented by EPA were likely to increase the time needed to finalize IRIS assessments and to further reduce the credibility of IRIS assessments.[2]

The witnesses will address the role of IRIS assessments in the regulatory process for implementing environmental statutes administered by EPA and by State, territorial, and tribal governments and the consequences of extended delay in the IRIS assessment process for public health. They will also address questions regarding the Bush Administration's evolving system to draft and review IRIS entries. Witnesses include:

- **Mr. Jerome Ensminger,** *Master Sergeant U.S. Marine Corps (ret.)*
- **Mr. Lenny Seigel,** *Center for Public Environmental Oversight*
- **Dr. Linda Greer,** *Senior Scientist, Natural Resources Defense Council*
- **Dr. David G. Hoel,** Professor, Medical University of South Carolina

What Is the Role of an IRIS Assessment in the Regulatory Process?

Federal and State governments adopt environmental and public health laws to protect natural resources and the public. EPA, State, territorial, anal tribal governments implement environmental statutes through the issuance of regulations that set standards for air and water quality and for clean-up of contaminated areas. Regulations also set deadlines for achieving the standards. At the federal level, EPA administers environmental statutes to protect public health and the environment, to establish criteria for the handling and disposal of hazardous materials, and that govern the clean-up of contaminated land and water. The preparation of a regulation requires assembling a wide variety of information to define risk and justify the risk management approach mandated by the regulation. In addition to the information and procedural requirements imposed by individual statutes, there are general statutes governing the issuance of regulations by federal agencies that also impose procedural and information requirements (e.g., *Administrative Procedures Act, Paperwork Reduction Act, Unfunded Mandates Reform Act*) and there are Executive

[1] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments Low Productivity and New Interagency Process Limit the Usefulness of EPA's Integrated Risk Information System.* GAO–08–440.

[2] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments EPA's New Assessment Process Will Further Limit the Productivity and Credibility of Its Integrated Risk Information System.* Testimony before the Subcommittee on Investigations and Oversight, Committee on Science and Technology, House of Representatives.

Orders and guidance from the Office of Management and Budget (OMB) that also require procedures and analyses to be done in support of a regulation.

Two of the most commonly required analyses are risk assessments and cost-benefit analyses. While not a regulatory product itself, IRIS is designed to help regulators set priorities about what to regulate and inform regulators on a safe exposure level for workers or communities. An IRIS assessment provides a hazard identification and dose-response analysis, scientific information that when combined with estimates of exposure allow regulatory agencies to produce a risk assessment. Delay in the production of the IRIS assessment translates into delay in implementation of environmental statutes and in establishment of standards to protect public health.

While some State governments have environmental programs that independently establish standards (e.g., California), many State governments and virtually all territorial and tribal governments rely upon the Federal Government to develop and evaluate the scientific information that will determine safe levels of exposure and allow regulatory agencies to set standards for air and water quality to protect public health and the environment. For example, in response to EPA's solicitation to set priorities for developing IRIS assessments, the State of Minnesota submitted a list of 52 chemicals of concern.[3]

The Case of Trichloroethylene: How Long Does a Controversial IRIS Assessment Take to Complete?

In its March 2008 report on EPA's IRIS program GAO examined six specific IRIS assessments that are in process.[4] One of the six assessments was of trichloroethylene or TCE. GAO's report provided the following timeline for the development of a cancer assessment of TCE for inclusion in the IRIS database: EPA developed a cancer assessment of TCE for inclusion in the IRIS database, but withdrew it in response to peer reviewers' comments in 1989. EPA initiated a new TCE cancer assessment in 1998 and issued a new draft assessment in 2001. This draft and its findings were controversial. It was reviewed by EPA's Science Advisory Board and released for public comment. The National Academy of Sciences (NAS) was asked to review the draft and to resolve issues raised in the SAB review and through the public comment process about methods EPA used to assess the risk of TCE. In 2006, the NAS panel released their report. The panel stated:

> The committee found that the evidence on carcinogenic risk and other health hazards from exposure to trichloroethylene has strengthened since 2001. Hundreds of waste sites in the United States are contaminated with trichloroethylene, and it is well documented that individuals in many communities are exposed to the chemical, with associated health risks. Thus, the committee recommends that federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously.[5]

Despite this direction from the NAS to move forward, EPA has not yet released its assessment of TCE. According to GAO, the assessment is back at the draft development stage and will not be finalized until 2010.

What Are the Consequences for Public Health When IRIS Assessments Are Delayed?

TCE is a solvent that has been in commerce since the 1920s. TCE is a degreasing agent and has been widely used in manufacturing and industrial settings. It is one of the most commonly identified contaminants at sites included on EPA's National Priority List (NPL) under the Superfund program. It is a found in air, water, and soils. A number of different cancers, reproductive and developmental problems, neurotoxic effects, and auto-immune disease have all been associated with exposures to TCE.

Since TCE is a contaminant of air, water, and soils its clean-up is determined through various statutes administered by EPA including: the *Safe Drinking Water Act,* the *Clean Air Act,* and the *Comprehensive Environmental Response, Compensation, and Liability Act* (CERCLA) or Superfund. Under each of these statutes, EPA

---

[3] Submission by the Minnesota Department of Health to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for the 2007 Program. Docket ID No. EPA–HQ–ORD–2006–0950.

[4] U.S. Government Accountability Office (GAO). 2008. *Chemical Assessments Low Productivity and New Interagency Process Limit the Usefulness of EPA's Integrated Risk Information System.* GAO–08–440.

[5] National Research Council. 2006. *Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues.* The National Academy Press. Washington, DC. p. 2.

has the authority to set maximum contaminant levels that define safe drinking water, set air quality standards that define clean air, and that set standards for clean-up of contaminated soil and water at Superfund sites. These standards cannot be strengthened, until EPA has completed the IRIS assessment, a risk assessment, and other supporting studies and information requirements (e.g., cost-benefit analysis, regulatory impact analyses, etc.) needed to support a regulation. Many people believe the TCE standards currently in place are inadequate to protect human health especially that of children and other sensitive sub-populations.

The Subcommittee will hear from two witnesses whose family or communities have experienced serious health impacts that are associated with exposure to TCE. One of the sites listed on the Superfund NPL is Camp Lejeune, the Marine Corps base in North Carolina. The drinking water source for the base is contaminated with TCE and tetrachloroethylene (PCE or perc): The Marine Corps closed contaminated drinking water wells in 1985, and the site was listed in 1989. The Agency for Toxic Substances and Disease Registry estimated that up to one million people were exposed to these toxic contaminants before the contaminated wells were closed in 1985.

The community of Mountain View, California has several TCE clean-up sites. Several of the contaminated sites are located on federal lands including the Orion Park Military Housing Area (U.S. Army). These areas are still undergoing clean-up and remediation and residents of the area are still exposed to TCE through a process known as vapor intrusion.

Mr. Ensminger and Mr. Seigel will discuss the experiences of their family and community, respectively and why they believe EPA's IRIS program needs reform.

Attachment

The Minnesota Department of Health Submission to the Integrated Risk Information System (IRIS); Request for Chemical Substance Nominations for 2007 Program

(DOCKET ID NO. EPA–HQ–ORD–2006–0950)

The Health Risk Assessment staff at the Minnesota Department of Health wish to nominate a list of chemicals to be included in the Integrated Risk Information System (IRIS); Request for Chemical Substance Nomination for 2007 Program. These chemicals are of concern to the Minnesota Department of Health because they are among contaminants found in Minnesota groundwater. In Minnesota, health based values are derived for such contaminants. When conducting risk. assessments, the Minnesota Department of Health has relied upon the IRIS summaries as a resource for the development of these health protective values. Therefore, it is our hope that you take our nominated chemicals in consideration. By obtaining IRIS summaries of these chemicals it will result in a more thorough and accurate risk assessment process.

1,2,3—Trichloropropane
1-Methylnaphtalene
1-Methylphenol
2,2—Dichloropropane
2,3,4,5—Tetrachlorophenol
2,3,5,6-Tetrachloroterephthalic acid
2,6-dinitrotoluene
2,6-diethylaniline (Alchlor degradate)
2-Nitrophenol
3,5-Dichlorophenol
4-Isopropyltoluene
Acetochlor ESA
Acetochlor OA
Alachlor ESA (degradate of Alachlor)
Alachlor OA (degradate of Alachlor)
Aluminum
Deaminated diketomethribuzin (degradate of Metribuzin)
Deaminated metribuzin (degradate of Metribuzin)
Deethylatrazine (degradate of Atrazine and Propazine)
Deisopropylatrazine (degradate of Atrazine, Cyanazine and Simazine)
Diallate
Diazion
Dichlorofluoromethane
Diketometribuzin (degradate of metribuzin)
Dimethenamid
Dimethenamid ESA (degradate of Demethenamid)
Dimethenamid OXA (degradate of Dimethenamid)
Ethafluralin
Hydroxyatrazine
Iron
Isopropyl ether
Isoxaflutole
Lithium
Metolachlor ESA
Metolachlor ESA
Metsulfuron-methyl (Ally)
Monomethyl tetrachloroterephthalic acid
n-Butylbenzene
Nicosulfuron
n-Propylbenzene
Primisulfuron-methyl (Beacon)
Radionuclides (all)
Sec-Butylbenzene
Sodium
Thifensulfuron methyl
Tin
Total petroleum hydrocarbons

Tribenuron-methyl
Triclopyr
Trinitro-phenylmethylnitramine
Triphenyltin hydroxide
Vanadium

In addition, the Minnesota Department of Health currently needs and uses reference concentrations and reference doses for less than chronic periods of exposure to assess risks from a variety of exposure scenarios. These scenarios include less than chronic exposures that commonly occur at contaminated sites resulting in the need for less than chronic toxicity values to assess current risks. The EPA 2002 "A review of the reference dose and reference concentration processes" has guided much of the practice of the Department in this area.

The Department has found that health effects that result from less than chronic periods of exposure, when combined with high drinking water exposures associated with specific life stages (e.g., childhood), result in drinking water values that are lower and therefore more appropriate as drinking water standards for the general population than the value calculated using a chronic reference dose and lifetime average dose. As a result, the Department is very interested in recent efforts by IRIS to develop less than lifetime reference values, and urges the EPA to continue to develop and publish these analyses. The Department also urges the EPA to consider the potential that effects observed in chronic studies result from early exposures rather than continuous exposure. To the extent that studies are available, the Department urges the EPA to present acute, short-term, longer-term, and chronic evaluations (recommendations for critical studies for each and resulting reference doses) for each chemical that undergoes review in the future.

Chairman MILLER. The hearing will come to order. Good morning, and welcome to our second hearing on EPA's Integrated Risk Assessment System, IRIS.

The glacial pace at which EPA is completing assessments of chemicals has real consequences for public health, and tragic consequences for human beings and their families. Completion of an IRIS assessment is just the first step in the process of protecting people from dangerous exposures to toxic chemicals. With an IRIS assessment in place, it is easier to deal with the clean-up of chemical contamination of the air or water, to adopt safer practices in the workplace, and to consider steps to regulate toxic substances that can harm our children and our communities.

The Government Accountability Office's recent report on IRIS concluded that EPA's process for initiating and completing IRIS assessments resulted in proposals that are now in preparation for more than five years, with some assessments taking more than a decade. The new process that EPA and OMB instituted just in April will add additional years to our assessments, according to the GAO conclusions.

The years of study and discussion regarding IRIS assessments comes on top of a regulatory process that is burdened with time-consuming steps for complete risk assessment, cost benefit analysis, and internal and external reviews, all as laid out in Executive Orders and in statute. Even after a regulation is finalized, it can be challenged in court and sent back to the Agency for revision. When finally established, a new regulation usually includes some time, often many years, for the affected parties to transition away from the practices that are being regulated.

During this entire process, exposures continue, toxic substances remain unregulated or under-regulated in commerce, and contamination is not cleaned up, or not cleaned up to a level that we think is actually safe.

Today, we will hear from people who have lived and are living with those consequences. These people will describe what their families and communities have endured for years, situations that no one would wish to endure for a day.

While the failures of the IRIS database are not responsible for these experiences, the gaps in IRIS and the improper intrusion of politics into database entries have likely contributed to the situations that these people and their communities have had to deal with. When State and local authorities get poor information or no information regarding the health hazards of a particular pollutant, their response to pollution in a community is likely to be confused and confusing. When citizens can't turn to IRIS for information—and the database gets 20,000 web hits a year—then it is hard for them to know what they are fighting in terms of clean-ups and health risks.

The worst thing about these families' experiences is that they are likely to be repeated because exposures that led to the chemical that led to the problems continue. TCE was discovered in the early 1900s and has been on the market and widely used since the 1920s as a degreaser. Discovery of its toxic properties eliminated its use as an analgesic in the 1930s, and by the 1970s, evidence in animal experiments showed that it might cause cancer. It is one of the

most frequently occurring contaminants in Superfund sites, and it is present in air, drinking water, and soils.

EPA has been working on a revised TCE assessment since 1989. Two years ago, following interventions by NASA, the Department of Energy, the Department of Defense, and OMB, the National Academy reviewed EPA's draft IRIS assessment and the science available on TCE, and said that "evidence on carcinogenic risk and other health hazards from exposure to TCE has strengthened since 2001. Priority should be given to finalizing the risk assessment so that risk management decisions can be made expeditiously."

Expeditious is not a word that describes this situation. GAO estimates that EPA will not complete their TCE assessment until 2010. That is 21 years from the start date. If they completed their assessment in 2010, we will still be years away from real regulatory action. People have been exposed to a known toxic substance for decades for a generation while their government has engaged in one study after another. Have we become so obsessed with getting the science exactly right that we have lost sight of our real goal, protecting public health? Or is getting the science exactly right a pretext for obstruction of any real protection of the public.

This system defies common sense. It is broken. It is condemning people to future health problems.

I now yield to my distinguished colleague, the Ranking Member of the Subcommittee, Mr. Sensenbrenner, for an opening statement.

[The prepared statement of Chairman Miller follows:]

PREPARED STATEMENT OF CHAIRMAN BRAD MILLER

Good morning and welcome to our second hearing on EPA's Integrated Risk Assessment System (IRIS).

The glacial pace at which EPA is completing assessments of chemicals has real consequences for public health and tragic consequences for individuals and their families.

Completion of an IRIS assessment is just the first step in the process protecting people from dangerous exposures to toxic chemicals. With an IRIS assessment in place, it is easier to deal with the clean-up of chemical contamination of the air or water, to adopt safer practices in the workplace and to consider steps to regulate toxic substances that can harm our children and our communities.

The Government Accountability Office's recent report on IRIS concluded that EPA's process for initiating and completing IRIS assessments resulted in proposals that are in preparation for more than five years, with some assessments taking more than a decade. The new process that EPA and OMB instituted just this past April will add additional years to IRIS assessments.

The years of added study and discussion regarding IRIS assessments come on top of a regulatory process that is burdened with very time consuming steps for a complete risk assessment, cost-benefit analyses, and internal and external reviews as laid down in Executive Orders and statute. Even after a regulation is finalized, it can be challenged in court and sent back to the Agency for revision. When finally established a new regulation usually includes some time, often many years, for the affected parties to "transition" away from the practices that are being regulated.

During this entire process, exposures continue, toxic substances remain unregulated or under-regulated in commerce, and contamination is not cleaned up or not cleaned up to a level that we think is actually safe.

Today we will hear from people who have lived, and ore living with, these consequences. These people will describe what their families and communities have endured for years—situations that no one would wish to experience for even one day.

While the failures of the IRIS database are not responsible for these experiences, the gaps in IRIS, and the improper intrusion of politics into database entries have likely contributed to the situations that these people and their communities have had to deal with. When State and local authorities get poor information, or no information, from IRIS regarding the health hazards of a particular pollutant, their re-

sponse to pollution in a community is likely to be confused and confusing. When citizens can't turn to IRIS for information—and the database gets 20,000 web hits a year—then it is hard for them to know what they are fighting for in terms of cleanups and health risks.

The worst thing about these families' experiences is that they are likely to be repeated because exposures to the chemical that led to their problems continue. Trichloroethylene or TCE was discovered in the early 1900s and has been on the market and widely used since the 1920s as a degreaser. Discovery of its toxic properties eliminated its use as an analgesic in the 1930s and by the 1970s evidence in animal experiments indicated it might cause cancer. It is one of the most frequently occurring contaminants in Superfund sites and it is present in air, drinking water, and soils.

EPA has been working on a revised TCE assessment since 1989. Two years ago, following interventions by NASA, the Department of Energy, the Department of Defense and OMB, the National Academy reviewed EPA's draft IRIS assessment and the science available on TCE and said that: "evidence on carcinogenic risk and other health hazards from exposure to trichloroethylene has strengthened since 2001 . . .. Priority should be given to finalizing the risk assessment so that risk management decisions can be made expeditiously."

Expeditiously? Expeditious is not a word that describes this situation. GAO estimates that EPA will not complete their TCE assessment until 2010—that's twenty-one years from their original start date.

If they complete the assessment in 2010, we will still be years away from regulatory action. People will have been exposed to a known toxic substance for decades, for a generation, while the government engages in study after study. Have we become so obsessed with getting the science right that we have lost sight of our real goal protecting public health? Or, is getting the science right a pretext for obstruction?

This system defies common sense. It is broken, and it is condemning people to future health problems.

I now yield to my distinguished colleague, the Ranking Member of the Subcommittee, Representative Sensenbrenner for an opening statement.

Mr. SENSENBRENNER. Thank you very much, Mr. Chairman. Before making my statement, let me say that Dr. David Hoel, who is the Minority witness at today's hearing, got stuck in the Atlanta airport last night because of bad weather. We kind of know about that the last couple of weeks in Wisconsin where I come from. I would like to ask unanimous consent that Dr. Hoel's testimony be placed in the record, and that he be instructed to respond to certain written questions by Members of the Committee and their staff, and that the responses to those questions also be placed into the record.

Chairman MILLER. Without objection, that is so ordered.

[*The statement of Mr. Hoel appears in Appendix: Additional Material for the Record.*]

Mr. SENSENBRENNER. Mr. Chairman, the Integrated Risk Information System, IRIS, process was originally developed for a specific task. Different offices throughout the EPA were relying on different assessments of the health effects of chronic exposure to toxic chemicals. IRIS was intended to establish a uniform database within the EPA.

However, over time, IRIS has become an authoritative resource on chemical toxicity. Other agencies, states, the international community, and the industries have been becoming increasingly reliant 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.

The GAO recently issued a scathing condemnation of the current state of the IRIS program. The report is titled *"Low Productivity*

and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System." Now, that is a mouthful, but I think it says where we are at now. In my opinion, it accurately sums up the GAO's findings. But IRIS' actual production numbers are even worse. EPA currently has a backlog of 70 ongoing assessments, and has managed to complete only two assessments in each of the last two years. Talk about a snail's pace. At the current pace, it will take 35 years for the EPA to finish its current backlog, and that is assuming it takes on no further tasks.

The EPA has attempted to develop uniform process for IRIS assessments. The Agency argues that it can expedite the IRIS process by involving other agencies earlier in the process. While preventing last-minute delays is an important reform, the ability of other agencies to extend the timeframe of assessments should be sharply limited. Data gaps in risk assessments will always exist as better science is always developing. EPA needs to limit the timeframe of assessments to prevent other agencies from indefinitely delaying the process.

EPA must also balance its need to complete assessments with the rights of interested parties to comment. The best way to achieve this balance would be to give more notice of its assessments. The EPA already publishes an annual agenda of the chemical it intends to assess in the *Federal Register*. If the EPA moves the date of that publication forward, thus providing more notice, the interested parties will have a longer period to comment on what they deem to be insufficiencies in the scientific record. During this comment period, EPA can focus on its backlog. Because it offered a comment period, EPA can then fairly limit the ability of outside parties to delay assessments once they are underway. The result would be a more efficient process that preserves taxpayers' money and promotes public health. In my opinion, that is a win-win.

I urge the EPA to consider these proposals, because IRIS must be fixed. In April, this subcommittee held a hearing on formaldehyde levels in trailers provided to the victims of Hurricane Katrina. In that hearing, we investigated how the Agency for Toxic Substances and Disease Registry struggled to identify the proper level of concern for long-term exposure to formaldehyde. EPA determined its formaldehyde assessment was outdated in 1997, but 11 years later, the assessment is still incomplete. These hurricane victims are the real world result of EPA's bureaucratic failures.

I yield back the balance of my time.

[The prepared statement of Mr. Sensenbrenner follows:]

PREPARED STATEMENT OF REPRESENTATIVE F. JAMES SENSENBRENNER JR.

The Integrated Risk Information System (IRIS) process was originally developed for a specific task. Different offices throughout the Environmental Protection Agency (EPA) were relying on different assessments of the health effects of chronic exposure to toxic chemicals. IRIS was intended to establish a uniform database within EPA.

Over time, however, IRIS became an authoritative resource on chemical toxicity. 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.

The Government Accountability Office (GAO) recently issued a scathing condemnation of the current state of the IRIS program. The report's title, *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System,* accurately sums up GAO's findings. But IRIS' actual production numbers are worse. EPA currently has a backlog of 70 ongoing assessments and has managed to complete only two assessments in each of the last two years. At the current pace, it will take 35 years for EPA to finish its current backlog.

EPA has attempted to develop a uniform process for IRIS assessments. The agency argues that it can expedite the IRIS process by involving other agencies earlier in the process. While preventing last minute delays is an important reform, the ability of other agencies to extend the timeframe of assessments should be sharply limited. Data gaps in risk assessments will always exist as better science is always developing. EPA needs to limit the timeframe of assessments to prevent other agencies from indefinitely delaying the process.

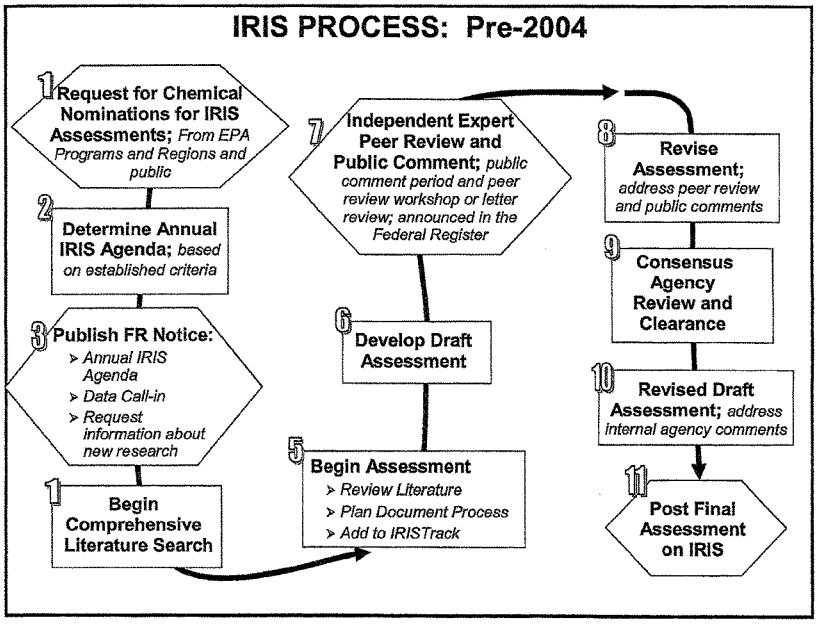
EPA must balance its need to complete assessments with the rights of interested parties to comment. The best way to achieve this balance would be to give more notice of its assessments. EPA already publishes an annual agenda of the chemical it intends to assess in the *Federal Register.* If EPA moves the date of that publication forward, providing more notice, interested parties will have a longer period to comment on what they deem to be insufficiencies in the scientific record. During this comment period, EPA can focus on its backlog. Because it offered a comment period, EPA can then fairly limit the ability of outside parties to delay assessments once they are underway. The result would be a more efficient process that preserves taxpayers' money and promotes public health.

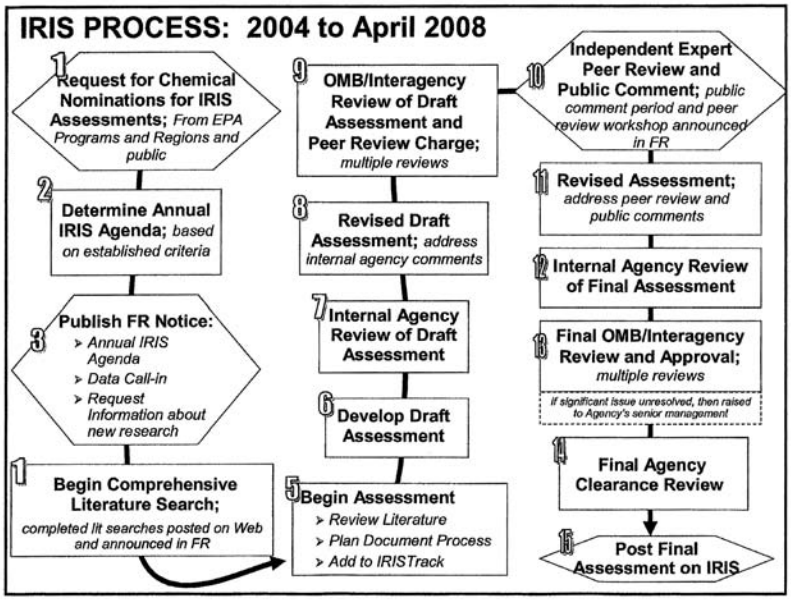
I urge EPA to consider these proposals, because IRIS must be fixed. In April, this subcommittee held a hearing on formaldehyde levels in trailers provided to the victims of Hurricane Katrina. In that hearing, we investigated how the Agency for Toxic Substances and Disease Registry struggled to identify the proper "level of concern" for long-term exposure to formaldehyde. EPA determined its formaldehyde assessment was outdated in 1997, but eleven years later, that assessment is still incomplete. These hurricane victims are the real world result of EPA's bureaucratic failures.

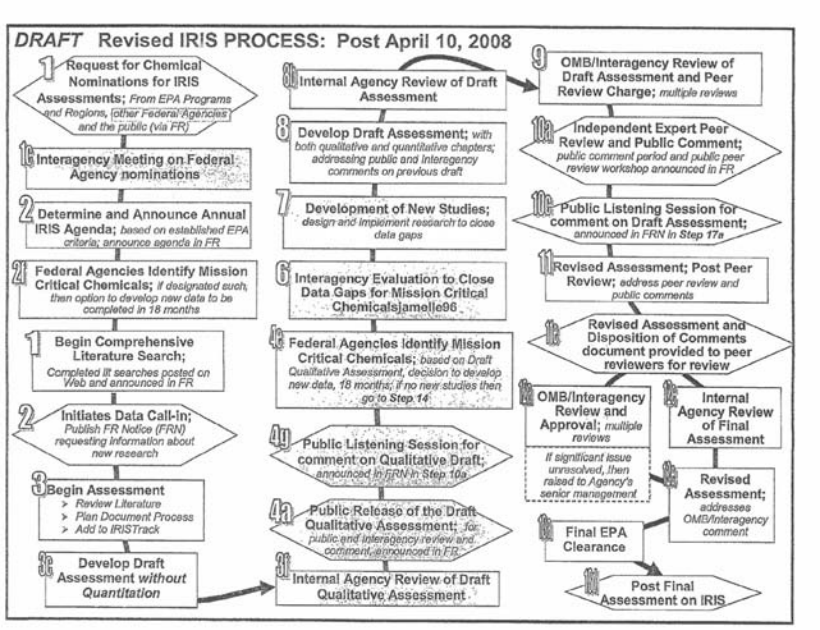
Chairman MILLER. Thank you, Mr. Sensenbrenner. Mr. Sensenbrenner spoke of the backlog and said that there was no further work for EPA to do, and an IRIS list that would take 35 years. Since 600 new chemicals enter the marketplace a year, it is reasonable to assume that there will be more for EPA to do.

I ask unanimous consent to enter documents for the record that had been provided to the minority. Without objection, it is so ordered.

[The information follows:]


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
1 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



Chairman MILLER. I also ask unanimous consent that any additional statements submitted by Members be included in the record. Without objection, so ordered.

[The prepared statement of Ms. Johnson follows:]

PREPARED STATEMENT OF REPRESENTATIVE EDDIE BERNICE JOHNSON

Thank you, Mr. Chairman. This is the second hearing in one month on the Integrated Risk Information System within the Environmental Protection Agency.

This system is intended to protect both environmental quality and human health through effective regulations and other policy implementation.

However, today's witnesses will make clear that environmental contamination has impacted their lives in the most severe ways.

It is my hope that this subcommittee can learn what influence the current Administration has had on IRIS, and how IRIS' functions have changed since the commencement of the current Administration.

Some of the problems with that process were the subject of this subcommittee's hearing two weeks ago.

Oversights as glaring and irresponsible have major consequences.

Today, we will hear true stories from Americans whose lives are forever changed as a result of needless, reckless pollution.

It is our duty to hear them, and to work out policies to prevent tragedies of this nature from ever occurring.

This subcommittee is aware that within the IRIS system, only four chemical listings have been finalized in the past two years.

While approximately 700 new chemicals enter commerce each year, and more than 80,000 chemicals reported under the *Toxic Substances Control Act,* it is beyond my comprehension that the E.P.A. is taking no action to inform the public on the health risks of no more than four chemicals.

This subcommittee seeks to closely evaluate the work—or lack thereof—of the E.P.A. when it comes to chemical toxicity and public health.

My condolences go to Ms. Holt-Orsted and Mr. Ensminger, who have seen loss of life as a result of environmental contamination.

My own constituents, in Dallas, have struggled with lead contamination in the past, and they continue to deal with long-term health effects.

This issue of the politicization of science—particularly environmental protection—is of gravest concern to me.

Congress is right to provide vigorous oversight in situations where the Federal Government may be guilty of failing its citizens in such an egregious manner.

Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman MILLER. And now, it is my pleasure to introduce our witnesses today. The first is a North Carolinian—at least, an adopted North Carolinian, Mr. Jerome Ensminger, retired Master Sergeant with United States Marine Corps. Second, Mr. Lenny Siegel, Executive Director of the Center for Public Environmental Oversight; and Dr. Linda Greer is the Director of the Natural Resources Defense Council's Health Program.

You will have five minutes for your spoken testimony, and your written testimony will be included in the record for the hearing. When you have completed your testimony, we will begin with questions. Each Member will have five minutes to question the panel.

It is the practice of the Subcommittee to take testimony under oath. Do any of you have any objection to being sworn in? The Committee also provides that you may be represented by counsel. Are you represented by counsel at today's hearing?

If you now would please stand and raise your right hand? Do you swear to tell the truth and nothing but the truth? All of the witnesses have responded in the affirmative.

Mr. Ensminger, you may begin.

STATEMENT OF MR. JEROME M. ENSMINGER, MASTER SERGEANT, U.S. MARINE CORPS (RET.)

Master Sergeant ENSMINGER. Good morning. My name is Jerry Ensminger, and I served my country faithfully for more than 24 years in the United States Marine Corp. I would like to thank the Chairman, the Committee Members, and their staff for all of the hard work that went into making these hearing possible. I must say that since 3 January 2007, I have been heartened and inspired by the oversight activities by this Congress. You have been taking on the important issues that matter to the majority of our citizens, not just the issues that reflect the benefit of special-interest groups and big business. I am appearing here today as a tragic example of the consequences of a system that ignores our environment and the inevitable health effects that result from it.

Marine Corp Base Camp Lejeune, North Carolina is quite possibly one of, if not the worst, water-contamination incidents in modern world history. The Agency for Toxic Substances and Disease Registry, or ATSDR, estimates that between 750,000 and one million people were potentially exposed to horrendous levels of toxins through their drinking water while stationed at Camp Lejeune. My daughter Janey was conceived while her mother and I lived in one of the base-family housing areas where the drinking water was affected by the contamination at the base. Just like our other children, Janey was born seemingly normal. That is until she was diagnosed with Acute Lymphocytic Leukemia, ALL, at the age of six.

In 1997, the ATSDR proposed a childhood leukemia and non-Hodgkin's lymphoma study for Camp Lejeune children who had been exposed to volatile organic chemicals, or VOCs, cleaning solvents, in utero, while their parents lived at the base, between the years of 1968 through 1985. The protocol and proposal for this

study outlines that the expected occurrences of the target illnesses in a cohort of 10,000 to 12,000 births for that time period would be 7.2 cases. The ATSDR has confirmed 14 cases of leukemia and two cases of non-Hodgkin's lymphoma. This more than 100-percent increase in the incidence of these childhood cancers.

Mr. Chairman, let me lay out some of the facts and figures relating to the Camp Lejeune water-contamination situation. The documented levels of contaminants in the finished drinking water, at the tap, were some 280 times higher than what is considered safe for these very same chemicals. The Navy Bureau of Medicine and Surgery issued strict regulations in their BUMED instructions 6240.3(b), in 1963, governing potable water-distribution systems on Naval Shore Facilities. Included in these regulations were preemptive measures to ensure that existing and future water supplies were not contaminated by extraneous sources. The Camp Lejeune family-area water-supply wells were located on the virtual property line, down gradient, and directly across the street from potential civilian contamination sources, gasoline stations, auto-repair facilities, dry-cleaning establishments, and known septic systems.

In 1971, the Naval Facilities Engineering Command from Norfolk, Virginia, came to Camp Lejeune and selected multiple sites for new drinking-water supply wells. One of these new wells was HP–651, which began producing well water for the Camp Lejeune Point Water Distribution Plan in January of 1972. The site which had been selected by the Navy engineers for the placement of HP–651 was at the back corner of the base disposal yard, the junk yard. The disposal yard had been in operation for decades by the time they selected for a water-supply well. In February of 1985, HP–651 tested positive for some 26,000 parts-per-billion of volatile organic chemicals. There is little doubt that this water-supply well was contaminated immediately upon or shortly after its construction.

The irony of all of this is the fact that many of the human exposures that took place at Camp Lejeune would have been avoided, had Navy and Marine Corp officials followed their own regulations. The most audacious and blasphemous truth to this entire water-contamination incident at Camp Lejeune is the fact that Navy and Marine Corp officials knew of the existence of this contamination in their drinking water for five years before they took any action to rectify the problem. Navy and Marine Corp officials were knowingly poisoning their own people. That is correct. All of this was known and taking place behind the scenes at the very same time that my daughter, Janey, was suffering through her fight with leukemia, and they said absolutely nothing.

Not only did they say nothing, they went as far as to return two of the three contaminated wells for the Tarawa Terrace Housing Area back online for two more years. They had the opportunity of tapping into the local community water lines, which were located just a few feet from the property line. Instead, Navy and Marine Corp officials opted against this idea because they did not want to owe the local government any reciprocating favors.

Since the ATSDR entered the gates of Camp Lejeune to execute their Congressionally mandated mission, representatives of the Department of the Navy have done all they could to obstruct their ef-

forts. I can make this statement with confidence, because I possess the documentation to back it up. As recently as the week before last, DOD and Department of the Navy officials were threatening to thwart the ATSDR initiatives at Camp Lejeune by withholding the funding.

I spoke earlier about my daughter Janey. My daughter Janey—and I do not know if anybody else in this room ever had a child that was diagnosed with a catastrophic illness, but I can assure you, when Janey was diagnosed, and they told me that she had leukemia, it took me to my very knees, in the hallway at the Naval hospital at Camp Lejeune. And my forehead went down on the deck, and I broke out in a sweat, and I could not move. Janey went through hell, and all of us that loved her went through hell with her. A six-year-old child, naturally, they have had their normal inoculations; but a child with leukemia is poked and prodded. You just cannot believe what they go through. I held my daughter in the treatment rooms when they took needles and broke through her hip to extract bone marrow to test, and she screamed in my ear, "Daddy, Daddy do not let them hurt me." And the only response that I could give her was, "Janey, the only reason I am letting them hurt you is because they have to hurt you. They are trying to help you."

When she got hit with chemotherapy, I would make it a few miles down the road, and she would get so sick, I would have to stop, and pull over, and hold her and rub her back while she threw her guts up, wishing that I could take that off of my child and put it on myself, but God would not do it.

Throughout Janey's treatment, when she was allowed to go back to school, her treatments made her look like a freak. She lost her hair. She gained more than 30 pounds at a time when she was on steroids. Her schoolmates would pick on her and call her Cabbage Patch Kid. She would come home from school crying. I do not know how many times I had to take Janey in the evenings and just go out to the beach and walk to try to make sense out of what was happening to her.

At Duke University Medical Center where Janey died, and where Janey was receiving a lot of her treatments, in the pediatric ward, the majority of the rooms up there have soft walls. They fold. There's two rooms at the corners, directly across from the nurses' station that have two solid walls. They are referred to by the parents as the dying rooms, and the closer your child comes to dying, the closer you are to those two rooms. When you get moved into one of them, you know you are next. It is like watching mortar rounds walking towards your bunker.

Nights in the hospital, I spend countless nights in a cot that folded down from the wall. And you lay in that hospital all hours of the night, listening to the kids that they got in the treatment rooms screaming bloody murder. I never cried in front of Janey the whole time she was being treated, which was nearly two-and-a-half years. That morning, that day, I started crying, and she looked up at me, and she had pneumonia, and she could hardly talk. And she looked at me, and she said, "Stop it." And I said, "Stop what?" And she said, "Stop crying, Daddy." She said, "I love you." And I said, "Janey, I know that." I said, "I love you." And she said, "I know."

Those were the last words my daughter spoke to me. She went into a coma. Thirty-five minutes later, she was dead.

Janey is dead now. Nothing is going to bring her back. But there were people who were exposed at Camp Lejeune, adults, the siblings of these in utero children, that are just now reaching the latency period for their exposures. They are, right now, developing cancers, adult leukemia, non-Hodgkin's lymphomas, male breast cancers—six cases of it that we found—renal failures. Those people need help. We do not need any more delays from DOD and the Department of the Navy and the United States Marine Corp.

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. It is quite obvious by their activities to thwart science that they have something to fear. What they fear is that past negligence and the liability that comes along with it. There is little wonder why DOD has been seeking immunities from environmental regulations for the last seven years running, and yet this Administration and past Congresses have allowed DOD's tentacles to infiltrate the realm of science.

We all need to just back off a little bit and allow science to speak for itself and let the chips fall where they may. Thank you, Mr. Chairman.

[The prepared statement of Mr. Ensminger follows:]

PREPARED STATEMENT OF JEROME M. ENSMINGER

Good morning, my name is Jerry Ensminger and I served my country faithfully for more than 24 years in the United States Marine Corps. I would like to thank the Chairman, the Committee Members and their staffs for all of the hard work that went into making these hearings possible. I must say that since 3 January 2007, I have been heartened and inspired by the oversight activities of this Congress. You have been taking on the important issues that matter to the majority of our citizens, not just the issues that affect/benefit special interest groups and big business!

I am appearing here today as a tragic example of the consequences of a system that ignores our environment and the inevitable health effects that result from it. Marine Corps Base, Camp Lejeune, North Carolina is quite possibly one of, if not the worst drinking water contamination incidents in modern world history! The Agency for Toxic Substances and Disease Registry (ATSDR) estimates that between 750,000 and 1,000,000 people were potentially exposed to horrendous levels of toxins through their drinking water while stationed at Camp Lejeune.

My daughter Janey was conceived while her mother and I lived in one of the base family housing areas where the drinking water was affected by the contamination at the base. Just like our other children, Janey was born seemingly normal, that is until she was diagnosed with Acute Lymphosytic Leukemia (A.L.L.) at the age of six. In 1997, the ATSDR proposed a childhood leukemia/non-Hodgkins lymphoma study for Camp Lejeune children who had been exposed to Volatile Organic Chemicals (V.O.C.'s, cleaning solvents!) in utero while their parents lived at the base between the years of 1968–1985. (Note: The start date of this study was based upon the beginning date for the computerization of birth records in North Carolina, not on potential exposure.) The protocol/proposal for this study outlined that the expected occurrences of the targeted illnesses in a cohort of 10,000–12,000 births for that time period would be 7.2 cases. The ATSDR has confirmed 14 cases of leukemia and two cases of non-Hodgkins lymphoma, this is more than a 100 percent increase in the incidence of these childhood cancers!

Mr. Chairman, let me layout some of the facts and figures relating to the Camp Lejeune water contamination situation. The documented levels of contaminates in

the finished drinking water (at the tap) were some 280 times higher than what is currently considered safe for these very same chemicals! The Navy Bureau of Medicine and Surgery issued strict regulations (BUMED INST 6240.3B [CLW 0144]) in 1963 governing potable water distribution systems on Naval Shore Facilities. Included in these regulations were preemptive measures to ensure that existing and future water supplies were not contaminated by extraneous sources.

The Camp Lejeune, Tarawa Terrace family housing area water supply wells were located on the virtual property line, down gradient, and directly across the street from multiple potential civilian contamination sources! (Gasoline stations, auto repair facilities, dry cleaning establishments, and known septic systems.) In 1971, the Naval Facilities Engineering Command from Norfolk, Va. came to Camp Lejeune and selected multiple sites for the construction of new drinking water supply wells for the base.

One of these new wells was HP–651, which began producing raw water for the Camp Lejeune Hadnot Point water distribution plant in January of 1972. The site which had been selected by the Navy engineers for the placement of HP–651 was at the back corner of the base disposal yard! (junk yard!) The disposal yard had been in operation for decades by the time this site was selected for a drinking water supply well. In February 1985, HP–651 tested positive for some 26,000 ppb of Volatile Organic Chemicals (CLW 5260)! There is little doubt that this water supply well was contaminated immediately upon, or very shortly after its construction! (Note: The ATSDR's on-going water modeling for the Camp Lejeune, Hadnot Point and Holcomb Blvd. water systems will verify this fact once it is completed.) The irony of all this is the fact that many of the human exposures that took place at Camp Lejeune would have been avoided had Navy and Marine Corps officials followed their own regulations!

The most audacious and blasphemous truth in this entire water contamination incident at Camp Lejeune is the fact that Navy and Marine Corps officials knew of the existence of this contamination in the drinking water for five years before they took any action to rectify the problem (CLW 0430–0432, 0436, 0438, 0441, 0443, 0592, 0593)! (Navy and Marine Corps officials were knowingly poisoning their own people!) That is correct, all of this was known and taking place behind the scenes at the very same time that my daughter Janey was suffering through her fight with leukemia and they said absolutely nothing! Not only did they say nothing, they went as far as to return two of the three known contaminated wells for the Tarawa Terrace housing area back on-line for two more years! They had the option of tapping into the local community water lines which were located just a few feet from the property line. Instead, Navy and Marine Corps officials opted against this idea because they didn't want to owe any reciprocating favors to the local community government! (CLW 1129–1131)

Since the ATSDR entered the gates of Camp Lejeune to execute their Congressionally-mandated mission, representatives of the Department of the Navy (DON) have done all they could to obstruct their efforts. I can make this statement with confidence because I possess the documentation to back it up! As recently as the week before last, DOD and DON officials were threatening to thwart the ATSDR's initiatives at Camp Lejeune by withholding funding! (CLW 2407, 0000, 0000 (A), 2995, 2999, 3243, 3307, 4925, 4926)

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 (DOD) obstructing science, they are also jeopardizing the public health for millions of people all around the world. It is quite obvious by their activities to thwart science that they have something to fear. What they fear is their past negligence and the liability that comes along with it! There is little wonder why the DOD has been seeking immunities from environmental regulations for the last seven years and yet this administration and past Congress' have allowed their (DOD's) tentacles to infiltrate the realm of science. We all need to allow science to speak for itself and let the chips fall where they may!

DEPARTMENT OF THE NAVY
Bureau of Medicine and Surgery
Washington 25, D.C.

BUMED 6240.3B
BUMED-7223-1ss
30 September 1963

BUMED INSTRUCTION 6240.3B

From: Chief, Bureau of Medicine and Surgery
To: All Ships and Stations

Subj: Standards for potable water

Ref: (a) ONMINST 5711.9 dated 16 May 1958 (NOTAL)
(b) BUMEDINST 5711.2 dated 30 January 1959 (NOTAL)

1. **Purpose.** To establish standards for water for drinking and culinary purposes throughout the Naval Establishment.

2. **Cancellation.** BUMED Instruction 6240.3A is canceled.

3. **Background**

a. **Policy.** The Department of Defense has established the policy of compliance by the Military Departments with United States Public Health Service Drinking Water Standards, as may be modified by the Medical Services of the Departments, or as may be modified by competent authority for purposes of international agreement.

b. **International agreement.** Naval Tripartite Standardization Agreement ABC-NAVY-STD-23 was promulgated by references (a) and (b). The object of the agreement is to provide the United States Navy, the Royal Navy, and the Royal Canadian Navy assurance that drinking and culinary water delivered to each other's ships from installations under their cognizance meets certain minimum standards of quality.

4. **Quality Standards.** The standards for bacteriological quality, physical and chemical characteristics, and radioactivity shall be those in "Public Health Service Drinking Water Standards, 1962." Department of Health, Education, and Welfare. The Standards, as modified, may be found in NAVMED P-5010-5, "Water Supply Ashore," available through the Navy Supply System.

5. **Definition of Terms.** The following terms are defined for clarification in interpretation of standards:

a. **Adequate protection by natural means** involves one or more of the following processes of nature that produce water consistently meeting the requirements of these Standards: dilution, storage, sedimentation, sunlight, aeration, and the associated physical and biological processes which tend to accomplish natural purification in surface waters and, in the case of ground waters, the natural purification of water by infiltration through soil and percolation through underlying material and storage below the ground water table.

b. **Adequate protection by treatment** means any one or any combination of the controlled processes of coagulation, sedimentation, absorption, filtration, disinfection, or other processes which produce a water consistently meeting the requirements of these standards. This protection also includes processes which are appropriate to the source of supply; works which are of adequate capacity to meet maximum demands without creating health hazards, and which are located, designed, and constructed to eliminate or prevent pollution; and conscientious operation by well-trained and competent personnel whose qualifications are commensurate with the responsibilities of the position.

c. **The coliform group** includes all organisms considered in the coliform group as set forth in Standard Methods for the Examination of Water and Wastewater, current edition, prepared and published jointly by the American Public Health Association, American Water Works Association, and Water Pollution Control Federation.

d. **Health hazards** mean any conditions, devices, or practices in the water supply system and its operation which create, or may create, a danger to the health and well-being of the water consumer. An example of a health hazard is a structural defect in the water supply system, whether of location, design, or construction, which may regularly or occasionally prevent satisfactory purification of the water supply or cause it to be polluted from extraneous sources.

e. **Pollution,** as used in these standards, means the presence of any foreign substance (organic, inorganic, radiological, or biological) in water which tends to degrade its quality so as to constitute a hazard or impair the usefulness of the water.

f. **The standard sample** for the bacteriological test shall consist of:

(1) For the bacteriological fermentation tube test, five standard portions of either:

(a) 10 milliliters
(b) 100 milliliters

CLW 0144

(2) For the membrane filter technique, not less than 50 milliliters.

g. **Water supply system** includes the works and auxiliaries for collection, treatment, storage, and distribution of the water from the sources of supply to the freeflowing outlet of the ultimate consumer.

6. Source and Protection

a. The water supply should be obtained from the most desirable source which is feasible, and effort should be made to prevent or control pollution of the source. If the source is not adequately protected by natural means, the supply shall be adequately protected by treatment.

b. Frequent sanitary surveys shall be made of the water supply system to locate and identify health hazards which might exist in the system.

c. Approval of water supplies shall be dependent in part upon:

(1) Enforcement of rules and regulations to prevent development of health hazards;

(2) Adequate protection of the water quality throughout all parts of the system, as demonstrated by frequent surveys;

(3) Proper operation of the water supply system under the responsible charge of personnel whose qualifications are acceptable to the Bureau of Yards and Docks or the Bureau of Ships, as appropriate;

(4) Adequate capacity to meet peak demands without development of low pressures or other health hazards; and

(5) Record of laboratory examinations showing consistent compliance with the water quality requirements of these Standards.

7. Standards. The limits listed below are generally those contained in "Public Health Service Drinking Water Standards, 1962." For sampling procedures and techniques, refer to NAVMED P-5010-5.

a. **Bacteriological quality: limits.** The presence of organisms of the coliform group as indicated by samples examined shall not exceed the following limits:

(1) When 10 ml. standard portions are examined, not more than 10 percent in any month shall show the presence of the coliform group. The presence of the coliform group in three or more 10 ml. portions of a standard sample shall not be allowable if this occurs:

(a) In two consecutive samples;
(b) In more than one sample per month when less than 20 are examined per month; or
(c) In more than five percent of the samples when 20 or more are examined per month.

When organisms of the coliform group occur in three or more of the 10 ml. portions of a single standard sample, daily samples from the same sampling point shall be collected promptly and examined until the results obtained from at least two consecutive samples show the water to be of satisfactory quality.

(2) When 100 ml. standard portions are examined, not more than 60 percent in any month shall show the presence of the coliform group. The presence of the coliform group in all five of the 100 ml. portions of a standard sample shall not be allowable if this occurs:

(a) In two consecutive samples;
(b) In more than one sample per month when less than five are examined per month; or
(c) In more than 20 percent of the samples when five or more are examined per month.

When organisms of the coliform group occur in all five of the 100 ml. portions of a single standard sample, daily samples from the same sampling point shall be collected promptly and examined until the results obtained from at least two consecutive samples show the water to be of satisfactory quality.

(3) When the membrane filter technique is used, the arithmetic mean coliform density of all standard samples examined per month shall not exceed one per 100 ml. Coliform colonies per standard sample shall not exceed 3/50 ml., 4/100 ml., 7/200 ml., or 13/500 ml. in:

(a) Two consecutive samples;
(b) More than one standard sample when less than 20 are examined per month; or
(c) More than five percent of the standard samples when 20 or more are examined per month.

When coliform colonies in a single standard sample exceed the above values, daily samples from the same sampling point shall be collected promptly and examined until the results obtained

from at least two consecutive samples show the water to be of satisfactory quality.

b. **Physical characteristics: limits.** Drinking water should contain no impurity which would cause offense to the sense of sight, taste, or smell. Under general use, the following limits should not be exceeded:

Turbidity	5 units
Color	15 units
Threshold Odor Number	3

c. **Chemical characteristics: limits.** Drinking water shall not contain impurities in concentrations which may be hazardous to the health of the consumers. It should not be excessively corrosive to the water supply system. Substances used in its treatment shall not remain in the water in concentrations greater than required by good practice. Substances which may have deleterious physiological effect, or for which physiological effects are not known, shall not be introduced into the system in a manner which would permit them to reach the consumer.

(1) The following chemical substances should not be present in a water supply in excess of the listed concentrations where, in the judgment of the Bureau of Yards and Docks and the Bureau of Medicine and Surgery, other more suitable supplies are or can be made available.

Substance	Concentration in mg/l (ppm)
Alkyl Benzene Sulfonate (ABS)	0.5
*Antimony (Sb)	0.01
Arsenic (As)	0.01
Chloride (Cl)	250.
Copper (Cu)	1.
Carbon Chloroform Extract (CCE)	0.2
Cyanide (CN)	0.01
Fluoride (F)	(See (3))
Iron (Fe)	0.3
Manganese (Mn)	0.05
Nitrate [1] (NO_3)	45.
Phenols	0.001
Sulfate (SO_4)	250.
Total Dissolved Solids	500.
Zinc (Zn)	5.

[1] In areas in which the nitrate content of water is known to be in excess of the listed concentration, the public should be warned of the potential dangers of using the water for infant feeding.

* Not contained in Drinking Water Standards but this limit was determined by the Public Health Service and the Bureau of Medicine and Surgery.

(2) The presence of the following substances in excess of the concentrations listed shall constitute grounds for rejection of the supply:

Substance	Concentration in mg/l (pp
*Antimony (Sb)	0.05
Arsenic (As)	0.05
Barium (Ba)	1.0
Cadmium (Cd)	0.01
Chromium (Hexavalent) (Cr^{+6})	0.05
Cyanide (CN)	0.2
Fluoride (F)	(See (3))
Lead (Pb)	0.05
Selenium (Se)	0.01
Silver (Ag)	0.05

* Not contained in Drinking Water Standards this limit was determined by the Public Health Service and the Bureau of Medicine and Surgery

(3) **Fluoride.** When fluoride is naturally present in drinking water, the concentration should not average more than the appropriate upper limit in the following Table I. Presence fluoride in average concentrations greater than two times the optimum values in Table I shall constitute grounds for rejection of the supply. When fluoridation (supplementation of fluoride drinking water) is practiced, the average fluoride concentration shall be kept within the upper and lower control limits in Table I.

TABLE I

Annual average of maximum daily air temperatures [2]	Recommended control limits--Fluoride concentrations in mg/l (ppm)		
	Lower	Optimum	Upper
50.0 - 53.7	0.9	1.2	1.7
53.8 - 58.3	0.8	1.1	1.5
58.4 - 63.8	0.8	1.0	1.3
63.9 - 70.6	0.7	0.9	1.2
70.7 - 79.2	0.7	0.8	1.0
79.3 - 90.5	0.6	0.7	0.8

[2] Based on temperature data obtained for a minimum of five years.

d. **Radioactivity: limits.**

(1) The effects of human radiation exposure are viewed as harmful and any unnecessary exposure to ionizing radiation should be avoide

Approval of water supplies containing radioactive materials shall be based upon the judgment that the radioactivity intake from such water supplies when added to that from all other sources is not likely to result in an intake greater than the radiation protection guidance [3] recommended by the Federal Radiation Council and approved by the President. Water supplies shall be approved without further consideration of other sources of radioactivity intake of Radium-226 and Strontium-90 when the water contains these substances in amounts not exceeding 3 and 10 μμc/liter, respectively. When these concentrations are exceeded, a water supply shall be approved by the certifying authority if surveillance of total intakes of radioactivity from all sources indicates that such intakes are within the limits recommended by the Federal Radiation Council for control action

(2) In the known absence [4] of Strontium-90 and alpha emitters, the water supply is acceptable when the gross beta concentrations do not exceed 1,000μμc/liter. Gross beta concentrations in excess of 1,000 μμc/liter shall be grounds for rejection of supply except when more complete analyses indicate that concentrations of nuclides are not likely to cause exposures greater than the Radiation Protection Guides as approved by the President on recommendation of the Federal Radiation Council.

[3] The Federal Radiation Council, in its Memorandum for the President, Sept. 13, 1961, recommended that "Routine control of useful applications of radiation and atomic energy should be such that expected average exposures of suitable samples of an exposed population group will not exceed the upper value of Range II (20μμc/day of Radium-226 and 200μμc/day of Strontium-90)."

[4] Absence is taken here to mean a negligibly small fraction of the above specific limits, where the limit for unidentified alpha emitters is taken as the listed limit for Radium-226.

8. **Technical Assistance.** Assistance with potable water problems may be requested from the following:

a. Preventive Medicine Units, in accordance with BUMED Instruction 6200.3A of 2 July 1957, Subj: U.S. Navy Preventive Medicine Units.

b. Bureau of Yards and Docks' Field Engineering Offices, in accordance with BUDOCKS Instruction 5450.19A of 21 September 1962, Subj: Sanitary Engineering Responsibilities of the Bureau of Yards and Docks Field Engineering Offices.

A. S. CHRISMAN
Deputy and Assistant Chief

Distribution:
SNDL Parts 1 and 2
Marine Corps List E less: 1050/1070/1080/2000/6200/7150/7200/7352/7503/7505/7506/8120/8121/8122/8180

Navy sample #651 received 2-7-85

JTC ENVIRONMENTAL CONSULTANTS, INC. CLW
PRIORITY POLLUTANT ANALYSIS DATA SHEET 0000005260
VOLATILE FRACTION

LAB SAMPLE LOG NO. VOA SPL 497 PROJECT NO. NF-12

SAMPLE DESIGNATION & DATE 12-0002 #651 1410 250 ml → 5000 1:20 Dilution

METHOD NO. 624 DETECTION LIMIT 200 ug/lit

ANALYSIS DATE 2/8/85

PARAMETER	RESULT ug/lit	PARAMETER	RESULT ug/lit
2V acrolein	N.D.	32V 1,2-dichloropropane	N.D.
3V acrylonitrile	N.D.	33V 1,3-dichloropropylene	N.D.
4V benzene	N.D.	38V ethylbenzene	N.D.
6V carbon tetrachloride	N.D.	44V methylene chloride	N.D.
7V chlorobenzene	N.D.	45V methyl chloride	N.D.
10V 1,2-dichloroethane	N.D.	46V methyl bromide	N.D.
11V 1,1,1-trichloroethane	N.D.	47V bromoform	N.D.
13V 1,1-dichloroethane	N.D.	48V dichlorobromomethane	N.D.
14V 1,1,2-trichloroethane	N.D.	49V trichlorofluoromethane	N.D.
15V 1,1,2,2-tetrachloroethane	N.D.	50V dichlorodifluoromethane	N.D.
16V chloroethane	N.D.	51V chlorodibromomethane	N.D.
19V 2-chloroethylvinyl ether	N.D.	85V tetrachloroethylene	397 ~~N.D.~~
23V chloroform	N.D.	86V toluene	N.D.
29V 1,1-dichloroethylene	N.D.	87V trichloroethylene 17600	~~N.D.~~
30V 1,2-trans-dichloroethylene 8070	~~N.D.~~	88V vinyl chloride *	179 ~~N.D.~~

N.D. = NOT DETECTED
N.A. = NOT APPLICABLE/ANALYZED

* Below Method Detection Limit

Doc. No.: CLCT-68248-1.02-10/31/80 0044

JENNINGS LABORATORIES, INC.

ANALYTICAL AND CONSULTING CHEMISTS

1118 CYPRESS AVENUE • P. O. BOX 851 • VIRGINIA BEACH, VA. 23451 • PHONE (804) 425-1498

VA (EPA) CERTIFIED LABORATORY for Drinking Water Analysis - Microbiological, Inorganic and Organic

ASBESTOS ANALYSIS – NIOSH 582

Official Referee Chemists for: AMERICAN OIL CHEMISTS SOCIETY; NATIONAL SOYBEAN PROCESSORS ASSOCIATION

Laboratory Certified by VA. STATE WATER CONTROL BOARD for Analysis of Effluents for NPDES PERMITS

CERTIFIED OFFICIAL U.S.D.A. LABORATORY FOR MEAT ANALYSIS

CERTIFICATE OF ANALYSIS

TO: Mr. Dave Goodwin
Building N-23 Atlantic Division
Naval Facilities Engineering Command
Norfolk, Virginia 23511

DATE: October 31, 1980

SAMPLE OF: WATER SAMPLES (8) FOR COMPOSITE FOR PRIORITY POLLUTANT SCAN

MARKED: Listed below

Samples picked up October 1, 1980

OFFICIAL SAMPLE BY: _____

EIGHT (8) SAMPLES OF WATER TO BE COMPOSITED AS PER INSTRUCTIONS:

SAMPLE MARKED	QUARTS	LOCATION	QUANTITY
#1	2	Hadnot Point Bldg 20	1552 ml
#2	1	Hadnot Point Bldg 670	708 ml
#3	1	Tarawa Terrace TT-38	452 ml
#4	1	Monford Point M-178	220 ml
#5	1	MCAS(H) Bldg 110	664 ml
#6	1	Courthouse Bay BB-190	132 ml
#7	1	Rifle Range RR-85	220 ml
#8	1	Onslow Beach BA-138	52 ml
			4000 ml

Pump Holds 5 of these

Administrative Record May 11, 1992
Section 1.0
Site Id BB in vol A,B

Respectfully submitted,
JENNINGS LABORATORIES, INC.

CLW

Laboratory Analysis No. 2518

E. R. Jennings 0000000430
CHEMIST

USE NO - CLCU - 00248 - 1.02 - 10/31/80

JENNINGS LABORATORIES, INC.

ANALYTICAL AND CONSULTING CHEMISTS

1180 SPRUCE AVENUE • P.O. BOX 851 • VIRGINIA BEACH, VA. 23451 • PHONE (804) 425-1100

EPA CERTIFIED DRINKING WATER LABORATORY for Trihalomethanes and Organics

ASBESTOS ANALYSIS - NIOSH 582

Official Referee Chemists for AMERICAN OIL CHEMISTS SOCIETY

NATIONAL SOYBEAN PROCESSORS ASSOCIATION

Laboratory Certified by VA. STATE WATER CONTROL BOARD for Analysis of Effluents for NPDES PERMITS

CERTIFIED OFFICIAL U.S.D.A. LABORATORY FOR MEAT ANALYSIS

CERTIFICATE OF ANALYSIS

TO Mr. Dave Goodwin
Building N-23 Atlantic Division
Naval Facilities Engineering Command
Norfolk, Virginia 23511

DATE October 31, 1980

SAMPLE OF WATER SAMPLES (8) - Blank made on each analysis.Bromochloromethane,

MARKED 2-bromo-1-chloropropane,1-4 dichlorobutane used as internal standard.

GC/MS calibrated with perfluorotributylamine, SIM MODE. All test run according to EPA TEST PROCEDURES.

OFFICIAL SAMPLE BY:

PURGEABLE ORGANICS			DETECTION LIMITS µg/l
Acrolein	None Detected		2.0
Acrylonitrile	None Detected		2.0
Benzene	None Detected		10.0
Toluene	None Detected		10.0
Ethylbenzene	None Detected		10.0
Carbon Tetrachloride	None Detected		.007
Chlorobenzene	None Detected		.03
1,2-Dichloroethane	None Detected		.006
1,1,1-Trichloroethane	.005 µg/l	MCL=.200 ppm	.005
1,1-Dichloroethane	.004 µg/l		.004
1,1-Dichloroethylene	.006 µg/l	MCL=.007 ppm	.006
1,1,2-Trichloroethane	.006 µg/l	MCL=.005 ppm	.006
1,1,2,2-Tetrachloroethane	.006 µg/l	MCL=.005 ppm	.006
Chloroethane	.01 µg/l	None listed	.01
2-Chloroethyl vinyl ether	.08 µg/l		.08

right at the detection limit

Respectfully submitted,
JENNINGS LABORATORIES, INC.

CLW

Laboratory No. 2518

E. R. Dougherty
CHEMIST

Doc No: CLEJ-00278-1.02-10/31/80

JEFFERSON LABORATORIES, INC.

PURGEABLE ORGANICS (continued)		DETECTION LIMITS ug/l
Chloroform	None Detected	.010
1,2-Dichloropropane	None Detected	.004
1,3-Dichloropropane	None Detected	.006
Methylene Chloride	None Detected	.010
Methyl Chloride	None Detected	.009
Methyl Bromide	None Detected	.03
Bromoform	None Detected	.02
Dichlorobromomethane	None Detected	.006
Trichlorofluoromethane	None Detected	.03
Dichlorodifluoromethane	None Detected	.01
Chlorodibromomethane	None Detected	.01
Tetrachloroethylene	None Detected	.007
Trichloroethylene	.005 ug/l ≈ .005 = MCL	.005
Vinyl Chloride	.01 ug/l .002 = MCL	.01
1,2-trans-Dichloroethylene	.006 ug/l .100 = MCL	.006
bis(chloromethyl)ether	.003 ug/l 2.0×10^{-7} = MCL	.003

BASE/NEUTRAL EXTRACTABLE ORGANIC COMPOUNDS		
1,2-Dichlorobenzene	None Detected	.04
1,3-Dichlorobenzene	None Detected	.04
1,4-Dichlorobenzene	None Detected	.04
Hexachloroethane	None Detected	.001
Hexachlorobutadiene	None Detected	.001
Hexachlorobenzene	None Detected	.002
1,2,4-Trichlorobenzene	None Detected	.006
Bis(2-Chloroethoxy)methane	None Detected	.40
Naphthalene	None Detected	.04
2-Chloronaphthalene	None Detected	.04
Isophorone	None Detected	5.0
Nitrobenzene	None Detected	5.0
2,4-Dinitrotoluene	None Detected	.06
2,6-Dinitrotoluene	None Detected	.06

CLW

LAB # 2518

BY E. R. [illegible] CHEMIST

0045

TTHM SURVEILLANCE REPORT FORM

tion MCB - LA JEUNE - HADNOT POINT

Date Collected 29 OCT 80 PM

AVE 34 APPROX.

Source	Sample Number	CCl_3	$CHCl_2Br$	$CHClBr_2$	$CHBr_3$	TTHM
WTP	086	18.6	138 (8)	5.1	0.3	32
HOSP NH-1	087	20.6	138 (9)	6.3	0.6	35
1202	088	19.3	138 (8)	5.4	0.3	33
65	089	18.8	137 (8)	5.5	0.4	33
FC-530	090	18.7	136 (8)	5.7	0.4	33
Reference OBS						
True						

Date Received 30 OCT 80

Date Analyzed 31 OCT 80

Remarks: WATER IS HIGHLY CONTAMINATED WITH LOW MOLECULAR WEIGHT HALOGENATED HYDROCARBONS. STRONG INTERFERENCE IN THE REGION OF $CHCl_2Br$. CANNOT DETERMINE TRUE VALUE OF THAT COMPOUND. EXPERIENCE SHOWS THAT THE TRUE CONCENTRATION IS LOW, SINCE THE [illegible]

William C. Neal

WILLIAM C. NEAL, JR.
Chief, Laboratory Services

CLW

00000436

0048
NAVY

TTHM SURVEILLANCE REPORT FORM

Installation CAMP LEJEUNE - HADNOT POINT
Date Collected 18 DEC 80 PM

Source	Sample Number	$CHCl_3$	$CHCl_2Br$	$CHClBr_2$	$CHBr_3$	µg/L TTHM
WTP	N111	20.0	?	6.2	1.0	27+
NW-1	112	18.7	?	7.0	1.2	25+
1202	113	19.3	?	6.8	1.1	27+
65	114	19.9	?	6.4	1.0	27+
FC-530	115	19.8	?	7.3	1.2	28+
Reference OBS						
True						

Date Received 29 DEC 80
Date Analyzed 5 JAN 81
Remarks: 22
HEAVY ORGANIC INTERFERENCE AT $CHCl_2Br$.
YOU NEED TO ANALYZE FOR CHLORINATED ORGANICS BY GC/MS.

William C Neal Jr
WILLIAM C. NEAL, JR.
Chief, Laboratory Services

USAEHA-S Form 7
20 Feb 80

CLW

0000000438

0050

TTHM SURVEILLANCE REPORT FORM

Installation CAMP LA JEUNE - HADNOT PT

Date Collected 29 JAN 81 PM

HEAVY INTERFERENCE

Source	Sample Number	$CHCl_3$	$CHCl_2Br$ ✓	$CHClBr_2$	$CHBr_3$	ug/L TTHM
WTP	161	22.7	?	6.2	0.9	30 +
NH-1	162	27.2	?	6.3	0.8	34+
1202	163	23.8	?	6.6	0.9	31+
65	164	24.3	?	6.8	0.9	32+
FC-530	165	27.5	?	7.2	1.0	36+
Reference OBS						
True						

↳ Dichlorobromomethane

Date Received 30 JAN 81

Date Analyzed 9 FEB 81

Remarks: YOU NEED TO ANALYZE FOR CHLORINATED ORGANICS BY GC/MS.

William C Neal Jr

WILLIAM C. NEAL, JR.
Chief, Laboratory Service CLW-

USAEHA-S Form 7
20 Feb 80

0000000441

0052

TTHM SURVEILLANCE REPORT FORM

Installation CAMP LA SEUNE HADNOT POINT

Date Collected 26 FEB 81 PM

AVE 63

Source	Sample Number	$CHCl_3$	$CHCl_2Br$	$CHClBr_2$	$CHBr_3$	mg/L TTHM
WTP	181	48.6	9.6	5.4	1.7	65
NH-1	182	54.5	13.8	5.5	0.2	74
1202	183	46.6	10.6	4.2	0.1	62
65	184	45.5	9.4	5.0	0.1	60
FC-530	185	43.6	8.5	4.2	0.1	56
Reference OBS						
True						

Date Received 9 MAR 81

Date Analyzed 9 MAR 81

Remarks:

WATER HIGHLY CONTAMINATED WITH OTHER CHLORINATED HYDROCARBONS (SOLVENTS)!

William C. Neal

WILLIAM C. NEAL, JR.
Chief, Laboratory Services

USAEHA-S Form 7
20 Feb 80

CLW

000-0000443

0121

GRAINGER LABORATORIES

INCORPORATED

ANALYTICAL AND CONSULTING CHEMISTS

709 West Johnson Street • Raleigh, North Carolina 27603

(919) 828-3360

ANALYTICAL LABORATORY

Environment Analysis
Construction Materials
Identification of Unknowns
Agriculture
Fuels
Textiles
Chemicals
Hazardous Waste

CONSULTATION

Metallurgical Services
Pollution Abatement
Process Development
Quality Control
Methods Development
Special Investigation
Pesticides
RCRA

August 10, 1982
82-4471

Commanding General
Marine Corps Base
Camp Lejeune, N.C. 28542

Attention: AC/S Facilities

Subject: Analyses of samples 206 and 207 from site coded "TT" and samples 208 and 209 from site coded "HP". Samples received July 29, 1982.

Discussion:

Previously all samples from site TT and HP presented difficulties in performing the monthly Trihalomethane analyses. Interferences which were thought to be chlorinated hydrocarbons hindered the quantitation of certain Trihalomethanes. These appeared to be at high levels and hence more important from a health standpoint than the total Trihalomethane content. For these reasons we called the situation to the attention of Camp Lejeune personnel.

Results:

The identity of the contaminant in the well field represented by samples 206 and 207 was suspected to be Tetrachloroethylene. This was confirmed by two analytical techniques and the results were 76 µg/l and 82 µg/l for samples 206 and 207 respectively.. Sample 86 from May 27, 1982 was reanalyzed as a part of our study. Sample 86 was from site TT and contained 80 µg/l tetrachloroethylene.

Samples 208 and 209 were also analyzed by the same analytical techniques. The magnitude of the contamination was not as great as previously observed from this same sampling point. Upon reanalyzing sample 120 from site HP May 27, 1982 , Trichloroethylene was identified and quantitated at 1400 µg/l. A lesser amount of Tetrachloroethylene was confirmed at 15 µg/l. Samples 208 and 209 contained 19 µg/l and 21 µg/l Trichloroethylene respectively; Tetrachloroethylene was not detected.

CLW

0000000592

Prior to this report, the samples from July 28, 1982 from site HP were analyzed. Traces of both solvents were found in this set. Though not quantitated, the level of Trichloroethylene seems to be in the range of that which was found in samples 208 and 209. The sample which showed the most contamination relative to the others was 205. Also sample 168 from site TT on July 28, 1982 was analyzed and shown to contain 104 µg/l Tetrachloroethylene.

Conclusion:

Tetrachloroethylene was identified as the contaminant in the well field coded "TT". Its concentration seems relatively stable over the period in which it has been examined. It was confirmed that the well field coded "HP" has shown contamination by Trichloroethylene and Tetrachloroethylene. These levels have been variable over the per studied and are now at significantly lower levels than when first encountered. The following table summarizes the findings:

Sample	Date Taken	Site Code	Tri chloroethylene	Tetra- chloroethylene
206	7-27-82	TT	-	76
207	7-27-82	TT	-	82
86	5-27-82	TT	-	80
168	7-28-82	TT	-	104
208	7-27-82	HP	19	<1
209	7-27-82	HP	21	<1
120	5-27-82	HP	1400	15
205	7-28-82	HP	No Data	1.0

Bruce A. Babson
Bruce A. Babson
Chemist

BAB/ab
Customer #92400

CLW

0000000593

Sep 22.1994 11:07AM FROM AC S Environmental Mgmt TO 5997 P.02

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Agency for Toxic Substances
and Disease Registry
Atlanta GA 30333

September 2, 1994

Ms. Yvonne P. Walker, CIH
Engineering Support Department
Navy Environmental Health Center
2510 Walmer Avenue
Norfolk, VA 23513-2617

Dear Ms. Walker:

I am responding to a letter received from Captain W.P. Thomas dated August 16, 1994 requesting a list of documents which ATSDR needs to conduct the public health assessment on Marine Corps Base (MCB) Camp Lejeune, North Carolina.

ATSDR identifies and obtains documents needed for evaluation to develop the public health assessment by discussing the public health issues with the installation and having them send us documents where the information can be found. As you are aware, we have had much difficultly getting the needed documents from MCB Camp Lejeune. We have sent MCB Camp Lejeune several requests for information and, in most cases, the responses were inadequate and no supporting documentation was forwarded. For example, ATSDR does not have any of the Remedial Investigation (RI) documents for this site nor do we have a copy of the administrative record index to help us identify which documents would be useful in our evaluation. The situation at MCB Camp Lejeune is also somewhat complicated in that several of our public health questions could not be answered with information from the RI reports (e.g., lead in drinking water).

The initial release of the MCB Camp Lejeune public health assessment is currently being prepared for the printer and will be released in the near future. For an ATSDR public health assessment to be useful, it is important that all pertinent information be provided for evaluation. The public health assessment lists the information ATSDR had available for evaluation for inclusion in the document. After the base has had an opportunity to read the MCB Camp Lejeune report, we must rely on the base personnel to identify and provide the additional source documentation as appropriate. We would appreciate your efforts to assure that this occurs.

Sincerely yours,

Carol H. Aloisio

Carol H. Aloisio
Office of Assistant Administrator

OLW

0000002407

Enclosure (1)

0203

HEADQUARTERS, MARINE CORPS BASE, CAMP LEJEUNE

ACTION BRIEF Date: 1 MAR 1985

Staff Section: Assistant Chief of Staff, Facilities

Subj: ALTERNATIVES FOR PROVIDING WATER TO THE TARAWA TERRACE AREA

Problem: Because of the recent shutdown of two water wells in the Tarawa Terrace water system due to the presence of Volatile Organic Chemicals (VOC) in the raw water, sufficient well capacity is not expected to be available to satisfy water demand this summer. A shortage of 300,000 gpd (gallons per day) is expected this spring/summer if the present situation remains unchanged.

Background/Discussion: The following alternatives are listed as possible options for addressing the problem.

a. Alternative 1: New well, Tarawa Terrace. Estimated cost: $80,000.

Advantages: Increase capacity by 100 gpm to 250 gpm (gallons per minute).

Disadvantages: Based on recent new wells and test wells in Tarawa Terrace, water in significant quantitities is difficult to locate (e.g., well TT-25 is producing approximately 100 gpm although designed for 150 gpm. New well would be abandoned after completion of expansion of Holcomb Blvd plant in approximately two years. Wells in Montford Point area are high in iron content. Construction of a new well by spring is questionable but could possibly be completed.

b. Alternative 2: Transport water via tanker trucks from other Camp Lejeune plants. Assume hauling 300,000 gpd with 5,000 gallon tankers which would require 60 trips per day. Assuming a tanker can make 12 trips per day, a total of five tanker trucks would be required. Estimated cost: $2,000 per day.

Advantages: Timely method of providing water.

Disadvantages: Logistics of loading/unloading/transporting; nonavailability of trucks.

c. Alternative 3: Tap to City of Jacksonville water line on Lejeune Blvd. Informal discussion with city officials indicates they probably could not provide 300,000 gpd at this time. No costs for taps or rates were quoted. A water line under Lejeune Blvd would have to be constructed. Estimated cost: Unknown.

Advantages: Timely response to problem, if available.

CLW

0000001129

Subj: ALTERNATIVES FOR PROVIDING WATER TO THE TARAWA TERRACE AREA

Disadvantages: Problems associated with connecting separate systems. Chance of requests for reciprocating favors from the City of Jacksonville would increase. VOCs in the city system could be higher than we are now facing. A quick test would have answered the last statement/excuse! J.M.S

d. Alternative 4: Change schedule of Holcomb Blvd plant contract to construct the water line to Tarawa Terrace immediately. The expansion of the Holcomb Blvd plant includes running a water line to TT and Camp Johnson. Contract has been awarded. Estimated cost: Unknown (additional cost to contractor).

Advantages: No unnecessary construction would be required.

Disadvantages: Serious doubts exist that contractor would complete line prior to high usage months. Line serving Tarawa Terrace is a 16" submerged line across Northeast Creek.

e. Alternative 5: Construct 8" water line from Brewster Blvd to Tarawa Terrace. Line could be tied to the railroad trestle to cross Northeast Creek. Estimated cost: $75,000.

Advantages: Timely response to problem.

Disadvantages: Problems related to material procurement and construction could surface. The temporary line may require State approval. Pressures and elevations of the two systems have been investigated to determine feasibility.

f. Alternative 6: Modify Tarawa Terrace plant to include aeration or granular activated carbon (GAC) capable of removing VOCs. Estimated cost: $300,000.

Advantages: Removal of VOCs would eliminate the problem.

Disadvantages: The modifications could not be made in the time frame required. The Tarawa Terrace plant will be discontinued upon completion of Holcomb Blvd plant expansion.

g. Alternative 7: Turn on contaminated wells that have been shut down if required to maintain adequate water levels. Estimated cost: None.

Advantages: Adequate quantity of water could be provided.

Disadvantages: Although no maximum contaminate levels have been set for VOCs and no regulations presently prevent using water containing VOCs, the potential health hazards must be weighed against the need and cost of providing water from other sources. The risk of health hazards obviously did not impact their decision, this is exactly what they did. J.M.S.

CLW

0000001130

Subj: ALTERNATIVES FOR PROVIDING WATER TO THE TARAWA TERRACE AREA

Recommended Action: Alternative 5, construct 8" line from Brewster Blvd to Tarawa Terrace. Preliminary engineering study indicates this would provide approximately 250 gpm (360,000 gpd).

Advantages:

(1) Timely - target date for completion 1 June 1985.

(2) Availability of water - can draw from Holcomb Blvd and Hadnot Point system.

(3) Auxiliary line for future use during repair/maintenance of other system.

(4) Minimum cost.

(5) Potential future use to return raw water from Tarawa Terrace wells.

Very respectfully,

M. G. LILLEY
AC/S, Facilities

Decision on Recommended Action:

CS Concur _____ Nonconcur _____

CG Approved _____ Disapproved _____

Need more info as we discussed

CLW

0000001131

To: Sab@emd1
From: GS-13 N NEAL PAUL@EMD
Originated by: GS-13 N NEAL PAUL@EMD
Cc: mps@EMD, tsm@EMD
BCC:
Subject: fwd: "A Civil Action" New Movie on the Superfu...
Attachment:
Date: 10/15/98 12:36 PM

Scott,
We will be briefing Maj Jack in early November - he will be in Italy until then. Tom is working on a point paper to document the events that have occurred since 1984. I feel its important for Maj Jack to know the entire story prior to advising us. Will continue to keep you posted.
V/R,
neal

ps. it appears we have put off the questionairres being mailed until at least Feb 99.

Original text
From: GS-13 N NEAL PAUL@EMD@MCB LEJEUNE, on 10/12/98 10:36 AM:
To: GS-14 SCOTT A BREWER@EMD1@MCB LEJEUNE
Cc: jsw@EMD@MCB LEJEUNE, MAJ SCOTT B JACK@CPAO@MCB LEJEUNE, mps@EMD@MCB LEJEUNE, tsm@EMD@MCB LEJEUNE

Scott,
With respect to the history campaign, since most folks no longer live in the area, we won't reach the formerly effected community. We would be able to educate our local community and this may help. ATSDR will be sending out questionaires with the next year and I need to see what info they will be including. My plans are to brief Maj Jack and get his thoughts. I'll keep you posted.
Thanks,
Neal

From: GS-14 SCOTT A BREWER@EMD1@MCB Lejeune, on 10/2/98 12:54 PM:
Neal: I suspect we're in for a lot of questions between this movie, and the (likely) upcoming ATSDR's study of the past TCE contamination. The real facts are hard enough to convey... i can't wait to see the Hollywood version. Should we begin a campaign of putting out the history (and/or other information) ahead of time? v/r sab
---
From GM-15 ROBERT L WARREN@EMD1@MCB Lejeune, on 10/1/98 8:03 AM:
To: GS-14 SCOTT A BREWER@EMD1@MCB Lejeune

Comments:
Forwarded for you information

CLW
0000002995

ATSDR

To: SMTP2@SMTP2[<dreyerk@hqi.usmc.mil>]
From: GS-13 N NEAL PAUL@EMD
Cc:
Bcc: GS-9 THOMAS S MORRIS@EMD
Subject: re: CAMP LEJEUNE PUBLIC HEALTH STUDY
Attachment:
Date: 10/23/98 8:13 AM

Good morning,
Whose public relations plan are you referring to here? Do we, the USMC, plan on implementing any PR efforts prior to the questionaires being sent ? Mick and I are briefing our PAO (in Italy now) in the beginning of Nov.

Just a thought, with the movie coming out in Dec, can we delay the questionaires until April/May time frame? The realty was that the survey was delayed until 1 Oct. 99. J.R.E

I've had an interesting week wrt LUCs? It appears we are close, waiting on Bernie to approve yearly certifcation language that will go in the ROD. Jon Johnston says he, Berniek, has already lost this battle in FL. If you look at the MOA, activities are required to provide an annual report to EPA/State certifying the LUCs are in place.

I definitely ruffled some feathers within EpA's ranks but I've talked to Jon smoothed things over. Jay Bassett was the instigator. ONe IMPORTANT NOTE, Jon feels like sinee Yaroschak, OLson and Elsie approve of MOA that this will be DoN policy, therefore he expects all Marine Corps activities to acquiesce to this adhoc policy. Did these folks ever brief you or include you on these discussions/ staffing of the LUCAP or were you on pregnancy leave at the time? This policy, albeit one that makes sense and is better than our BMPs, may not be accepted by all states in the region. I'm thinking specifically of Albany and PI. Should I take the lead on this, from a REC standpoint, and iniate the LUCAP at these activities or will you be doing that?

Let me know your thoughts - I'll be on a conf call at 9 to discuss with EPA and other TIer 3'ers.
Respectfully,
Neal

Original text
From: "GS13 KELLY A DREYER" <dreyerk@hqi.usmc.mil>, on 10/23/98 8:09 AM:
Capt. Newman,

I called to return your call this morning. I will be in today and most of next week. Please give me a call.

STATUS OF CAMP LEJEUNE PUBLIC HEALTH STUDY

CLW

The Base prepared and provided a chronology of events that [illegible]

0000029999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Agency for Toxic Substances
and Disease Registry

DEC 6 8 2005

Lieutenant General Richard S. Kramlich
Deputy Commandant of Installations and Logistics
Department of the Navy
Headquarters, United States Marine Corps (Code LFL)
2 Navy Annex
Washington, D.C. 20380-1775

Dear Lt. General Kramlich:

The Agency for Toxic Substances and Disease Registry (ATSDR) is conducting an epidemiologic case-control study of the children whose mothers were pregnant while living on base at Camp Lejeune from 1968-1985. ATSDR staff briefed Lt. General Kelly and other headquarters Marine staff on the status of the current study, including the water modeling component, in August 2005. The purpose of this letter is to seek your assistance in resolving outstanding issues that may delay ATSDR's ability to complete the current health study on time. The issues are as follows:

- ATSDR has experienced delays in obtaining requested information and data pertaining to historical water-quality sampling data and site remedial investigation reports. Attached for your information is a detailed list of these data, previously provided (during February – August 2005) to U.S. Marine Corps (USMC) Headquarters and Camp Lejeune staff, which outlines the needs of ATSDR to complete its water modeling activities;
- ATSDR staff has recently been made aware of the existence of a substantial number of additional documents, previously unknown and not provided to ATSDR staff. These documents are designated as "CLW" documents by the Camp Lejeune Environmental Management Division [EMD] and include summary data files and "document searching software" that could relate to and potentially impact our water modeling activities and analyses;
- The existence of a compilation of historical maps of water system changes at Camp Lejeune from 1941–2000. ATSDR needs to obtain these maps and all supporting spatial and temporal data files to assess the accuracy of ATSDR's understanding of historical changes in water-system configurations at Camp Lejeune; and
- ATSDR's need to have cooperation from and coordination with the USMC contractor currently engaged in a base-wide records discovery program. The contractor should be made

CLW 00000

aware of the types of records the agency is seeking and of ATSDR's water modeling and study completion time lines. We also request the timely sharing of these documents by your contractor to ATSDR.

ATSDR staff is attempting to meet the project completion timelines discussed with Marine Corps staff in August. To do so, we must be provided all documents that relate to base-wide water issues immediately. The Marine Corps is responsible for the identification and timely sharing of all relevant documents relating to the base-wide drinking water system. This includes documents that ATSDR may not be aware of as well as documents that are in the possession of DOD but may no longer be located at the Camp Lejuene base. Discovery of this documentation must not rely on specific requests from our staff, but on our shared goal of ensuring the scientific accuracy of our study and DOD's responsibility to provide the information. ATSDR staff can coordinate with USMC staff to determine the appropriateness of any document as it relates to our study. We request that your staff verify and confirm the existence of the documents listed in the attachment. We also request that your staff identify for us any other documents that may be useful to ATSDR for its water modeling analyses and make them available to ATSDR by December 31, 2005. In addition, we request that ATSDR be provided with any information or data that may be discovered at a future date that may have a bearing on our water modeling activities (e.g., information on water system interconnections and the actual production dates for supply of water from the Holcomb Boulevard water treatment plant).

A thorough review and assessment of such a large volume of documents at this late date and the incorporation of related information into nearly complete model investigations and analyses may require additional funding to review these documents and modify our model analyses if necessary. Completion of this assessment and required modifications to our model analyses may extend the timeline for the current health study by an additional 6 – 12 months.

If you or your staff have questions or would like to further discuss this matter, please contact Dr. Frank Bove, Senior Epidemiologist, Surveillance and Registries Branch, Division of Health Studies, ATSDR at (404) 498-0557.

Thank you again for your cooperation and continued interest in the work of ATSDR.

Sincerely,

Howard Frumkin, M.D., Dr.P.H.
Director, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry

Attachment:
ATSDR information and data needs

cc:
Director, DHAC/ATSDR
Director, DHS/ATSDR
Washington Office, ATSDR
OGC/CDC
Mike White, DOD
Frank Bove, DHS/ATSDR
Morris Maslia, DHAC/ATSDR

Information and Data Needed by ATSDR to Complete Water Modeling Activities in Support of the Current Epidemiologic Case-Control Study

1. Camp Lejeune Water Documents: All documents designated as "CLW" by Camp Lejeune and any software developed by or for Camp Lejeune EMD to assist with searching or locating "CLW" documents by key words, topics, dates, etc.

2. Camp Lejeune EMD Summary Files: All files developed by or for Camp Lejeune EMD whose purpose is to aggregate and summarize data that may relate to ATSDR water modeling analyses. These may be such files as MS Excel or MS ACCESS files describing water-supply well information, water-quality sample data, etc.

3. Historical Water System Maps: All maps, map files, spatial data layers, and associated attribute information relating historical changes in Camp Lejeune water systems for years 1941–2000.

4. JTC Environmental Consultants, Inc., Reports: Laboratory reports from sampling conducted by Camp Lejeune and analyses performed by contract laboratory, JTC Environmental Consultants. These reports were submitted to U.S. Environmental Protection Agency, Region IV, by letter dated 25 April 1986. (Request for these data have been made previously on several occasion to Camp Lejeune and headquarters EMD staff)

JTC Report No.	Date of Report
67	5/2/1985
99	7/19/1985
130	9/12/1985
131	9/18/1985
153	10/3/1985
157	10/11/1985
161	10/17/1985
166	10/25/1985
175	11/7/1985
181	11/14/1985
183	11/27/1985
187	11/27/1985
192	12/9/1985
199	12/18/1985
201	12/31/1985
208	1/2/1986
209	1/2/1986
214	1/21/1986
218	1/27/1986
221	1/30/1986
226	2/20/1986

JTC Environmental Consultants, Inc., Reports–continued

JTC Report No.	Date of Report
229	2/25/1986
231	2/26/1986
237	2/28/1986
243	3/12/1986
253	3/27/1986
261	3/27/1986
265	4/14/1986

5. Site Information and Data: Miscellaneous information and data related to historical remedial investigation/feasibility studies (RI/FS) conducted at various sites (operational units) located at Camp Lejeune. (Request for these data have been made previously on several occasion to Camp Lejeune and headquarters EMD staff)

Operational Unit Number	Site Number Recent	Site Number 1983	Site Name
1	21	21	Transformer storage lot #140
1	24	24	Industrial area fly ash dump
1	78	--	Hadnot Point industrial area
2	6	6	Storage lots 201 and 203
2	9	9	Fire fighting training pit
2	82	--	VOC disposal area at Piney Green Rd.
5	2	2	Former nursery/day-care center
7	1	1	French Creek liquid disposal area
7	28	28	Hadnot Point burn dump
8	16	16	Montford Point burn dump
11	7	7	Tarawa Terrace dump
11	80	--	Paradise Point-golf maintenance area
12	3	3	Old creosote site
15	88	--	Bldg. #25
Pre-RI site	84	--	Bldg. 45 area
Pre-RI site	85	--	Camp Johnson battery dump
Pre-RI site	4	--	Sawmill Road dump
Pre-RI site	5	--	Piney Green Road

Site Information and Data--continued

Operational Unit Number	Site Number Recent	1983	Site Name
Pre-RI site	8	--	Flammable storage warehouse-TP#451
Pre-RI site	8	--	Flammable storage warehouse-TP#452
Pre-RI site	10	--	Original base dump
Pre-RI site	11	--	Pest control shop
Pre-RI site	12	--	Golf course construction dump site
Pre-RI site	15	--	Montford Point dump
Pre-RI site	18	--	Watkins Village site
Pre-RI site	19	--	Naval Research lab dump
Pre-RI site	20	--	Naval Research lab incinerator
Pre-RI site	22	--	Industrial area tank farm
Pre-RI site	23	--	Roads and grounds, Bldg. 1105
Pre-RI site	25	--	Base incinerator
Pre-RI site	26	--	Coal storage area
Pre-RI site	27	--	Naval Hospital area
Pre-RI site	29	--	Base sanitary landfill
Pre-RI site	32	--	French Creek

6. Contract Information: Information and data related to various contracts. (Request for these data have been made previously on several occasion to Camp Lejeune and headquarters EMD staff)

Contract Number	Remarks
N62470-87-C-9266	Well at holding pond Sprinkler system for golf course
N62470-93-C-5318	Well numbers 1, 3, 4, 5, 6, and 8 S. H. Barner, Inc.

Robert E. Faye & Associates, Inc.
610 High Shoals Drive
Dahlonega, Georgia 30533

Phone: 706-219-1738
Email: refaye@alltel.net

Morris L. Maslia, P.E., D.WRE, DEE
Research Environmental Engineer
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
4770 Buford Highway
Mail Stop F-59, Room 02-004
Atlanta, Georgia 30341-3717
U.S.A.

Dear Morris, May 20, 2008

Per our recent conversations, I am writing to update my estimate of time to complete the monitor well location, well construction, ground-water level, ground-water contaminant, geohydologic, and hydraulic characteristic data bases for the Holcomb Boulevard – Hadnot Point study areas. Currently, I have completed these data bases for all of the CERCLA sites for which we have data; these include sites #1, 2, 3, 6, 9, 10, 21, 24, 74, 78, 80, 82, 84, 88, 94 and ancillary sites #22 and "G".

When recently completing data bases for site #84, I discovered references to additional ground-water investigations related to several locations of above-ground and underground storage tanks for refined petroleum products. I had no previous knowledge of these investigations as related reports were **not** included in the CERCLA and CLW documents provided to us by Camp Lejeune. The site names of these locations are, to the best of my knowledge, A-47/SA-21, S-889 to S-891, H-28, Building 45 – S-941-2, 820, and Building 21. I asked for and recently received digital copies of all reports related to these storage tank sites from the Environmental Management Division, Camp Lejeune. Many of these reports are substantial and contain numerous data that must be accounted for when constructing and calibrating our planned flow and transport models. Accordingly, I must herein revise my previous planned date for completing all data bases to August 1, 2008. In suggesting this date, I am accounting for work time lost to a planned vacation during the third week of June and the fact that my hours are restricted to 100 or 110 hours per month. I regret pushing the completion date forward but there is a great volume of data that we must accommodate and account for.

Please call if you have questions or wish to further discuss this issue.

Sincerely,

Robert E Faye

Robert E. Faye, P.E.

Another example of delays created by DoD entities not providing data!
J.M.E.

Raines GS12 Rick H

From: Paul GS13 Neal N
Sent: Thursday, November 16, 2000 9:41 AM
To: Cone GM14 Frederick E
Cc: Brewer GS14 Scott A; Raines GS12 Rick H; Jungreis Capt Jeremy N
Subject: Water Distribution Systems at Camp Lejeune

Fred,
See CMC HQ's request. Please let me know when you can meet on this.

-----Original Message-----
From: Dreyer GS13 Kelly A
Sent: Thursday, November 16, 2000 9:40 AM
To: Paul GS13 Neal N
Cc: Sakai GM14 Craig K; Raines GS12 Rick H
Subject: Water Distribution Systems at Camp Lejeune

Neal -

There seems to be a little confusion regarding when each of the water distribution systems at Camp Lejeune were installed and the timeframe and area each of them served. It's important to set the record straight.

ATSDR published a report in 1998 which assumes that the Holcolmb Blvd water distribution plant has always provided water to the Midway Park, Paradise Point, Berkeley Manor, and Watkins Village housing areas. I don't think the Holcomb Blvd Plant was even built until 1972 which makes this assumption incorrect. We are also receiving several calls from concerned citizens wanting to know where their water came from.

Can you please work with Facilities to compose a memo from Camp Lejeune to ATSDR with a copy to CMC and NEHC that contains the following information:

(1) All water Distribution systems
(2) When each water distribution system was built
  (a) which wells are connected to which water distribution system
  (b) which wells were contaminated (when and what were the levels)
  (c) Which wells were closed
(3) What areas each water distribution provided water to (housing, administrative, etc.)
  (a) the number of housing units in each housing area
  (b) Bldg numbers for Administrative buildings
(4) The timeframe each water distribution provided water to the specific area
(5) Any other pertinent information about a distribution system (e.g. Holcomb blvd was shut down and connected to the Hadnot Point system for 9 days).
  WHAT WELLS SHUT DOWN / THE REPOT ON LINE

If possible, an easy to read table would be a great format to present the information in. I'd like to have the memo signed out by 1 Dec 00 at the latest. Please let me know if you need clarificaiton or are not able to meet the deadline. I really appreciate your assistance. It's important to get this information to ATSDR so they can prepare an accurate report and also update previous studies that may be incorrect.

VR,
Kelly Dreyer
Environmental Restoration Program Manager
HQ Marine Corps
DSN 225-8302, ext 3329
COM (703) 695-8302, ext 3329
dreyerka@hqmc.usmc.mil

The correction of this incorrect data was never executed. Please note the date of this email. Please note the date this was requested to be completed. Now go to the next page. J.W.E.

- DOES SHE WANT DISC. SYS NOT INCLUDED IN STUDY / TIME FRAME

CLW

0000003243

- DO WE NEED 3rd PARTY REVIEW
- SLIDE ON DATE | UPDATE BY NEXT WEEK
- BREACHES /

0624

Raines GS12 Rick H

From: Dreyer GS13 Kelly A
Sent: Friday, March 16, 2001 11:16 AM
To: Raines GS12 Rick H
Cc: Paul GS13 Neal N; Sakai GM14 Craig K; Jungreis Capt Jeremy N; Reed Jr Maj Leslie H; James Brennan (E-mail); Baker GM13 Carl H
Subject: REQUEST FOR CLARIFICATION

Rick,

As we discussed earlier, here is a summary of what I see needs to be clarified and sent to ATSDR in writing. The Royal Netherlands Navy also requested the same information.

I am aware that you and Carl have already put most of these items together, but prior to releasing them, let's make sure they are accurate. It would also be useful to know what reports the new data contradicts. For starters, I am aware that the 1998 ATSDR report has some incorrect well construction dates, and mistakenly assumes that the Holcomb Blvd plant always supplied water to certain housing areas. There may also be other reports, correspondence, etc that needs to be clarified.

Areas which require research/clarification/documentation

(1) Which water supply systems served which base locations (including housing areas) from construction/operation to present?
(2) When were wells that supplied water systems constructed, closed, sampled, and what were the results?
(3) Where are all the present/former Dry Cleaners located on base? Which ones were merely drop off points?
(4) Where are other suspected sources of TCE/PCE on base (i.e. motor pool areas, UST areas, etc.)

Don't limit your analysis to TT and Hadnot point areas, we also need information from MCAS, Camp Geiger, etc.

In addition to setting the record straight, this information will help us answer questions on the Toll free line as well as provide written responses to the numerous citizen and congressional inquiries we receive.

I appreciate your help and look forward to hearing about the conclusion of this issue from Oregon.

VR (and best wishes always),
Kelly

This is (4) months later, and Ms. Dreyer is still trying to get what she had requested. This information was never corrected by the USN/USMC & notified the ATSDR of this error in 2003!
J.M.E

CLW
0000003307

Copy - filed 6-2-87

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION IV

345 COURTLAND STREET
ATLANTA, GEORGIA 30365

FEB 3 1986

REF: 4WD-ER

Commander
Atlantic Division
Naval Facilities Engineering Command
Norfolk, Virginia 23511- 6287

Attention: J. R. Bailey, P.E.
Environmental Quality Branch

Dear Sir:

On November 1, 1985, Messrs. Mathis and Holdaway of this Agency met with Facilities Engineering Staff at MCB Camp Le Jeune to review activities and progress in assessment of past waste disposal practices through the NACIP program. During the course of discussion, the subject of ground water quality, and particularly the quality of the water obtained from wells in the Hadnot Point Area of Camp Le Jeune, was reviewed at some length.

Both Messrs. Holdaway and Mathis became aware that there was evidence, from sampling as early as 1983 or 1984, of diffuse contamination of the ground water with unspecified organic substances, and that as a result of detection of unspecified volatile organic compounds in raw potable water samples certain potable wells at Hadnot Point were taken out of service. In consideration of the fact that the major portion of the resident population of Camp Le Jeune, is dependent on the Hadnot Point well field as its potable water supply, the parties in the meeting agreed that any potential contamination of this resource should be investigated as expeditiously as practical. It was also established that there was no contamination detected in treated potable water distributed at Camp Le Jeune, however the extent and sensitivity of analytic procedures for specific organic substances was not fully discussed.

What?!! These people lied to the EPA - the E.

Mr. Mathis suggested it would be desirable to analyze ground water samples from the monitoring wells involved in the NACIP confirmation studies for the 129 priority pollutants (CFR261 Appendix 8), and that the same analysis should be performed on raw water from all potable wells to insure that there was no contamination of the Camp Le Jeune water supply. When EPA informally requested a copy of the analytical results from monitoring wells and potable wells, we were advised that these data were still in raw form and under review.

If these data are now available, please furnish us a copy. If these data have not been published yet, we would appreciate a brief description of what substances were analyzed, what substances were detected, and when the data will be available.

CLW 0000004925

This Agency is concerned that a potential for human exposure to hazardous substances and hazardous wastes via the Camp Le Jeune water supply may exist due to the presence of such materials in ground water in the general vicinity of the potable well field. The existance of such a potential exposure would warrent consideration of this area for inclusion on the National Priority List, with an attendant increase in the expediency of investigation and remediation.

We appreciate your assistance in obtaining these data in order that this potentially significant problem may be addressed.

If you have any questions, please do not hesitate to contact me at (404) 347-3776 or FTS 257-3776.

Sincerely,

Arthur G. Linton

Arthur G. Linton, P.E.
Regional Federal Facilities Coordinator
Environmental Assessment Branch
Office of Policy and Management

cc: Commander, MCS Camp Le Jeune
Lee Berwig
Paul Bubbell, Navy Department, Washington, DC

CLW
0000004926

Chairman. MILLER. Mr. Ensminger, I know that Mr. Sensenbrenner joins me in extending our condolences for the loss of your daughter and all that you and your family have gone through.

Mr. Siegel.

STATEMENT OF MR. LENNY SIEGEL, EXECUTIVE DIRECTOR, THE CENTER FOR PUBLIC ENVIRONMENTAL OVERSIGHT (CPEO)

Mr. SIEGEL. Good morning. I am from the town of Mountain View, California. We have about seven or eight Superfund sites and numerous other contamination sites. I work with communities all over the country. I visit communities, folks from Camp Lejeune, and lots of places, and I hear lots of stories like Jerry's.

The Environmental Protection Agency's integrated risk information system is the foundation of most of the federal, State, and tribal risk-management decisions that determine the safety of the air that we breathe, the water we drink and the soil under our feet. Quantitative judgments embedded in IRIS may read like a foreign language or quantum physics to most Americans. People do not understand it. But those judgments affect our health, our environment, and our property.

Unfortunately, over the past several years, the White House and federal agencies that are among the world's greatest polluters, Department of Energy, Department of Defense, and NASA, have essentially hijacked EPA's authority to conduct human health-risk assessments. EPA's announcement in April of the new process for IRIS simply institutionalizes an approach that has been used, at least for perchlorate and trichloroethylene. This is an approach that unnecessarily puts Americans at risk. In lay terms, the fox is now managing the hen house.

In my prepared testimony, I tell the story of trichloroethylene. I could tell perchlorate because I have worked on that as well. Federal agencies have delayed and perhaps prevented, in the long run, the establishment of more protective health standards for TCE. The process they use for that is apparently the precedent for the new IRIS process that EPA announced in April.

In 2001, EPA issued a draft human health-risk assessment for TCE. Though its Science Advisory Board generally endorsed the study, EPA, under pressure from the White House and federal polluting agencies, withdrew its 2001 findings, and it turned the issue of TCE toxicity over to what was called the interagency working group, and that working group sent it to the National Academy of Sciences for re-review.

In early 2003, January 2003, EPA scientists came to my community of Mountain View to discuss the migration of TCE vapors into homes and businesses at, at least, four contamination sites. One of them was not Superfund. The others were Superfund. Over 400 people attended that meeting. The picture is up there.

January 2003 meeting in Mountain View, California

EPA told us that, based on the 2001 risk assessment, that TCE was five to 65 times as toxic as previously believed. I learned about a year later from a friend in the Navy that that provisional risk assessment would never be implemented, that the EPA was going to withdraw it and go through the process I just mentioned.

They weakened the standards, and those weakened standards have led to less protection for the people in my community and communities throughout the country, even though, as Chairman Miller read, the Academy of Science's review committee found that the evidence that TCE caused cancer was even stronger than EPA believed in 2001. Still, EPA has really done almost nothing to move forward to establish new standards for TCE.

The key point of my testimony is that these numbers in IRIS actually make a difference in people's lives and their health and what happens to their property. This is a picture of my friend Jane's house, about a half-mile from my house.

Jane's house in Mountain View

She lives across the street from the birthplace of the semiconductor industry, and they originally thought that the plume boundary from TCE was in the middle of the street in front her house. It turns out the plume goes under her house, because when they tested her son's bedroom, they found 0.8 micrograms per cubic meter of TCE in the air. According to the initial standard that the EPA science brought based on the 2001 health-risk assessment, that was almost two orders of magnitude higher than what the standard should be, what was considered a legally safe cancer risk. With the standard that was in place before the 2001 health-risk assessment, he was considered safe, so it made it a difference.

Now, fortunately, and it is really not fortunate at all, but the measurements in the basement of the house were higher, and so they installed a fan to ventilate the house and lower the contamination. After age 11, her son's exposures went down because we did something about it. We do not know whether he will get sick as a result. Jane does know that she is going to have a lot of trouble selling her house because it has the mitigation system there.

This is a picture of where Shirley lived in Bayport, Minnesota.

Shirley's former house in Bayport, Minnesota

She had contamination in her private drinking water supply, between the five parts per billion, which is the longstanding standard for TCE in drinking water, and one which is where everybody expected the number to go if the 2001 human health-risk assessment had been implemented. Her nephew wrote me. Because the rule was for this Superfund site in Bayport, Minnesota is that people who had contamination above five would have treatment systems on their private wells. She did not get it, and she died of cancer a couple of years ago. And her son asked me, you know, why is it that she did not get the protection? I cannot say. I am not a scientist, and I am not sure scientists can tell you she got sick because of that exposure or to what degree it added to the risk she faced, because we drink this stuff, breathe this stuff all over the place. But I do know that that number made a difference as to whether her water was treated for the trichloroethylene that she was drinking and was showering in and was being exposed to.

The numbers also make a difference to these polluting agencies. We found on the Web an Air Force presentation a few years back, around the time that this was all happening, that figured out that it would cost the Department of Defense $5 billion extra to clean up TCE if the standard went from five parts per billion to one part per billion for drinking water. I do not know if that is really true. There are reasons why it might not have been as high, but it might have been higher. The point is that the Defense Department's interest in this is primarily one that they are a responsible party, rather than their mission is to protect human health and the environment.

So the people that I work with, the people who are impacted, the people who are breathing and drinking the contamination of these

sites are calling on EPA to withdraw the revision that it made in the IRIS process in April because they are basically institutionalizing something that has been putting people at risk already.

And we have come up with three principles that we think the IRIS process should involve. The IRIS process is not the entire process, but it is the foundation of it. First, all stakeholders, including the affected public, private polluters, federal polluting agencies, including the Defense Department, should have the same access to the decision-making process for the assessment of hazardous substances. This notion of a deliberative process in which the federal polluters meet privately with EPA to design the studies is unacceptable.

Secondly, federally funded risk-relevant research should be managed by agencies that do not have conflicts of interest. What happened with perchlorate is that the Defense Department sponsored some research and did not like the results, so they sponsored more research to disprove it. I'm much more comfortable when the Centers for Disease Control does studies because they are not encumbered by the conflict of interest.

The third one, the entire process of assessing hazardous substances should be carried out in the sunshine, with oversight by the public, the press, and by Congress. I'm not a toxicologist or an epidemiologist. I assume that Members of this committee are not, the same, as well. We are not in a position to determine whether it should be 1, 5, or 50 for TCE, but we are calling upon you.

This is the people who are living and breathing this stuff. We are calling upon you to ensure that we have a fair, open, and timely process to evaluate not only the chemicals that we are discussing today, but the many more than impact our lives. Thank you.

[The prepared statement of Mr. Siegel follows:]

PREPARED STATEMENT OF LENNY SIEGEL

Getting the Fox out of the Henhouse: Restoring the Integrity of EPA's Process for Determining the Toxicity of Industrial and Military Chemicals

Executive Summary

The Environmental Protection Agency's Integrated Risk Information System (IRIS) is the foundation of most of the federal, State, and tribal risk management decisions that determine the safety of the air we breathe, the water we drink, and soil under our feet. The quantitative judgments embedded in IRIS may read like a foreign language or quantum physics to most Americans, but they affect our health, our environment, and our property.

Unfortunately, over the past several years, the White House and federal agencies that are among the world's greatest polluters have hijacked EPA's authority to conduct human health risk assessments. EPA's April announcement of a new IRIS process simply institutionalizes an approach—used for perchlorate and trichloroethylene (TCE)—that unnecessarily puts Americans at risk. In lay terms, the fox is now managing the henhouse.

In my prepared testimony I tell the story of trichloroethylene. Federal agencies have delayed and perhaps prevented the establishment of more protective health standards for TCE, following a pattern that appears to be a precedent for the new IRIS process. In 2001 EPA issued a Draft Human Health Risk Assessment for TCE. Though its Science Advisory Board generally endorsed that study, EPA—under pressure from the White House and federal polluting agencies—withdrew the 2001 findings. It turned the issue of TCE toxicity over to the Interagency Working Group and sent it to the National Academies of Sciences for re-review. Meanwhile, EPA scientists significantly weakened the standards they were using to guide vapor in-

trusion investigations in my community of Mountain View, California. Though in July 2006 the Academies of Sciences told EPA and the other agencies to move quickly to promulgate a TCE standard, EPA has done little.

EPA risk findings make a difference. It's the difference between response and inaction in the bedroom of Jane's son in Mountain View, California. It's the difference between water treatment and inaction in Shirley's former home in Bayport, Minnesota. According to an Air Force scientist, it's a difference of $5 billion in the cost of groundwater treatment at 1400 Defense Department sites.

People impacted by TCE, perchlorate, and other toxic substances have called upon EPA to withdraw its recent IRIS changes and instead create a process based upon the three following principles:

1. All stakeholders, including the affected public, private polluters, and federal polluting agencies, should have the same access to the decision-making process for the assessment of hazardous substances.
2. Federally funded risk-relevant research should be managed by agencies that do not have conflicts of interest—that is, agencies that will incur significant costs or encumbrances associated with more protective health and environmental standards should not control these research activities.
3. The entire process of assessing hazardous substances should be carried out in the sunshine, with oversight by the public, the press, and by Congress.

The TCE Risk Assessment

The Environmental Protection Agency's Integrated Risk Information System (IRIS) is the foundation of most of the federal, State, and tribal risk management decisions that determine the safety of the air we breathe, the water we drink, and soil under our feet. The quantitative judgments embedded in IRIS may read like a foreign language or quantum physics to most Americans, but they affect our health, our environment, and our property.

Unfortunately, over the past several years, the White House and federal agencies that are among the world's greatest polluters have hijacked EPA's authority to conduct human health risk assessments. EPA's April announcement of a new IRIS process simply institutionalizes an approach that unnecessarily puts Americans at risk. In lay terms, the fox is now managing the henhouse.

Today I am going to tell the story of trichloroethylene (TCE), the once-universal solvent that is one of the most common contaminants at both federal and private hazardous waste sites across the country. Federal agencies have delayed and perhaps prevented the establishment of more protective health standards for TCE, following a pattern that appears to be a precedent for the new IRIS process.

In August 2001 EPA issued a *Draft Human Health Risk Assessment for Trichloroethylene.* In considering the impact of the compound on young children, as well as cumulative exposures, it found that TCE was much more toxic than previously believed. In December 2002, EPA's Science Advisory Board peer review praised the "ground-breaking" assessment, finding:

> The Board advises the Agency to move ahead to revise and complete this important assessment. The assessment addresses a chemical, trichloroethylene (TCE), significant for being a nearly ubiquitous environmental contaminant in both air and water, being a common contaminant at Superfund sites, and because it is "listed" in many federal statutes and regulations. The draft assessment is also important because it sets new precedents for risk assessment at EPA. We believe the draft assessment is a good starting point for completing the risk assessment of TCE. The Panel commends the Agency for its effort and advises it to proceed to revise and finalize the draft assessment as quickly as it can address the advice provided in this report.

Meanwhile, in November 2002, EPA issued tables along with its Draft Vapor Intrusion Guidance. Vapor intrusion is the migration of volatile compounds such as TCE from the subsurface into homes, schools, offices, and other structures. Those tables included target indoor air, soil gas, and groundwater concentrations for TCE based upon the 2001 draft Risk Assessment. That Draft Vapor Intrusion Guidance remains in limbo; EPA has no plans to finalize it.

In January 2003, EPA scientists convened a public meeting in my community of Mountain View, California to discuss the emerging pathway of vapor intrusion at a number of local TCE cleanup sites. Over 400 people attended. EPA scientists explained that TCE was now considered five to 65 times as toxic as previously believed, and they introduced a screening level for TCE in indoor air, .017 micrograms per cubic meter ($\mu g/m^3$), corresponding to a one-in-a-million ("ten to the minus six")

excess lifetime cancer risk. In fact, most EPA regions adopted that number as a provisional goal.

Mountain View, California Meeting, January 2003

EPA and the Mountain View responsible parties (polluters), including the Navy and NASA, continued their vapor intrusion investigations. Testing, using the provisional screening level, showed that most of the homes at an award-winning new housing development were safe after all. However, despite the Navy's misinterpretation of site data, we were eventually able to show that military families were being exposed to unsafe levels of intruding TCE vapors in the Army-run Orion Park Military Housing Area, formerly part of Moffett (Field) Naval Air Station.

In March 2004 I attended an EPA-sponsored workshop on vapor intrusion in San Diego. I was surprised to hear there, from a Navy friend, that I shouldn't worry about the vapor levels in Mountain View. EPA—the Navy had been assured—was going to withdraw the 2001 draft Risk Assessment. And indeed, that's what happened.

Back home in Mountain View, EPA adopted an interim action level of 1.0 $\mu g/m^3$ for TCE in indoor air. EPA explained the status of the health standard in its June 2004 *Draft First Five-Year Review Report for the Middlefield-Ellis-Whisman (MEW) Superfund Study Area, Mountain View, California:*

> EPA's ORD [Office of Research and Development] and OSWER [Office of Solid Waste and Emergency Response] have requested additional external peer review of the draft TCE Health Risk Assessment by the National Academy of Sciences. Consequently, review of the toxicity value for TCE may continue for a number of years. In the interim, because of the uncertainties associated with the draft TCE Health Risk Assessment, EPA Region 9 is considering both the draft TCE Health Risk Assessment toxicity values, as well as the California TCE toxicity value (similar to EPA's previously listed TCE toxicity value from 1987), in evaluating potential health risks from exposure, and in making protectiveness determinations.

That October a high EPA official told *U.S. Today* that the agency was "not forced to go to the National Academy of Sciences." I told the same reporter that EPA's action was like "voluntarily" jumping off the railroad tracks as a speeding train approached.

The National Academies Review

EPA actually moved the TCE issue to the same Interagency Working Group that weakened EPA's drinking water guideline for perchlorate—an essential component of solid rocket fuel—from an expected 1 ppb to 24.5 ppb. I actually learned that EPA, the White House, NASA, and the Departments of Energy and Defense were following the perchlorate game plan for TCE over dinner at a perchlorate meeting in Las Vegas in September 2004. Making conversation with a gentleman sitting across the table, I found that he too had an interest in TCE. In fact, as a Department of Energy—not EPA—official, he was awarding the study contract to the National Academies of Sciences for its TCE review, just as he had done with perchlorate.

I had been at one of the Academy meetings about perchlorate, and I knew what a juggernaut of federal agencies and their contractors had weighed in calling for weaker perchlorate standards. So I encouraged people from TCE-impacted communities to attend Academy TCE Committee meetings and testify, and I was impressed by their response. For example, in March 2005 a carload of people from Endicott, New York took the day off work and drove down to DC on their own dime, and then drove back the same day, only to be caught in a Pennsylvania blizzard. In June, West Coast activists attended and spoke at the TCE Committee meeting in Irvine, California, displaying the photos of workers who died following exposure to TCE at the View-master plant in Beaverton, Oregon. People from impacted communities did not pretend to have toxicological or epidemiological expertise. They simple reported that they and their neighbors of family members had been exposed to TCE. Many had contracted serious illnesses. And they wanted the experts on the Committee to think about them, not just the well-funded testimony of polluters, when it continued its deliberations.

It was at the first Academy TCE Committee meeting that the Interagency Working Group went public—at least about TCE. A White House official introduced a panel that not only included an EPA official, but also representatives of three federal polluting agencies: NASA, the Department of Energy, and the Department of Defense. What I had known for some time was finally out in the open: Federal agencies whose primary concern about TCE was the hundreds, maybe thousands of sites for which they were responsible for cleanup, were overseeing the government's efforts to update the health risk data that would be incorporated into IRIS. That is, the foxes had been given the keys to the henhouse.

In July 2006 the Academy TCE committee issued its report. It was long and complicated, and it provided detailed advice on how to conduct additional studies. But its overall conclusion was clear:

> The committee found that the evidence on carcinogenic risk and other health hazards from exposure to trichloroethylene has strengthened since 2001. Hundreds of waste sites in the United States are contaminated with trichloroethylene, and it is well documented that individuals in many communities are exposed to the chemical, with associated health risks. Thus, the committee recommends that federal agencies finalize their risk assessment with currently available data so that risk management decisions can be made expeditiously.

So what did EPA and the Interagency Working Group do? While in early 2005 they spent only a month implementing Academy recommendations for a weaker perchlorate standard, they moved slowly on TCE, even in the face of the strong Academy recommendation. They moved so slowly that one year later Senator Clinton, Senator Dole, and three other Senators introduced legislation designed to accelerate the development of new risk data and to create an interim vapor intrusion standard for TCE. Still EPA stalled, and EPA officials told Congress that the necessarily slow process could actually lead to a less protective standard.

Finally, in April 2008 EPA announced its new IRIS process, essentially institutionalizing the informal process that it had applied to TCE, as well as perchlorate. Activists from throughout the country responded by sending the attached "Grassroots Letter" to EPA, calling EPA's action "an attempt to cement a privileged position for federal polluting agencies, in which they would have recurring, generally secret ('deliberative') input into EPA's findings." Ironically, one key provision in the new process will not apply to TCE because it cannot be a "mission-critical chemical substance." In general, federal agencies no longer use TCE, though some contractors apparently do.

It Makes a Difference

The risk data for TCE is not just an abstract principle. It makes a difference in the real world.

- My neighbor, Jane, in Mountain View, California lives across Whisman Avenue from the birthplace of the American commercial semiconductor area, now known as the Middlefield-Ellis-Whisman (MEW) Superfund Study Area. Historically, official maps showed her home just outside the five parts per billion (ppb) contour line that defined the edge of the regional TCE groundwater plume. In March 2004, she finally got EPA and the MEW Responsible Parties to test the air in her house. They found that TCE from the MEW plume was intruding into her home. TCE levels in her 11-year-old (at the time) son's bedroom was .8 $\mu g/m^3$, above the screening level EPA had originally presented to the community, but below the interim action level. Only because levels in her basement were about 4 $\mu g/m^3$, above that action level, did EPA and the companies install a ventilation system.

Jane's House, Mountain View, California

- In Bayport, Minnesota, Shirley lived down gradient of a metal-plating shop that released enough TCE to place much of the town on the Superfund National Priorities List (NPL). Shirley's private drinking water well tested TCE at 2.5 ppb in 1988. In 1999, just before she moved, her well tested at 4 ppb of TCE. In 2002, she was diagnosed with cancer. In 2005 she died. Her family wants to know, "If Shirley's well never got over 4 ppb of TCE, and she died of cancer, why is the minimum for installing wellhead treatment systems 5 ppb?" I have no way of knowing whether the TCE in Shirley's well was a primary cause of her illness. The point is that the risk management decision is a function of the Maximum Contaminant Level (MCL), which in turn is based upon IRIS data.
- In April 2003, an Air Force scientist estimated that if EPA were to lower the MCL for TCE to 1 ppb (from 5 ppb), it would cost the Defense Department an additional $5 billion in current dollars to address groundwater contamination alone at its estimated 1400 TCE sites. I'm not convinced by the Air Force calculations, but it's clear that Defense environmental officials believed that the adoption and implementation of standards based upon EPA's 2001 draft Human Health Risk Assessment would be very costly.

Shirley's Former House, Bayport, Minnesota

Three Principles

Three Principles

Neither I nor the people with whom I work, people who have been exposed to significant levels of TCE and other toxic compounds, have the expertise to determine exactly what is safe. We count upon our government, directed by you, our elected officials, to establish a fair, open process to develop risk data. We ask you to direct EPA to reverse its recent IRIS pronouncements and instead to create a new process based upon the following three principles from the "Grassroots Letter."

1. All stakeholders, including the affected public, private polluters, and federal polluting agencies, should have the same access to the decision-making process for the assessment of hazardous substances.
2. Federally funded risk-relevant research should be managed by agencies that do not have conflicts of interest—that is, agencies that will incur significant costs or encumbrances associated with more protective health and environmental standards should not control these research activities.
3. The entire process of assessing hazardous substances should be carried out in the sunshine, with oversight by the public, the press, and by Congress.

To protect our health and the health of future generations, Congress must guarantee the integrity of the IRIS process.

Grassroots Letter Attachment

April 28, 2008

Stephen Johnson, Administrator
Environmental Protection Agency

George Gray, Assistant Administrator, Office of Research and Development
Environmental Protection Agency

Dear Sirs:

On April 10, 2008, U.S. EPA's Office of Research and Development announced revisions in the process it uses to update the Integrated Risk Information System (IRIS), which provides human health risk information on more than 540 environmental contaminants—changes that allow polluters a preferential and secret seat at the table. We call on EPA to reverse those changes and instead institute a process that will level the playing field between those impacted by environmental pollution and those responsible for it.

IRIS is the data base used by EPA, state, territorial, and tribal environmental agencies throughout the United States, as well as health agencies throughout the world, to set standards that limit the release of toxic chemicals and determine objectives for hazardous waste cleanup. Though little known, IRIS's numerical values have a direct effect on the water we drink, the air we breathe, and the soil that underlies our homes, schools, businesses, and parks.

EPA states that the new IRIS process will "increase its transparency and efficiency." We believe it will instead institutionalize the growing influence of federal polluting agencies such as the Defense Department, Department of Energy, and NASA over the establishment of toxicity standards in the U.S. These agencies are the biggest contributors to toxic Superfund sites, as well as thousands of additional contaminated properties, across the country. Their recent intervention in the IRIS process has weakened and delayed EPA's findings on such widespread toxic contaminants as perchlorate, an essential component of solid rocket fuel, and the solvent trichloroethylene (TCE), which is the most common pollutant in the nation's Superfund sites. These agencies have a conflict of interest because environmental standards, based on IRIS values, restrict their operations and those of their contractors, and changes in those standards for just one high-profile substance could cost or save them billions of dollars.

The new process is an attempt to cement a privileged position for federal polluting agencies, in which they would have recurring, generally secret ("deliberative") input into EPA's findings. We believe that polluters, whether or not they are government agencies, should have no greater access to EPA risk assessors than does the public at large.

Furthermore, the federal polluting agencies will initiate targeted discussions with EPA on the development of risk assessments for chemicals that they determine to be critical to their missions. We believe that the mission-criticality of a substance has nothing to do with its toxicity, which is and should be based on science.

EPA, under pressure from the Bush White House, has given the foxes the keys to the

environmental protection henhouse. We call upon EPA and the Bush Administration to abandon these revisions to IRIS and instead adopt an approach that generates and applies rigorous, independent, and timely assessments of chemicals that impact human health and the environment, based upon the following three principles:

1. All stakeholders, including the affected public, private polluters, and federal polluting agencies, should have the same access to the decision-making process for the assessment of hazardous substances.

2. Federally funded risk-relevant research should be managed by agencies that do not have conflicts of interest—that is, agencies that will incur significant costs or encumbrances associated with more protective health and environmental standards should not control these research activities.

3. The entire process of assessing hazardous substances should be carried out in the sunshine, with oversight by the public, the press, and by Congress.

Our health and the health of future generations depend upon it.

Sincerely,

In alphabetical order by last name
*For identification purposes only

Sarah Anker, President, Community Health and Environment Coalition, Mt. Sinai, NY

Cal Baier-Anderson, Environmental Defense Fund

William Preston Bowling, Executive Director, Aerospace Cancer Museum of Education, Chatsworth, CA

Andrea Byron, The Few, The Proud, The Forgotten www.tftptf.com Trenton, OH

Jeff Byron, Camp Lejeune Community Assistance Panel,* The Few, The Proud, The Forgotten www.tftptf.com Fairfield, OH

Mary Byron, The Few, The Proud, The Forgotten www.tftptf.com Fairfield, OH

Alise Cappel, Environmental Law Foundation, Oakland, CA

Ken and Regina Deschere www.Ithaca-SHIP.org Ithaca, NY

Barry Durand, Weaverville, NC

J. M. Ensminger, Camp Lejeune Community Assistance Panel,* The Few, The Proud, The Forgotten www.tftptf.com Richlands, NC

Amanda Evans, Founder and Board President, Victims of TCE Exposure www.victimsofteexposure.org and View-Master Health Study Citizens Advisory Group,* Hillsboro, OR

Neil Fischbein, The TCE Blog

Debra Hall, Hopewell Junction (NY) Citizens for Clean Water

Theodore Henry, Westminster, MD

Gina Horecky, Citizens Advisory Group (under EPA)*, Mills Gap Road Groundwater, Asheville, NC

Glen Horecky, Chairman of Citizens Advisory Group (under EPA)*, Mills Gap Road Groundwater, Asheville, NC

Jane Horton, Mountain View, CA

Sue Hughes, United Neighbors Improving Tomorrow's Environment (UNITE), Royalton, NY

Layna LaBarge, Hopewell Junction (NY) Citizens for Clean Water

Larry Leroy Ladd, Community Advisory Group for Aerojet Superfund Site Issues,* http://www.perchlorate.org Rancho Cordova, CA

Tim Leed, Save Wiccopee Organization www.wiccopee.org

Dee Lewis, National Disease Clusters Alliance www.clusteralliance.org

Jim Little, Endicott, NY

Denita McCall, Camp Lejeune (NC) Community Assistance Panel*

Jill McElheney, MICAH's Mission (Ministry to Improve Childhood & Adolescent Health), Winterville, GA

Carol Meschkow, President, Concerned Citizens of the Plainview-Old Bethpage Community, NY

Emily Monosson, Montague MA

Mary Moore, Vice President, Lindon Park Neighborhood Association and Community Advisory Group member, Motorola 52nd Street Superfund Site*, Phoenix, AZ

Bob Moss, Community Co-Chair, Moffett Field Restoration Advisory Board* and Board of Directors, Barron Park Association Foundation

Dave Ness Jr., Bayport, MN

Robert J. O'Dowd, www.mwsg37.com Somerdale, NJ

Laura Olah, Executive Director, Citizens for Safe Water Around Badger, Merrimac, WI

Bruce Oldfield, Co-Chair, New York Vapor Intrusion Alliance, Binghamton, NY

Paula Orellana, The Few, The Proud, The Forgotten, Chambersburg, PA

Mike Partain, Community Assistance Panel Member,* Camp Lejeune, NC

Julianne Rizzo, United Neighbors Improving Tomorrow's Environment (UNITE), Royalton, NY

Lenny Siegel, Executive Director, Center for Public Environmental Oversight www.cpeo.org

Bob Spiegel, Edison (NJ) Wetlands Association

John Uldrich, Chairman, Uldrich-Integris Media Inc.

Christina Walsh, Executive Director, www.Cleanuprocketdyne.org Chatsworth, CA

Laura Ward, President, Family Oriented Community-United Strong (FOCUS), Tallevast, FL

Wanda Washington, Vice-President, Family Oriented Community-United Strong (FOCUS), Tallevast, FL

Richard Wiles, Executive Director, Environmental Working Group

Bill Wolfe, Director, New Jersey Public Employees for Environmental Responsibility (PEER)

Shirley's Former House, Bayport, Minnesota

Getting the Fox out of the Henhouse:

Restoring the Integrity of EPA's Process for Determining the Toxicity of Industrial and Military Chemicals

Lenny Siegel
Center for Public Environmental Oversight

Testimony before the
Investigations and Oversight Subcommittee
House Science and Technology Committee
June 12, 2008

January 2003 meeting in Mountain View, California

Jane's house in Mountain View

Shirley's former house in Bayport, Minnesota

1. All stakeholders, including the affected public, private polluters, and federal polluting agencies, should have the same access to the decision-making process for the assessment of hazardous substances.

2. Federally funded risk-relevant research should be managed by agencies that do not have conflicts of interest—that is, agencies that will incur significant costs or encumbrances associated with more protective health and environmental standards should not control these research activities.

3. The entire process of assessing hazardous substances should be carried out in the sunshine, with oversight by the public, the press, and by Congress.

Lenny Siegel

Center for Public Environmental Oversight

c/o PSC, 278-A Hope St., Mountain View, CA 94041

Voice: 650/961-8918 — Fax: 650/961-8918

lsiegel@cpeo.org — http://www.cpeo.org

BIOGRAPHY FOR LENNY SIEGEL

Education:

Valedictorian, Culver City High School, Culver City, California, 1966
Stanford University (Physics), 1966–1969

Employment:

Pacific Studies Center, Mountain View, Director, 1970–present
Center for Public Environmental Oversight (CPEO), Executive Director, July, 1994–present

Teaching Experience:

UCLA Department of Urban Planning, Guest Professor, Spring, 1995 and Winter, 1997
UC–Berkeley Extension, Guest Lecturer, "Strategies for Site Remediation: A Case Studies Approach," Winter, 1995, 1996, and 1997; Fall, 1998
Council of Energy Resource Tribes, Guest Lecturer, "Mitigation of Environmental Impacts to Indian Lands due to Department of Defense Activities," Summer, 1994 and 1995

Award:

U.S. Environmental Protection Agency, Region 9, Environmental Achievement Award, November, 2001

Sample Publications:

"Independent Review of the Draft Site Management Plan for the Mott Haven Schools Complex Bronx, New York," March, 2008; "Community Perspectives on VOC Response at Department of Defense Installations," September, 2007; "Independent Review of the Cleanup of the Mott Haven Schools Complex, Bronx, New York," January, 2007; "Homes, Schools, and Parks: Where, When, and How to Build on Contaminated Sites," December, 2006; "Gulf Coast Reconstruction: The Biggest 'Brownfield,'" October, 2005: "A Stakeholder's Guide to 'All Appropriate Inquiries,'" August, 2005.

"Vapor Intrusion: The New Frontier of Toxic Cleanup," (BNA, September, 2004); *Stakeholders' Guide to Munitions Response* (Spring, 2004); *Stakeholders' Guide to Federal Facilities Cleanup* (Summer, 1997); *Military Contamination and Cleanup Atlas for the United States—1995* (September, 1995); *Covering The Map: A Survey of Military Pollution in the United States* (May, 1993); *Citizens' Guide to Military Base Clean-Up and Conversion* (September, 1993). He is also a contributor to *Community Risk Profiles: A Tool to Improve Environment and Community Health* (Rockefeller University, April, 1995). For additional publications, see *http://www.cpeo.org/pubs/pub.html*

Consulting Experience

Council of Energy Resource Tribes
Kaho'olawe Island Reserve Commission
Military Toxics Project
New York Lawyers for the Public Interest
Physicians for Social Responsibility–Los Angeles Office
RAND Corporation
Rockefeller University Program on the Human Environment
Silicon Valley Toxics Coalition

Committees (italicized are current):

Air Combat Command Project on Streamlined Oversight, External Review Group
ASTM/ISR Brownfields Steering Committee
California Base Closure Environmental Advisory Group
California Brownfields Reuse Advisory Group (Co-Chair)
California CLEAN Loan Committee
California Site Mitigation Update advisory group

California Superfund Working Group
Clean Sites Independent Review of Program Performance, Defense Environmental Restoration Program, Blue Ribbon Review Panel
Community Environmental Health Assessment Project Steering Committee, National Association of City and County Health Officials
Compliance Assistance Advisory Committee (U.S. EPA)
Defense Science Board Task Force on Unexploded Ordnance Clearance Operations
Department of Toxic Substances Control (California) External Advisory Group
Federal Facilities Environmental Restoration Dialogue Committee
Interstate Technology & Regulatory Council Perchlorate Work Team
Interstate Technology & Regulatory Council Vapor Intrusion Work Team
Moffett Naval Air Station Restoration Advisory Board
National Environmental Justice Advisory Council Subcommittee on Waste and Facility Siting
National Environmental Justice Advisory Council Federal Facilities Working Group
National Policy Dialogue on Military Munitions
National Research Council Committee on ACWA Secondary Wastes
National Research Council Committee on Army Non-Stockpile Chemical Demilitarization Program (three iterations)
National Research Council Committee on Environmental Remediation at Naval Facilities (two iterations)
Northeast Mountain View Advisory Council (Board member)
Peer Review Panel for the VOC Historical Case Initiative
Range Rule Partnering Team
Range Rule Risk Methodology Partnering Team
Western Region Hazardous Substance Research Center Outreach Advisory Committee

Chairman MILLER. Thank you, Mr. Siegel. Not only am I not a toxicologist, I could not pronounce the chemical.

Dr. Greer.

STATEMENT OF DR. LINDA E. GREER, DIRECTOR, HEALTH PROGRAM, NATURAL RESOURCES DEFENSE COUNCIL

Dr. GREER. Good morning, and thanks for the opportunity to testify. I am a toxicologist. I direct the health program at the Natural Resources Defense Council, where I have been for 15 years, and I have watched the EPA's evaluation of toxic chemicals for many years, both in my capacity as the director of the health program at NRDC, as a member of the executive committee of EPA's Science Advisory Board, where I served for six years, and on many committees at the National Academy of Sciences, including, most recently, the Committee on Emerging Issues in Toxic Chemicals. I commend you, Mr. Miller, for your interest in the IRIS review process, and more specifically, in your concern in the Committee's concern about the recent changes that have been made to this program.

IRIS is, as you have said, as cornerstone program at EPA, which provides the scientific information necessary to develop our nation's air and drinking-water standards as well as hazardous-waste clean-up levels. The changes that are the subject of today's hearing are yet another escalation of the Administration's war on science and public health that has gone on for nearly eight years. It's a record of political interference with the work of government scientists across a range of environmental issues, including global warming or even endangered species, has been well established. Things are no better in the case of analyzing and regulating toxic

chemicals that pose a risk to health. In this area, the Administration has attempted and in some cases succeeded in blocking, weakening, and delaying health standards for a very long list of pollutants, including arsenic, mercury, lead, benzene, perchlorate, formaldehyde, particulates and ozone, and of course, trichloroethylene. In addition, the Administration has weakened the public's right to know about the release of toxic chemicals into their community.

Thus, the recent changes to the IRIS program that are the subject of today's hearing are properly viewed as one part of a much broader agenda to sacrifice public health protections and limit public understanding of the risk of toxic chemicals in a manner that benefits a host of polluting industries and federal agencies.

For many years, IRIS assessments were developed by EPA scientists. Drafts were released simultaneously for public comment and external independent peer review. OMB and government agencies, such as DOD or DOE, who sometimes had a stake in the outcome of the evaluation because of their obligation to address contamination at their facilities, had an opportunity to review and comment on the draft when it was released for public comment. These procedures allowed EPA scientific experts to create and own the assessment and kept influence by government agencies with polluter profiles to a minimum. The new process established by the White House turns this process on its head. It invites interference by OMB and other agencies, both at the onset of the process, in the middle, and at the bitter end—a license-to-kill, so to speak—if the process did not end as they wished.

Importantly, these newly introduced intervention points are considered deliberative, and hence shielded from public view, forcing EPA to respond to concern behind closed doors, and alarmingly the new opportunities are not limited to data critiques. One particularly misguided new feature offers agencies outside of EPA up to two years to undertake their own additional studies of "mission critical" chemicals, suspending EPA's evaluation of these contaminants for a very substantial period of time while they take advantage of this opportunity to delay a potential day of reckoning.

Although current EPA leadership argues that the new process was developed in order to provide "greater transparency, objectivity, balance, rigor, and predictability" to the IRIS assessment, we would characterize these changes quite differently. In our view, the new process is designed precisely to give the polluting agencies more access, more opportunity for delay, and more influence to what has historically been an objective scientific evaluation process and to allow these opportunities to occur behind closed doors, hiding the exercise of that influence from public view.

In fact, if one's intention was to design a new system that would deliver greater influence to government agencies with pollution problems over EPA rules, it would be hard to think of a system that would be better than this one. The claim that the new process will result in a more balanced and objective result simply does not pass the laugh test.

Before closing, I would like to turn briefly to the issue of timeliness, which as we have seen from our other witnesses, is a real problem in the IRIS program. The IRIS program has always struggled to keep pace with EPA's regulatory needs and many environ-

mental contaminants lacking IRIS assessments are quite important to public health, TCE, for one, perchlorate for another. There is no IRIS risk assessments for nearly one-third of the 189 hazardous air pollutants, for example. Furthermore, even where important chemicals are in the IRIS database, the risk assessments available for many of these chemicals are outdated. The average assessment on IRIS is over 13 years old with the oldest having not been significantly revised since the mid-1980's, and, as has been mentioned, these problems greatly exacerbate the already long period of time required for EPA standard-setting procedures, up to a decade in some cases, and have been the focus of criticism for some time.

Clearly, constructive reform of the IRIS program is needed and constructive reform would focus on increasing resources available to undertake IRIS reviews as well as policy changes that would streamline the difficult decision-making inherent in the process. The new procedures run completely counter to these goals and will only exacerbate the backlog. Properly implemented, the EPA IRIS program provides a crucial scientific service to the public, and I emphasize speed is important but scientific integrity is paramount. These changes hit IRIS on both fronts in a terrible way, slowing the process further and compromising its content. We request that the Science Committee and the Subcommittee work with other House colleagues to ensure that the new IRIS process is overturned or withdrawn and that you require IRIS health assessments to be reviewed in an open process without inappropriate political interference. Thank you very much for this opportunity to testify.

[The prepared statement of Dr. Greer follows:]

PREPARED STATEMENT OF LINDA E. GREER

Good morning and thank you for this opportunity to testify on the failure of the EPA IRIS program to serve the needs of the public.

My name is Linda Greer, and I direct the Health Program at the Natural Resources Defense Council, where I have worked for more than fifteen years. I have a Master's degree in public health and a Ph.D., in environmental toxicology. I have watch-dogged EPA's evaluation of toxic chemical hazards and risks for many years, both in my capacity as the Health Program Director at NRDC and as a member of the Executive Committee of EPA's Science Advisory Board, where I served for six years. I have also served on many committees of the National Academy of Sciences, including most recently the Committee on Emerging Issues in toxic chemicals and served on the NAS Board on Life Sciences from 2001–2004. The Natural Resources Defense Council (NRDC) is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Founded in 1970, NRDC has 1.2 million members and online activists, served from offices in New York, Washington, Chicago, Los Angeles, San Francisco and Beijing.

NRDC's Health program focuses on toxic chemical pollutants in air, water, food, and shelter. Over the years, we have focused our particular attention on the "biggest pollutants" in these media, the ones disproportionately responsible for the biggest threats to human health. This has led to successful efforts to substantially reduce diesel air emissions from trucks and buses, for example, and to take a number of dangerous and outdated pesticides off the market. There are more than 70,000 chemicals in commerce, but some are much more toxic than others, and we can make great progress in environmental health protection if eve focus on the chemicals pollutants that pose the greatest threat to human and ecological health.

We commend the Science and Technology Committee and this subcommittee for its interest in the EPA Integrated Risk Information System (IRIS) chemical review process and its oversight of recent changes made by EPA and the Bush Administration. These changes are yet another escalation of the Administration's war on science and public health that has gone on for nearly eight years. Its record of political interference with the work of government scientists across a range of environ-

mental issues including global warming and endangered species has been well-established. Things are no better in the case of analyzing and regulating toxic chemicals that pose a risk to public health. In this area, the Administration has attempted (and in some instances succeeded) to block, weaken, or delay health standards for a long list of dangerous pollutants including arsenic, mercury, lead, benzene, perchlorate, formaldehyde, particulates and ozone. In addition, the Administration has weakened the public's right to know about the release of toxic chemicals into their communities.

Thus, the recent changes to the IRIS process that are the subject of today's hearing should properly be viewed as one part of a much broader agenda to sacrifice public health protections and limit public understanding of the risk of toxic chemicals, in a manner that benefits a host of polluting industries and federal agencies. Indeed, by attempting to weaken the IRIS process, the Administration has zeroed in on one of the earliest and most fundamental steps in the process of protecting public health, that in which EPA's scientists identify the health risks posed by exposure to certain chemicals. The Committee's hearings should preface Congressional action to reverse the recent changes to the IRIS process and ensure the integrity and effectiveness of the program is restored.

The importance of the IRIS database

The IRIS database is a publicly available database which contains EPA's evaluation of potential human health effects from exposure to more than 540 chemicals, including highly hazardous chemicals such as vinyl chloride, butadiene, benzene, lead, mercury, and asbestos.[1] While these evaluations are not regulations *per se,* they are used by both State and federal regulators and by the international community for a range of environmental health regulation and management purposes. For example, the information can be used in combination with exposure data to set cleanup levels at hazardous waste sites, or to set exposure standards for air, water, soil, and food. Thus, the accuracy, credibility, and timeliness of IRIS assessments have real world consequences for human health.

The global importance of this database cannot be overstated. For example, in May, 2008 alone, the IRIS website received almost 25,000 requests (an average of over 800 per day), from over 2,000 separate computer sources and from over 60 different countries.[2]

IRIS conducts scientific assessments, not policy documents

Risk assessments involve the integration of hazard identification, dose-response assessment, and exposure assessment to estimate the probability (likelihood) of harm. Rather than conducting entire risk assessments, the IRIS program is limited to conducting hazard identification and assessing dose-response relationships for environmental chemicals; EPA factors in exposure scenarios and risks under its regulatory programs.

Hazard identification, the first step in a risk analysis, determines whether or not the substance of concern is likely to have adverse health effects. This step requires a thorough review of relevant toxicologic data and may include human epidemiology, whole animal studies, non-animal data, and field data. The result is a scientific determination of whether or not a substance causes adverse health outcomes such as cancer, neurological disease, birth defects, or death. Since reliable human data is often not available, hazard evaluations generally rely heavily on identifying whether the substance is toxic in animals or other test systems.

The dose-response assessment follows hazard identification and is designed to identify safe levels of exposure for chemicals that pose harm. This assessment consists of scientifically characterizing the relationship between the amount of exposure (dose) and the incidence of an adverse health endpoint. Methodologies for dose-response assessment often differ between cancer and non-cancer effects and between acute and chronic exposure scenarios. They are often scientifically controversial, because they must extrapolate from high experimental doses to more typical ambient exposure levels.

Ideally, epidemiological data would be available that clearly illuminate the hazards and the dose-response relationships for chemicals of concern in human populations. Unfortunately, this is nearly never the case. Most chemicals lack key studies of effects in humans as well as studies of effects in animals at ambient levels.

---

[1] Integrated Risk Information System (IRIS) *http://cfpub.epa.gov/ncea/iris/index.cfm*

[2] IRIS (Integrated Risk Information System). Web Statistics for iriswebp. Washington, DC: U.S. Environmental Protection Agency. Available: *http://www.epa.gov/reports/objects/iriswebp/iriswebp/iriswebp*

As a result, IRIS assessors are called upon to make informed judgments regarding the relevance of the animal data to humans, and to select the most appropriate extrapolation method. Further, the IRIS assessments require independent expert judgment to decide whether various safety factors should be applied to assessment data to ensure public health protection. For example. EPA often decides to include margins of safety to protect vulnerable populations, relevant genetic variations, vulnerable life stages, disease states, concomitant exposure to complex mixtures, and other relevant factors that may influence the probability of an effect caused by exposure to the substance of concern.

Importantly, decisions made in the IRIS program are informed by various EPA guidance documents that are publicly-available and publicly-documented, and have been publicly-vetted. Reliance on these important guidance documents is crucial to ensure that evaluations are consistent across substances and as objective as possible.

The new process established by the White House turns this process on its head: it invites the injection of non-scientific considerations into the IRIS assessments, and further, it shields from public scrutiny the input from other parts of the government with a potential financial or political interest in the outcome of a particular assessment. When political appointees, perhaps acting on behalf of regulated industries, and polluting agencies are able to interfere in a non-transparent and inappropriate manner, the whole process is severely compromised.

Summary of the new process

The new 2008 IRIS process introduces three new opportunities for OMB and other non-health agencies to weigh in on EPA's health assessments, where previously there was only one. Importantly, interagency comments and OMB comments for all three of the new intervention points are shielded from public view: the first two bites at the apple, and the last one. Thus, whereas the pre-2004 IRIS process provided the agencies and OMB with the draft assessment at the same time as it was provided to the public, the new process injects polluting agencies such as DOD and DOE into the assessment process at an earlier stage, and forces the IRIS staff to address the interests of the agencies and OMB, whether they are consistent with health-protective policies or not. These exchanges take place out of the public eye. Following this negotiation, the draft review is publicly noticed. But then there is a final intervention point provided to OMB and the other agencies that require that the IRIS staff to resolve any outstanding concerns by OMB and the other agencies, including polluting agencies, before the assessment can be finalized. While the 2008 process boils down to 'death by a thousand cuts,' this ability to have the last word—and to axe an assessment at the bitter end—may be the deepest cut of all.

The U.S. Government Accountability Office (GAO) recently released its review of the new process, in a report entitled: *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System.*[3] This report provided a detailed and highly critical assessment of the failures of the IRIS program to meet its deadlines and requirements, blaming in large part the interference by polluting agencies and political appointees. The GAO report predicts that the new process will produce IRIS assessments that lack credibility, and will worsen what is already a critical backlog of new and updated assessments. NRDC agrees with the GAO evaluation, whose many findings validate our years of work to right this cornerstone program for public health protection.

For many years, IRIS assessments were developed by EPA scientists. Drafts were released simultaneously for public comment and external (independent expert) peer review. OMB and government agencies such as DOD or DOE, who sometimes had a stake in the outcome of the evaluation because of their obligations to address contamination at federal facilities, had an opportunity to review and comment on the draft when it was released for public review and comment.

---

[3] United States Government Accountability Office. *Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System.* Report to the Chairman, Committee on Environment and Public Works, U.S. Senate. Report No. GAO–08–440; March 2008. Available at *http://www.gao.gov/new.items/d08440.pdf*

A summary of the report is also available online at: Toxic Chemicals: *EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals,* GAO–08–743T, April 29, 2008. Summary at *http://www.gao.gov/docsearch/abstract.php?rptno=GAO-08-743T*

Table 1: A comparison of the new and previous (pre-2004) process to conduct and review chemical assessments for the IRIS program

NEW PROCESS	COMPARISON WITH PREVIOUS PROCESS
Scientific literature review (60-90 days)	No significant change
Data call-in (45-60 days)	New
IRIS staff develops a Draft Qualitative Assessment (without any quantitation)	New. In the past, qualitative and quantitative assessments had been presented together; the new process adds an extra assessment to the review cycle
Draft Qualitative Assessment must pass ORD clearance	New
Draft Qualitative Assessment must undergo Inter-Agency review and comments. Comments are deliberative.	New. Note that neither the draft nor the agency comments are publicly accessible and that Inter-Agency review is not restricted to health agencies.
Public release of Draft Qualitative Assessment for public and interagency review and comment (45-60 days)	New
Federal Agencies identify mission critical chemicals	New
Interagency evaluation to close data gaps for mission critical chemical: Agencies can submit a research plan for 'closing data gaps' for mission critical chemicals (90 days)	New
Proposed research and peer review conducted for mission critical chemical; development of new studies (up to 540 days)	New
IRIS staff completes Draft IRIS Toxicological Review (both qualitative and quantitative chapters), addressing public and interagency comments (120-270 days)	No significant change
Interagency review (45-105 days) For mission critical chemicals, EPA cooperates with other agencies to determine peer review process (eg, NAS, SAB); OMB/Interagency review of peer review charge	New
External (independent expert) peer review and public comment (120-280 days)	No significant change
IRIS staff address peer review and public comments, revises IRIS Tox Review and develops IRIS Summary (120-150 days)	No significant change
IRIS staff initiates final OMB/ interagency review and approval of IRIS Tox Review and IRIS Summary (30-45 days)	New to include OMB and interagency approval at this point.
IRIS staff addresses and resolves OMB/interagency remaining issues in consultation with OMB and other agencies. EPA makes final decision.	New to include OMB consultation and approval at this point. Used to be Agency review and clearance only.
EPA completes IRIS Tox Review and IRIS Summary (60 days)	No significant change

The new IRIS process introduces significant new steps that are both time-consuming and undermine the objectivity and transparency necessary for credible and valid assessments (see Table 1). Significant aspects of the new process are as follows:

1. In the 2008 process, IRIS staff is now required to develop a qualitative draft assessment, prior to the quantitative assessment, which must undergo both public and interagency review. This qualitative draft serves as a summary of the scientific literature that the staff intends to rely on to supports its assessment. Although this procedure sounds benign, it seriously compromises the timeliness and transparency of the IRIS program. First, it allows other government agencies to delay an assessment far nearly two years to do additional research on any chemicals that an agency deems to be "mission critical," thereby significantly stalling the start of the formal IRIS evaluation. Even more alarming, the comments and submissions of the other agencies to the qualitative draft are considered 'deliberative' which, if unchallenged or upheld by the courts, would shield the comments from public scrutiny.
2. In the new 2008 process, agencies outside of EPA are invited to designate chemicals as 'mission critical' and to intervene in the IRIS assessment of these chemicals. Mission critical chemicals are defined as those that are, "an integral component to the successful and safe conduct of an Agency's mission in any or all phases of its operations. Impacts on use of mission critical chemicals include cessation car degradation of the conduct of the mission *and/or unacceptable resource constraints."* [emphasis added] In other words, "mission critical" chemicals includes not only those that are vital and have no viable substitute, but also those where the potential cost to an agency of cleaning up a pollution mess it (or its contractors) have created is "unacceptable" or where potential future limitations on use (such as stricter exposure standards) are deemed too expensive by the agency. These are exactly the kinds of policy considerations that should *not* be allowed to intrude on the IRIS assessment process.
3. Following the quantitative draft, the IRIS staff develops the draft quantitative assessment (the Toxicological Review). This is subjected to public and interagency review, followed by external (independent expert) peer review. The important difference is that prior to 2004, this represented the first and simultaneous opportunity for both the public and the other agencies to comment, with all comments publicly accessible. By contrast, with the 2008 process this is now the second public comment. opportunity, and the third OMB/interagency intervention point, but the first where the OMB/interagency comments would be publicly accessible.
4. Finally, before the IRIS assessment can be finalized and publicly released, the 2008 process requires OMB and interagency approval. The pre-2004 process had only required internal agency review. This 2008 process invites the fourth and final opportunity for OMB/interagency interference with the evaluation. Although the new process says that EPA has the power to make the final decision, it is clear that the other agencies and OMB will have significant access and influence over the final editing choices.

Although current EPA leadership argues that the new process was developed in order to provide "greater transparency, objectivity, balance, rigor and predictability"[4] to the IRIS assessments, we strongly disagree. In fact, the administration's claims are Orwellian. This new process is designed precisely to give the polluting agencies more access and more influence to what has historically been an objective scientific evaluation process—and to add at least two or more years to the review of mission critical chemicals.

To put it plainly, in this new proposal, the Administration is attempting to provide those agencies with the most at stake in the degree of protection established for a particular chemical multiple opportunities to weigh-in and influence the outcome of EPA's decisions, while hiding the exercise of that influence from the public. The Administration's claim that, for example, providing the Department of Defense multiple opportunities to weaken or delay setting a health standard for TCE—a chemical for which DOD is responsible of widespread contamination of drinking water—completely outside of public view, will result in a more balanced and objective result, doesn't pass the laugh test.

The EPA leadership further claims that the outcome of the new process is expected to 'streamline' the IRIS process and make it more 'transparent.' Again, we

---

[4] Revised IRIS Process Question & Answers (pdf). *http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190045*

EPA announces improvements to IRIS process. EPA press release, 04/10/2008. *http://yosemite.epa.gov/opa/admpress.nsf/03dd877d6f1726c28525735900404443/1365469639099e6585257427005bb22a!OpenDocument*

strongly disagree. The new process allows public review at only one stage, which is review of the qualitative draft. All other evaluation steps occur behind closed doors, shielded from accountability to the public or other more objective, outside scientific experts.

It is indicative of the Administration's disregard for public input on its changes to the IRIS process, and its eagerness to put them in place, that OMB admonished GAO for being so critical of a draft proposal, and assured the GAO that "[i]ndeed, the process will not be complete until EPA circulates its draft to the public for comments and then releases a final product that is responsive to those comments." Assurances notwithstanding, some six weeks later the Administration finalized this deeply flawed proposal without any opportunity for public review or comment. This short-circuiting of the public comment process does not square with the principles of public right-to-know, or EPA's lip service in support of an open and transparent process.

Backlog at IRIS: Timeliness is already a terrible problem that cannot bear to be compounded by further delay

In the U.S., there are about 8,000 chemicals in commerce deemed "economically significant" (i.e., produced or imported at a rate greater than 10,000 pounds per site annually). Unfortunately, only about 550 chemicals in total have been evaluated in the IRIS program. Even when compared just to the universe of chemicals regulated by EPA, IRIS is obviously failing to adequately serve the public's needs. For instance, the EPA is responsible for regulating the emissions of 188 hazardous air pollutants (HAPs) under the *Clean Air Act,* but only 129 of them appear in the IRIS database. In other words, in almost 20 years since. IRIS was created, the EPA has been unable to complete Toxicological Reviews for nearly one-third of these dangerous pollutants.

Furthermore, even when important chemicals are in the IRIS database, the risk assessments available for many of these chemicals are outdated: the average assessment on IRIS is over 13 years old, with the oldest having not been significantly revised since the mid-1980s. Considerable new evidence of toxicity has emerged for many of these chemicals since their last assessment, which renders tile conclusions potentially obsolete and limits their usefulness and credibility with regulatory agencies.

According to the IRIS website, the program has finalized only thirteen assessments since 2004. As GAO notes "[t]he IRIS database is at serious risk of becoming obsolete because EPA has not been able to routinely complete timely, credible assessments or decrease its backlog of 70 ongoing assessments." [5]

Consider for example *Trichloroethylene* (TCE), a solvent used as a degreasing agent. TCE is one of the roost common contaminants of Superfund sites across the Nation, primarily from military uses, and is linked to cancer, including childhood cancer, and birth defects.[6] The IRIS draft was initiated a decade ago, in 1998. In 2001, EPA concluded that TCE was "highly likely" to cause cancer and specifically noted the added health risks when exposures took place during childhood. Finalization of that assessment has been held up after repeated objections from military contractors and the Department of Defense. Finally it was reviewed by the National Academies, which issued their report in July 2006, finding that the data linking TCE with cancer was even stronger than EPA IRIS staff had determined, and recommending that the IRIS assessment be finalized as soon as possible. Nonetheless, the Defense Department continued to insist that it not be finalized until more data was available, and today the assessment has still not been finalized.

Clearly, constructive reform for the IRIS program would focus on increasing resources available to undertake IRIS reviews as well as policy changes that would streamline the difficult decision-making inherent in the process. The new procedures run completely counter to these goals and will only exacerbate this backlog.

Delays to IRIS assessments result in continued unsafe exposures to humans and wildlife

Setting a health assessment standard under IRIS is only the first step in a long regulatory process. For example, for the EPA to establish a national drinking water standard, the Agency would typically reach out to stakeholders for input and perhaps even convene a Federal Advisory Committee, which could take over a year. Ad-

---

[5] Toxic Chemicals: *EPA's New Assessment Process Will Increase Challenges EPA Faces in Evaluating and Regulating Chemicals,* GAO–08–743T, April 29, 2008. Summary at *http://www.gao.gov/docsearch/abstract.php?rptno=GAO-08-743T*

[6] ATSDR ToxFAQs for trichloroethylene. *http://www.atsdr.cdc.gov/tfacts19.html*

ditionally, the docket for a proposed rule could remain open for at least a few months to collect comments from the public. Depending on the extent of the comments received, the Agency could again take up to a year or more to address and respond to those comments. In the end, it could take the Agency years, even decades, to finalize a drinking water regulation.

As new or updated IRIS assessments continue to languish, or get weakened to satisfy the demands of OMB and federal agencies including the Department of Defense and Department of Energy, the process of setting health standards becomes unspeakably prolonged. And the public continues to suffer due to lack of adequate public health protections.

For example. the Administration has successfully blocked a much needed update of the IRIS assessment for formaldehyde. An updated assessment reflecting recent science that shows greater health hazards posed by formaldehyde could ultimately be the basis of establishing stricter emissions or exposure limits from building materials and other sources. Meanwhile, people living in temporary trailers provided by FEMA after Hurricane Katrina have complained of a host of illnesses they believe are related to the high levels of formaldehyde which they have been exposed to in those trailers.

Similarly, delay in IRIS has contributed to an inexcusable failure to develop a national health-protective standard for perchlorate, a component of rocket fuel and other explosives, in drinking water. Scientific evidence is overwhelming that exposure to perchlorate, an iodine uptake inhibitor in the thyroid gland, can cause significant development problems for developing infants. Subtle alterations of thyroid hormones during pregnancy—even within the normal range—have been associated with decreased intellectual and learning capacity in childhood.

Approximately 350 public water systems serving over 41 million have reported perchlorate detections.[7] The source of the contamination at many of these sites is defense and aerospace facilities and military installations.[8] The Defense Department mounted a years-long battle, and elicited White House support, against IRIS draft assessments in 1998 and in 2002 that had determined that even low doses of perchlorate may be harmful to early development of the human brain.[9] The final IRIS assessment was not completed until 2005. Due to the year's long delay in assessing and quantifying the harm posed by perchlorate in the IRIS program, the public remains years away from a national drinking water standard that will protect their health.

Objectivity and transparency of IRIS review is paramount

IRIS assessments must be shielded from political interference and be open to public scrutiny to ensure their scientific rigor and adherence to public health protective policies.

Under the new IRIS process, polluting federal agencies are provided excessive and redundant opportunities to intervene in the development of the IRIS assessments, shielded from scrutiny by the scientific community and the public. This is indefensible. The IRIS assessments and the comments provided by federal agencies, academics, industry, public interest groups, the general public, and others regarding drafts are supposed to be about science. The Administration has no reason for insisting upon secrecy other than to shield injection of politics and policy into the scientific debate, and avoid public airing of scientific arguments that won't stand up to public scrutiny.

Political appointees in the EPA undermine EPA's mandate to protect human health and the environment

The Director of the IRIS program, George Gray, is clearly subverting the mission of the EPA in the development of the new IRIS process, essentially carrying out the mission of the OMB instead. Gray, who is EPA Assistant Administrator for the Office of Research and Development, was previously the Director of the Harvard Center for Risk Analysis, a seemingly prestigious academic center but one quite notorious for its extensive support from with corporate money and its tendency to promote industry perspectives in environmental health policy deliberations. With Gray holding direct management power over the IRIS program, the Administration has

[7] U.S. EPA Unregulated Contaminant Monitoring Rule (UCMR) database, January 2005 data release, and data collected by State agencies in Arizona, California. Texas, and Massachusetts.

[8] *Wall Street Journal* online. Inside Pentagon's Fight to Limit Regulation of Military Pollutant. Peter Waldman. December 29, 2005.

[9] *Wall Street Journal* online. Inside Pentagon's Fight to Limit Regulation of Military Pollutant. Peter Waldman. December 29, 2005.

ensured that EPA resistance to the agenda of undermining public health protections will be minimal, and, more often, will be aided by its political appointee.

A documented example of Gray's role in blocking the work of his own IRIS staff is the case of the Toxicological Review of tetrachloroethylene also known as perchloroethylene (perc), a dry cleaning and degreasing chemical and widespread groundwater contaminant. The IRIS assessment was initiated in 1998. In 2006 *Risk Policy Report* revealed that George Gray was insisting that his staff re-analyze the cancer risks of the chemical to try to fit the data to a model that would have assumed (without scientific evidence) that low doses were safe, whereas the staff's careful review of all available data did not support this assumption.[10] In addition, Gray's directive contradicts EPA's established, peer-reviewed cancer guidelines. Had the IRIS staff complied with Gray's directive, it would have resulted in a less-protective assessment. This assessment has still not been updated.[11]

In short, the political appointee currently in charge of the IRIS program, and defending the Administration's new reforms to Congress and the public, has blocked an updated assessment of a chemical polluting groundwater across the Nation, and is insisting EPA scientists use unsupported and unprotective assumptions in a model intended to downplay the potential harm posed to the public by the chemical.

According to NRDC discussions with IRIS staff, additional instances of interference by George Gray to delay or weaken assessments include:

- blocking IRIS from posting acute (less than 24 hour) risk values.[12] Acute risk values are relevant to communities that are exposed to chemicals by burst releases of toxics (smokestacks, etc.) that may not exceed short-term (days-weeks) or long-term (months-years) regulatory standards, but may still pose a hazard to acutely exposed individuals.
- blocking IRIS from posting summaries of its assessments online, arguing that the summaries give a naïve public and regulators inaccurate impressions, contribute to misunderstandings, and are misused.
- blocking the IRIS staff recommendations to apply a 10-fold safety factor to site-specific assessments where children may be exposed to ethylene oxide, a potent human carcinogen with evidence that exposures during early life significantly increase the risk of developing cancer. Use of such a safety factor under precisely these conditions is specifically recommended in the *EPA Supplemental Cancer Guidelines on Children's Exposure.*

These examples should be alarming to any Member of Congress, and any member of the public, who cares about ensuring that the best science is used by EPA to determine the risks posed by dangerous chemicals and who cares about fully informing the public about the risks posed by exposure to toxic chemicals. It also illustrates why NRDC and other environmental and public health groups, as well as the GAO, are so concerned about the changes to the IRIS process that will allow more of the decision-making to take place behind closed doors, where political appointees can make demands on career employees, without having to defend the merits of their scientific arguments (or the injection of policy and political preferences in a scientific process) before the public.

Conclusion

Properly implemented, the EPA IRIS program provides a critical scientific service to the public. Like other vital EPA programs, it must be preserved and protected so that EPA's scientists can conduct their work without political interference. The EPA's authority to determine the risks posed by hazardous chemicals should not be sacrificed to the desire of other federal agencies' or industry interests in avoiding clean-up costs or requirements for additional controls on emissions and exposures.

We request that the Science Committee work with other House colleagues to ensure that the new IRIS process is overturned or withdrawn and require IRIS health assessments to be reviewed in an open process, without inappropriate political interference.

---

[10] Clean Air Report via InsideEPA.com. Staff rebuff ORD Chief's bid for new risk study for key solvent. Inside Washington Publishers. Vol. 17, No. 20. October 5, 2006. Originally reported in *Risk Policy Report,* September 26, 2006, p. 1.

[11] On January 25, 2007, the California Air Resources Board ordered the phase-out of the use of perchloroethylene, from dry cleaning, with a complete ban by 2023. See details in news release at: *http://www.arb.ca.gov/newsrel/nr012607b.htm*

[12] *EPA Eyes Expanded Risk Database Used in Toxic Regulation, Clean-ups.* "The managers of an EPA chemical risk database are considering adding short-term and acute exposure categories on several chemicals to gauge the resources needed to add the broader risk data to the system." January 27, 2003. Inside Washington Publishers.

There are hundreds of potentially dangerous chemicals that are either already in the IRIS database but need to be updated, or that have not yet been added. Without an open, credible, effective, science-based, fully-funded program to develop these assessments without political interference from the White House or other federal agencies, EPA will continue to fall further behind in a fundamental program that serves as the foundation for fulfilling its mission: protecting the environment and public health.

Thank you for the opportunity to testify today.

BIOGRAPHY FOR LINDA E. GREER

Linda E. Greer joined the Natural Resources Defense Council (NRDC) in 1990 as a Senior Scientist specializing in public health issues, especially toxic chemicals and hazardous waste. She now is the Director of the Environment and Health Program. Linda is currently focusing on the scientific controversies in determining toxicity of chemicals in regulation and on mercury pollution. Prior initiatives have most notably included pollution prevention opportunities at large chemical manufacturing facilities, where she directed a large and successful collaborative project to reduce toxic wastes and releases with the Dow Chemical Company. Linda has been appointed to the Board of Life Sciences for the National Academy of Sciences as well as the U.S. EPA Science Advisory Board Executive Committee, and she serves several other technical and policy advisory groups.

Dr. Greer teaches an intensive summer course, "Scientific Fundamentals of Risk Assessment" for law students and practicing lawyers, which she has done for ten years, and she has taught a graduate-level class to scientists in toxic chemical impact and regulation.

She received her Ph.D. in Environmental Toxicology from the University of Maryland in 1989, M.S.P.H. in Environmental Sciences and Engineering from UNC–Chapel Hill, and B.S. in Biology from Tufts University.

Dr. Greer is the author of over a dozen technical and policy articles on environmental matters, and has frequently testified before Congress.

DISCUSSION

DELIBERATIVE, INTERAGENCY DECISION-MAKING

Chairman MILLER. Thank you, Dr. Greer.

At this point we will have our first round of questions, and the Chair now recognizes himself for five minutes. Mr. Ensminger, as you know, as other witnesses have testified, the current IRIS process allows repeated interagency, intragovernmental discussions about the health risk assessments. Those discussions, to use the word that Dr. Greer quoted, are deliberative. You would probably call those secret. The doors are closed. We are not entirely sure what happens in there. But your testimony made it pretty clear that you do not believe that your former employer, the Department of Defense, talks about public health or expresses concern for public health. They are more concerned about potential clean-up costs, Mr. Siegel said perhaps as much as $5 billion. What they are not doing is talking about the public good. I have always thought that democracy dies behind closed doors. To use Justice Brandeis's phrase, sunlight is the best disinfectant and the electric light the most efficient policeman, but last week in our hearings, Susan Dudley, the head of OIRA, the Office of Information and Regulatory Affairs at OMB, the office within OMB that supervises this interagency, intragovernmental process, extolled the virtues of closed-door meetings. She said that it encouraged candor, that people could say exactly what was on their mind and not worry about the consequences of it because they knew that what they had to say would go no further and therefore they could say exactly what they thought and that the process was better as a result. Do you

have any thoughts on her view of the virtues of closed-door meetings and a deliberative process to decide?

Master Sergeant ENSMINGER. Mr. Chairman, it is my opinion that if somebody has to go behind closed doors to say something, they have something to hide, and why else wouldn't they want to say it out in the open. If you can't say it out in front of everybody, maybe you better keep your mouth shut.

Chairman MILLER. Right out in front of God and everybody, as we would say in North Carolina.

Mr. Siegel, do you have a——

Mr. SIEGEL. I have a slightly different perspective. I have served on a number of National Academy of Science's committees dealing with various contaminations at Department of Defense facilities, and those meetings, they exclude DOD and we have a number of scientists talking frankly, and that works because I am in the room, because they have a representative of the public interest in the room to make sure that it is not just a few people trying to pull the wool over everybody else's eyes. There are stages and various processes where, you know, private discussions may make sense but not if a major interest group is excluded.

Chairman MILLER. And I am sorry, who would you include as a major interest group?

Mr. SIEGEL. Well, I am basically there representing the impacted public from the sites.

Chairman MILLER. You are considering yourself or the public as an interest group?

Mr. SIEGEL. Yeah, and I strongly believe that my presence affects what other people in the room say because, you know, not that I am going to run to the press and leak something but they have to treat things differently when they know that there is somebody who is asking real questions.

Chairman MILLER. You think perhaps the candor that Susan Dudley thought was a virtue of being able to say whatever you thought was actually not such a virtue and——

Mr. SIEGEL. I mean, this is almost like a brainstorming session where people are saying I think this but I am not really sure, and so in the privacy of that environment, people will say things they aren't sure of and then say oh, I see, you are right, and they aren't quoted in the press and the thing isn't taken too far, but that only works if it is open to other people with other interests, and that is a scientific discussion. That is not a political discussion.

Chairman MILLER. Dr. Greer.

Dr. GREER. Well, I think the important principle here is transparency and accountability of the decision-making process, and what we have seen through the IRIS experiences is that behind closed doors, arguments are made, data is hidden, and the decision that comes out in the end is not transparent and is not accountable, so although there may be a minor role for informal conversations to try to get your act together, the general principle for all EPA rule-making is one of transparency and accountability to the public and to all affected parties, and that is what we lose with these closed-door deliberations, which are decision-making deliberations.

OIRA'S ROLE IN THE IRIS PROCESS

Chairman MILLER. The current interagency process, the IRIS listing process, the one—actually the one that preceded the one that was adopted in April seemed to have the OIRA, OMB really in control because it was interagency and now it seems to be more clearly in control in a process that statutes seem to contemplate the EPA would run. Do you think the EPA is capable of conducting an interagency discussion on its own or they need OMB standing over their shoulder or actually being the ones themselves to decide, Dr. Greer?

Dr. GREER. Well, EPA is absolutely capable of doing that. I mean, this is really at the core of scientific deliberation. They have guidance documents on principles of how to make these decisions and they have decades of experience in making these decisions. I would contrast that against any of the scientific experts in any of these agencies who are really in a much less expertise, less experience and this is really EPA's arena.

Chairman MILLER. Mr. Siegel.

Mr. SIEGEL. I think that not only does EPA have the capacity but I think that the other agencies—there are a lot of good people at the Department of Defense who are trying to do good science too and they are capable of communicating with EPA and EPA is capable of communicating back, and the OIRA involvement to me smacks of a political involvement, that you have people who are involved not primarily because of their scientific expertise but because of their political obligations.

THE IRIS PROCESS

Chairman MILLER. My time is expired, but Mr. Sensenbrenner is not here so I will recognize myself for a second round of questions.

Mr. Whittaker, I think you are the audiovisual guy. There were two charts in the hearing last week. Chart 3, that is—actually could I see Chart 1 first? All right. That chart based on Susan Dudley's testimony last week is the very complicated process. That is actually prepared by the EPA and it is the flow chart to show the IRIS process, which she—before 2004, and then there was an interim one and then Chart 3, Mr. Whittaker, that is the chart that she said streamlined the IRIS process. Mr. Siegel, does that—is it your impression like GAO's that that actually will further complicate, not streamline it? It does not look just to my own lying eyes to be a simplification of the earlier chart.

Mr. SIEGEL. As I said, you know, there are a lot of good people at EPA and career people I talk to, you know, are very concerned about this sort of thing, and I tease them. I say it takes the EPA 30 days to put in a light bulb, and basically you have that not just with IRIS but with a large number of processes, things just drag on and on while people are already exposed. It is one thing if there is a delay and nobody is being exposed but you basically have people like Shirley, like Janey Ensminger, people who are being exposed while this is being—this process goes on. So again, things that take a long time that are complicated are okay if people are safe, but if you don't know that they are safe, you need to act quickly, and when we have tried to accelerate some of these studies

like on perchlorate, they say, we can't possibly do it by such and such a date. Well, I guess that is because they don't really care about the exposures that are going on. That is all I can think of.

Chairman MILLER. Mr. Ensminger, you appear to want to comment.

Master Sergeant ENSMINGER. I had a researcher make the comment to me the other day exactly about OMB overruling the EPA. I believe the OMB has one toxicologist on their staff.

Chairman MILLER. I asked Susan Dudley that last week and I did not get a clear answer.

Master Sergeant ENSMINGER. They have one toxicologist on their staff who overruled the thousands that work at EPA. Boy, isn't that something?

Chairman MILLER. Well, again, what you just said is consistent with what I had heard. When I asked Susan Dudley that, the head of OIRA, I did not seem to get a clear answer and she said that they had access to other expertise that they employed.

Master Sergeant ENSMINGER. And Mr. Siegel made a comment a while ago about the DOD had good researchers on their staff as well. Why are we duplicating these efforts? Why is DOD authorized to use taxpayers' money to do research on these chemicals when we are already funding somebody else to do it, the EPA? I mean, this is ludicrous. Is it the Department of Defense or is it the Department of Legal Defense?

Chairman MILLER. When Susan Dudley testified last week, I asked her if in any of these old mini blocks, I haven't actually counted how many blocks there are, other than the public comment section periods, whether there was an opportunity for anyone in the private sector to be part of deliberative discussions and obviously public comment is not a deliberative discussion or secretive, as I am sure you would say, and I would too, and she said no, that actually all the participation by the private sector would be through public comment. There was no opportunity for them to have any say, any opportunity to influence an IRIS decision, an IRIS assessment, not TCE manufacturers, not any private sector companies that might face clean-up costs, no opportunity except during public comment. Mr. Siegel, is that consistent with your own observations of the process?

Mr. SIEGEL. It is my understanding that through the perchlorate study group, and you may have the documents, that the contractors for these federal polluting agencies have a direct line to the Defense Department, NASA participants because these agencies end up in many cases paying for the clean-up of the contractor obligations. I mean, it is little known, when Congress looked at this over 10 years ago, that companies like Lockheed and Aerojet charged the costs of their clean-up off as overhead on their government contracts and the people in the Defense Department who are in charge of dealing with it, know it so they are very open to input from these companies when they go to EPA. I don't know that the companies are actually in the room in the meetings with EPA, but their information is.

Chairman MILLER. Dr. Greer.

Dr. GREER. Yes, that is right. I was going to say the same thing, that the perchlorate study group is a great example of how that is

really not the case, that what Susan Dudley was talking about, there is plenty of precedent for that not being true. You know, in this case, that was a group set up by the military. They were present in the so-called interagency deliberations, and Aerojet was actually the chair of the deliberations in many of the meeting notes that NRDC has. So they were running the deliberation, let alone not present.

Chairman MILLER. Dr. Greer, if there were not this streamlined process, interagency IRIS process, could federal agencies still weigh in on an IRIS assessment and how would they go about that?

Dr. GREER. Well, you know, federal agencies have always had an opportunity to comment and weigh in on these assessments. That has been the case all the time. They have weighed in during the public comment period but not in secret and, you know, not with a license to kill. That is the big difference between what we are looking at today and the normal procedures. We certainly would not object to having these agencies weigh in with the public, you know, on the record, so to speak.

Mr. SIEGEL. You know, one of the things that I wonder is what these agencies, polluting agencies say in private versus what they are actually saying in public, that we have no way of knowing that.

TRACKING CITIZEN EXPOSURE TO TCE

Chairman MILLER. Mr. Ensminger, obviously a lot of folks have lived on Camp Lejeune. The military is transient by nature. I grew up in Fayetteville. As you pointed out when we talked yesterday, I know you have less than warm feelings for Fayetteville since you see it as an Army town. I know that people are on and off of military bases, their families are on and off military bases all the time, and keeping track of all the people who have been exposed is no small task. How is the government doing in identifying the people who have been exposed and trying to see what health outcomes they have had, whether they have had health consequences that are consistent with the TCE exposure risk?

Master Sergeant ENSMINGER. To answer your question, Mr. Chairman, to date, to date, there have been no studies done on any population groups at Camp Lejeune other than the in utero population. In other words, the siblings of those in utero children, their parents, the men and women who were stationed at Camp Lejeune, the Marines and sailors, and the civilian employees that work aboard the base, to date, no studies have been done on them. Trying to get the Department of Defense, Department of the Navy and the United States Marine Corps to execute a notification process, actually had to go to the extreme of getting an amendment to the Defense Authorization bill through the Senate last year to force them to live up to their own motto, which is semper fidelis, always faithful.

SCIENCE POLICY

Chairman MILLER. When Dr. Gray of the EPA, the official who seems to be in charge of IRIS, and Ms. Dudley from OMB, from OIRA appeared last week, they, particularly Dr. Gray, used the phrase that IRIS includes both science and science policy. I pushed

him some on exactly what he meant by science policy and I think most people would think that science policy was just part of science. Occam's razor, for instance, appears to be science policy rather than strictly science. Dr. Greer, can you give us some idea of what elements of a policy might be in an IRIS listing?

Dr. GREER. Yes. So, you know, there is a mixture of science and some decisions that I would call policy decisions in an IRIS assessment. For example, deciding whether the data has enough certainty to negate the need for a safety factor or deciding whether or not a certain study shows that there really is disproportionate vulnerability in a certain type of population. I think the key thing here though to focus on is that those policy decisions are best made by relying on existing EPA guidance documents because the key here is consistency. The key here is consistency and how you make those decisions so that you get objective, clear and health-protective decisions, and those guidance documents are publicly vetted, publicly commented on and open, and so what I get worried about in this distinction between science and policy is that we lose the plot here, that the plot here is how to make consistent decisions that err on the side of protecting public health and that is not about individual analysts or even the boss, George Gray, inserting his own personal opinion on how he thinks something ought to go. That is about following the rules of the road that EPA has in those longstanding documents.

Mr. SIEGEL. May I add something?

Chairman MILLER. Mr. Siegel.

Mr. SIEGEL. One of the innovative things in the TCE human health risk assessment, the draft for 2001, is that it incorporated cumulative exposures because as you are exposed to other similar chemicals to TCE or even alcohol can enhance the impact of the exposure and the scientists who led that study explained it to me with an analogy of taxes. If you make zero dollars a year and then all of a sudden you make $5,000 more, your taxes don't really go up. You barely pay any taxes anyhow. But if you start out at $100,000 and you go to $105,000, your taxes might go up a couple thousand dollars, and the same is true with the body. If you already have a load of exposure to chemicals that affect the kidney or affect the liver or various parts of the body and it goes up, it has an impact. The 2001 human health risk assessment incorporated that. That is a policy decision. Some people argue the other side and say no, we should address that at the risk management stage when we decide whether or not to treat the well, to treat the air, something like that. That is a viable argument. It is a policy debate. Unfortunately, I don't know of any place where that cumulative exposure is addressed at the risk management stage. So I think I would go with the 2001 health risk assessment and say yes, we should do it in the risk assessment phase and that should be part of IRIS. But that is a policy decision that affects how the science comes out.

Chairman MILLER. Mr. Ensminger, you seem to want to answer this.

Master Sergeant ENSMINGER. No, I wanted to go back to that thing about the studies. Now, there are some feasibility studies that have been proposed by ATSDR for some of these other popu-

lation groups. The protocols have just been written for them. They are in the peer review process now and approval process but like I said in my testimony, just the week before last, the Department of Defense and Department of the Navy were balking at $1.6 million and ATSDR is estimating that next year's feasibility studies and their water modeling at Camp Lejeune is going to come somewhere close to $12 million. I can just hear them now, that, you know, they are doing everything they can to kill the Camp Lejeune efforts and they are going to use every excuse in this world to make that possible, but I will be here fighting them.

ASSESSING CUMULATIVE EXPOSURES

Chairman MILLER. Mr. Ensminger, I want to come back to you in just a second on your experience with ATSDR, which has also gotten the Subcommittee's attention. But Mr. Siegel and I think Dr. Greer, Mr. Ensminger has obviously done a good deal of research and it is obvious what his motivation is from having heard his testimony, that the typical expectation for a population the size of the children who were exposed in utero would have been 7.2 cases, and ATSDR has now confirmed 14 to this point of childhood leukemia, two cases of non-Hodgkin's lymphoma. That is more than twice what would be expected, but Mr. Siegel, your discussion of the cumulative effect, is that—is it likely that that baseline does include a fair number of folks whose leukemia is a result of environmental exposures? Did that question make sense?

Mr. SIEGEL. Yes. I mean, basically it is very difficult to show, unless you have a specific disease like mesothelioma—I can't pronounce that one.

Chairman MILLER. We have Dr. Greer here to pronounce everything for us.

Mr. SIEGEL. There are some specific diseases that have fingerprints. Most diseases are not caused by a single exposure to a single chemical and so it is very difficult to show that the particular—even in Janey's case, it is difficult to show that that particular exposure caused the disease but we know that if we know something about the exposures, that it was probably a very major percentage of the cause, not just—you know, but if there were other exposures, that would have also increased it, and the problem—we have a problem, a burden of proof in this country, and I will give you an example. A man I met in Kentucky earlier this year where he was one of the key subjects in a study by the University of Kentucky which showed that there is a relationship between TCE and Parkinsonism, and he was obviously very sick and the woman who was with him wasn't exposed as much and she wasn't quite as sick and they used this for this very well, you know, regarded published scientific study, and that is great, you know, that they can show that there is—that TCE is a factor in Parkinsonism. They told me that the doctor who did the study on him, that included him, would not certify for his purpose of workers' compensation that he was sick because of that exposure and so with all the studying that is going on and a lot of scientists are, you know, getting awards and degrees and all kinds of stuff for doing it, but the problem I have is that the studies go on and they don't end up helping people and that is something that needs to be addressed.

Chairman MILLER. Dr. Greer, I guess my question was, is there reason to think that the baseline is not actually a clean baseline that assumes no environment exposures but may in fact the baseline be the result of, in some part, to some extent of environmental exposures?

Dr. GREER. Yeah, I mean to some extent, you know what they try to do is compare against a control population that looks the same about everything except the exposure of concern, but I will tell you that an environmental epi study that shows twice as high as expected is very alarming. I mean, two times as high is a high rate for an environmental epi study, and the reason for that is because unlike laboratory animals that you control every single thing that they are exposed to, people are exposed to a lot of things. People smoke and people have other diseases, et cetera, et cetera. So when you are comparing a disease caused by an environmental exposure with a baseline of disease, it is sort of muddy and you have a hard time seeing trends. Two times is high for an environmental study and would certainly be a red flag for most environmental epidemiologists as, you know, something that looks like a real concern.

THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

Chairman MILLER. Mr. Ensminger, you mentioned ATSDR is involved in this. ATSDR is an agency of the Federal Government I had never heard of a year ago. The Agency for Toxic Substances and Disease Registry is part of the CDC, the Centers for Disease Control. They were involved in the FEMA trailers, the, I guess, hundreds of thousands of people who were living in trailers provided by FEMA as a result of being victims of Katrina, being displaced by Katrina and Rita. Mr. Sensenbrenner mentioned that in his opening remarks, that we had had a hearing on FEMA trailers and formaldehyde exposure. The formaldehyde was used in those trailers as a very cheap building material, an adhesive that held together particleboard that was used for walls and flooring and cabinets and that since 1997 the IRIS assessment process has had before them a reassessment of formaldehyde that EPA has yet to act upon. With a fairly active effort to influence the process by the industry, our impression of ATSDR was that they were entirely too eager to please FEMA. FEMA asked ATSDR for a health assessment. It obviously would not have done them a lot of good to go to IRIS to find out what the effect of formaldehyde was, and ATSDR provided a health assessment that they knew was not appropriate to the circumstances because they were trying to please FEMA, give FEMA what they wanted. What has been your own impression of ATSDR from your dealing with them?

Master Sergeant ENSMINGER. Well, specifically—and ATSDR is many, many different departments, several different departments. Their largest department is the Department of Health Assessments and Consultations. For lack of a better term, the public health assessment for Camp Lejeune is a piece of crap, okay.

Chairman MILLER. Could you put that in lay terms?

Master Sergeant ENSMINGER. They—and there are so many errors in that public health assessment, and every one of those errors

have been pointed out to those people. And they absolutely refused to pull that health assessment down and correct it.

Last year, there was a hearing held specifically about Camp Lejeune, and we almost had to beat them into submission just to get them to put a disclaimer up at the beginning of that public health assessment so people weren't looking at that thing and relying on the erroneous information that they have on their website.

Now, public health assessments and consultations with ATSDR, when we discussed this yesterday with some of your staff, ATSDR was given an exception when they were created back in the early '80s to bypass the peer review process because of the backlog in Superfund sites that they needed to do assessments on. So Congress gave them a pass on the peer review process for public health assessments. That backlog is done. There is no backlog for Superfund sites anymore. ATSDR needs to be held to the same standard as everybody else and those public health assessments need to go through a peer review process. And I will guarantee you, if this is instituted, you will see a much better product coming out of ATSDR than you see now.

Matter of fact, I would make the—I would bet you that there are a lot of people working at ATSDR who are so used to pulling out their little tray in their desk that got all their little standard quotes that they can just slip in there and nobody ever questions. I bet you if you make them go through the peer review process you will see a lot of people that work at ATSDR that won't be working there later.

Chairman MILLER. Mr. Siegel or Dr. Greer, do you have any experience with ATSDR?

Mr. SIEGEL. Well, you know, when I visit a community that has just found out about contamination in their water there, everybody wants a health study. Often that means bringing in ATSDR. But ATSDR's batting average is very low. They almost never find, with their methodology, with the burden of proof, that people are sick as a result of environmental exposures.

I would ask them, you know, how many times out of all the health assessments that you have done, have you found that there is a direct link between the exposure and disease? And the problem is, to me, with their methodology, and their methodology may be good for some purposes, but not for the purpose that they have been assigned, you know, to help guide risk management decisions at these sites.

Unless you believe that people really don't get sick as a result of exposures to these chemicals, and there are people who believe that, in which case, ATSDR's batting average is very good. But almost—friends of mine wrote a report, *"Inconclusive by Design,"* 20 years ago about ATSDR, and the same is true today.

Chairman MILLER. Dr. Greer, anything?

Dr. GREER. Well, as I said in my oral statement, you know, the changes to the IRIS program that we were talking about are just part of what we regard as the Administration's war on science and public health protection, and I think ATSDR is another—is an area which shows the influence of the Administration on some of their deliberations.

It is true, actually, that ATSDR is sometimes inconclusive by design. What we urge them strongly to do is if they are going into a community where they know that it is a small community and statistics will not allow them to ever find something significant, because there just are not enough people to study, that they should say that it is scientifically not possible to do a study, rather than going in and doing a study and saying we didn't find anything statistically significant, which sounds like there is nothing wrong here.

So they really need to develop a bright line threshold that they make an evaluation at the outset to say is there enough people or enough type of disease here that we could actually study this scientifically, or this doesn't lend itself to a scientific study and we need to make a decision to move forward, erring on the side of protecting human health, to do it without the study. And that is what we have urged upon them many times without success.

Chairman MILLER. Mr. Ensminger.

Master Sergeant ENSMINGER. Also, the researchers at ATSDR—now, I am going to take their side for a minute here, which is unusual, but ATSDR's researchers, when they go to a DOD site specifically, all the information gathering for their health assessment—DOD Superfund sites are placed on an honor system. They are on an honor system. These people are the keepers of all the records on that—for that base, and these researchers are literally thrown to these wolves when they go to these bases and have to rely on these people. These people withhold—I mean, I have got letters that I provided with my testimony back in 1994 where ATSDR was complaining that the people at Camp Lejeune weren't providing them with the documents they needed to do their required mission. And when they did provide them with data, there was no supporting documentation to back up what they were giving them.

I mean, how can you place a polluter on an honor system? They have already shown they don't have any honor, and they have proven it time and time again in the Camp Lejeune situation, dragging their feet, putting up road blocks, stalling, giving incorrect data. And I have documented situations at Camp Lejeune where they knowingly provided incorrect data to ATSDR, which skewed one of their studies, and never corrected. They relied on us to correct it.

Chairman MILLER. We are getting short on time, and Mr. Siegel?

Mr. SIEGEL. This is a systemic problem. ATSDR does not do studies. They take data that is provided to them by the polluter, sometimes by the regulator which really doesn't do its own studies, and they do an assessment. But they do not generate any new data. They don't go out and do sampling, they don't go out and interview people like a university study would do. They just take the existing data and make a judgment based upon it, which in my experience—that is what I have seen. Somebody may know more about it, but that is generally the way they operate when they are asked to conduct a public health assessment.

THE EUROPEAN REACH PROGRAM

Chairman MILLER. This probably needs to be a final question, but this morning when I rolled out of bed and walked down to the corner to get the *Washington Post* thinking of today's hearing, there was an article on the front page on a decision by the European Union that has been adamantly opposed by the Bush Administration and the chemical industry that would take a fundamentally different approach to regulating chemicals that may be toxic.

What we have been talking about today is just the very initial stages of a regulatory process before cost benefit analysis, for instance, is supposed to be taken into effect. Just assessing which chemicals have what toxic effect, and in this case, we can see that two assessments are coming out when 600 new chemicals enter the marketplace a year. TCE, which appears to cause a great deal of damage, has taken 20 years, formaldehyde, 11 years and counting.

This hearing has been about how to fix that IRIS assessment process, but Mr. Siegel, Dr. Greer, do you think maybe our fundamental approach should be different? EU, by the way, is 500 million people in developed economies. We are 300 million people in a developed economy. It is hard to imagine that industry will simply stop producing goods from the European market, which is significantly two-thirds, again, the size of our economy.

Mr. Siegel.

Mr. SIEGEL. The short answer is yes. I mean, I have actually been to a Defense Department-sponsored meeting with their contractors where the European approach, the REACH program has been presented. And very clearly, with the Defense contractors, they are already finding that they are changing their practices, phasing out certain uses of chemicals like chromium, because of their need to market globally. American companies are at a competitive disadvantage if they do not recognize this new approach. But unless, you know, the American Defense Department adjusts its specifications, which would actually require the use of toxic substances, it will be limited.

But this is definitely—you know, it is being heard, it is being felt, and it would be so easy for the U.S.—I mean, the implementing would be hard, would take a while, but it would be so easy, so helpful to put the burden of proof on the people who are using these toxic substances, rather than on the people who are the victims, that there is a problem.

Chairman MILLER. Dr. Greer.

Dr. GREER. Well, you know, we Americans really like to think of ourselves as number one, and at the head of the pack globally on so many things, but I have to tell you that Europe is far ahead of us on these issues of public health protection and environmental contaminants. And the REACH program really has a tremendous amount of promise. I mean, it sort of takes—you know, here a chemical is innocent until proven guilty, and you see how long it takes to get proven one way or the other. Under their new system, a chemical is going to be guilty until proven innocent; that is, data is going to be required before a chemical can get on the market so that we don't get this big bad backlog. And of course, the incentive

will be to get that information forward, because they want to put it on the market.

So it is a really smart idea. I think because we are in such a global economy, we may be the accidental beneficiaries of a lot of that work because when global companies need to make certain products, the European standards are going to be higher than the American standards, and they probably will benefit from that. But you know, we have had our feet in cement shoes for almost a decade now on these toxic chemical issues, and we have got our work cut out for us to get back to where some of these colleagues in the other developed countries have really been on this scientifically.

Chairman MILLER. It seems unlikely they will produce two versions of their product——

Dr. GREER. Exactly.

Chairman MILLER.—so the safe European version and the toxic American version.

Mr. Ensminger, do you have any thoughts on it? You don't have to have any thoughts on this, you have had thoughts on a lot of things.

Master Sergeant ENSMINGER. I do. Well, basically the European Union is concerned about their people. It makes you wonder what our government is concerned about. Is it people or money?

Chairman MILLER. That is a pretty good valedictory statement from the witnesses.

I want to thank all of you for appearing today for this hearing. Under the rules of the Committee—the Subcommittee, the record will be open for an additional two weeks for any Member to submit additional statements and any additional questions that could go to you for written response.

The hearing is now adjourned. Thank you.

[Whereupon, at 11:28 a.m., the Subcommittee was adjourned.]

Appendix:

Additional Material for the Record

STATEMENT OF DAVID G. HOEL
MEDICAL UNIVERSITY OF SOUTH CAROLINA
CHARLESTON, SOUTH CAROLINA

Discussion of EPA's IRIS and the Health Effects of Trichloroethylene

I am a University Distinguished Professor in the Department of Biostatistics, Bioinformatics and Epidemiology at the Medical University of South Carolina in Charleston. Prior to joining the University, I was employed for over twenty years at the National Institute of Environmental Health Sciences of the National Institutes of Health.

There I was Director of the Division of Risk Assessment, and served for a time as Acting Scientific Director of the Intramural Research Program. I was a member of the Environmental Protection Agency's scientific panels for perchlorate and for trichloroethylene (TCE). I was a peer reviewer of the National Research Council's report on TCE.

The opinions I state today are my own.

I will comment on the general process used by EPA (e.g., IRIS) for calculating permissible dose levels of environmental carcinogens with a focus on the example of TCE. I will conclude with a few recommendations.

- EPA 2001 TCE Report

The EPA 2001 TCE risk assessment had a number of shortcomings that were pointed out by individual scientists and EPA's Scientific Advisory Board's TCE Advisory Panel. Although there were several health endpoints under consideration, cancer is the predominant outcome used for exposure standard setting. This is due in part to the target of one in a million lifetime cancer risk, and the assumption of a linear no threshold dose-response for carcinogens. It should be noted that the NRC report discussed this assumption and the need to validate it. The usual method for estimating cancer risk was applied to TCE. Basically, a few selected epidemiological studies and a few high dose rodent studies were individually fit to a linear dose response function in order to estimate the dose which would correspond to a lifetime risk of one in a million. Figure 1 is a reproduction of a graph of the results of this process taken from the EPA draft report, with Table 1 giving the numbers used in Figure 1.

First there is a question of the selection of epidemiological studies used for this process.

EPA used three studies: Henschler (1995) kidney cancers among workers in a German cardboard factory, Anttila (1995) Finnish workers who were monitored for TSE (kidney, liver and NHL) and an ecological study of drinking water in New Jersey (NHL).

The data from animal studies was also treated in a manner similar to human studies. Using kidney cancer as the primary example, EPA gave three dose estimates. They were derived from the rat study, the German worker study and the Finnish worker study. EPA calculated the dose estimates to be (see Table 1).

$$3.3 \times 10^{-3} \text{ mg/kg-d (rat)}$$

$$5 \times 10^{-5} \text{ mg/kg-d (German)}$$

$$5 \times 10^{-7} \text{ mg/kg-d (Finnish).}$$

This represents a range in estimated dose by a factor of almost 10,000, suggesting that the process is so variable as to be meaningless. It should be noted that the most extreme result produced by EPA was from the Finnish study, which was not statistically significant, and the workers had fewer kidney tumors than were expected. It is not clear why this study was included in the analysis.

Multiple studies are often quantitatively combined using meta analysis or joint data analysis techniques. A meta-analysis was carried out by EPA (Wartenberg et al., 2000), but not used in the calculating cancer risk. The specific TCE application

has been criticized in the scientific literature and most recently by the NRC 2006 report. If done correctly, with consideration of exposure, as has been done with radiation and cancer (e.g., Lubin and Boice, 1997), one could avoid using selected studies and their less stable risk estimates. Further Bayesian statistical methods can adjust for exposure uncertainties which vary among studies. The NRC report gives very detailed recommendations concerning the meta analysis process.

I feel that without a considerably more sophisticated analysis, which does not selectively choose individual studies and treat them independently, the low-exposure cancer risk estimates in EPA 2001 are unreliable and should not be used to set environmental standards.

- NRC 2006 TCE Report

The NRC (2006) report on TCE recommended that low dose cancer risk estimates be based on rodent bioassays and human data be used as validation of the rodent studies. This is a reasonable approach, which I support. The human epidemiological data is thought to be preferable but the very large uncertainty of exposures plus the confounding of other chemical exposures, as well as lifestyle issues, greatly decreases the value of the data for quantitative risk estimation.

Basic toxicological research focuses on a compound's mode of action (MOA); that is, how it and its metabolites affect the carcinogenesis process. Also, the use of physiologically based pharmacokinetic models (PBPK) to evaluate the relationship between routes of exposure and the formation of reactive metabolites of interest is critical to quantitative risk estimation. This information, although discussed, was not incorporated into the EPA cancer risk models. This PBPK model information, along with MOA understanding, is key to evaluating the validity of the predictability of rodent cancer effects to man. The NRC report discusses these important issues and makes specific research recommendations for improved TCE risk estimation.

An issue of increasing concern is the variability in response by various susceptible human subgroups. This is frequently discussed but rarely employed in evaluating the degree of sensitivity in subgroups. These subgroups include age, medical conditions and genetic variability. For example, Bronley-Delancey et al. (2007) measured the variability of TCE metabolism by genetic subgroups by using human hepatocytes. This basic type of human data provides guidance on possible adjustments of environmental exposure levels for genetic subgroups in the population.

All of this is important applied science which is essential to quality risk estimation, but it suffers from two problems.

First, the risk assessors are not integrating enough scientific information into their actual cancer risk estimates. There are modern statistical methods for accomplishing this. The ongoing effort in radiation carcinogenesis is one area where reanalysis is performed as new, better methods are developed, and it is a good example of scientific responsiveness to innovation.

The second issue is that there are no longer effective government programs directed at solving these issues through academic research. This work is too applied for NIH (i.e., NIH's toxicology grant study section no longer exists) and other agencies are not focused on these issues. Considering the cost of inappropriate risk estimates, in either dollars or health effects, this seems foolish from a societal viewpoint.

Finally, EPA's IRIS process involves both risk estimation and risk management. EPA should consider using outside scientific experts to carry-out the risk estimation. This is done successfully by WHO's IARC for qualitative risk assessment of chemical carcinogens and by the NRC for quantitative risk estimation of various radiation types. Through the use of independent scientific experts and a rigorous peer review process these risk estimates are considered authoritative. Some 30 years ago EPA had the NRC develop quantitative cancer risk estimates for chemical contaminants in drinking water. The Agency could then use exposure levels and the NRC risk estimates to establish standards based upon risks and benefits.

Conclusions and Recommendations

- EPA must develop cancer risk estimates for TCE using an integrated approach following the advice of the SAB Panel and the NRC Committee. Further, it should focus on the best estimate of risk, including an estimated uncertainty. EPA should also seriously consider the NRC's recommendation of developing the risk estimates based upon the animal and laboratory studies and using the human studies as validation of their risk models.
- While developing risk estimates, EPA should consider obtaining quality outside scientific advice before and during the process, instead of waiting until the document is completed. EPA should consider having risk assessment, but

not risk management, for the more important chemicals carried out by a committee of outside experts. The National Academies' NRC is well suited for this purpose.

- EPA and other governmental agencies should sponsor extramurally the development and refinement of risk assessment methodology in general. Also, they should support key laboratory and human studies directed at specific problems associated with any major chemical problem, such as TCE.
- Greater attention must be given to potentially sensitive subgroups and to adverse health outcomes other than cancer.

Figure 1

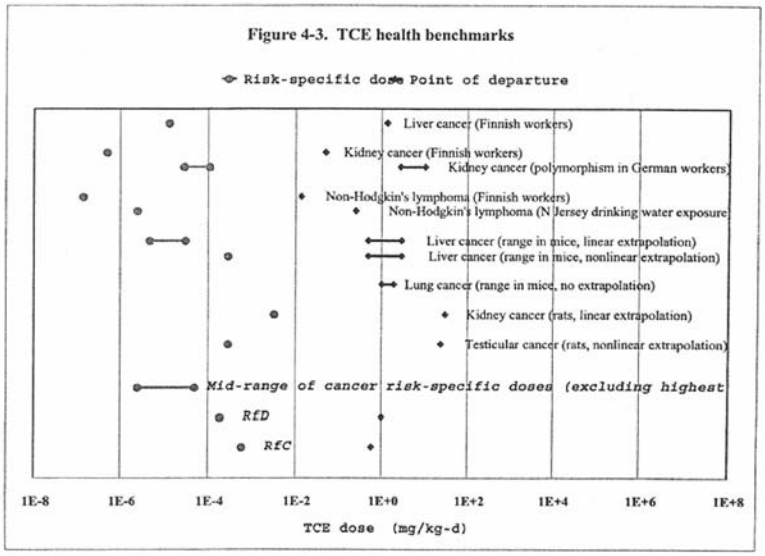


Table 1

Table 4-9. Compilation of cancer estimates

	Point of departure (mg/kg-d)	Slope factor $(mg/kg\text{-}d)^{-1}$	Risk-specific dose[a] (mg/kg-d)
Cancer estimates based on human studies			
Liver cancer			
Finnish cohort[b]	1.4[c]	7×10^{-2}	1.4×10^{-5}
Kidney cancer			
Finnish cohort[b]	0.05[c]	2×10^{0}	5×10^{-7}
German cohort	5[c]	2×10^{-2}	5×10^{-5}
Non-Hodgkin's lymphoma			
Finnish cohort[b]	0.014[c]	7×10^{0}	1.4×10^{-7}
New Jersey cohort	0.25[c]	4×10^{-1}	2.5×10^{-6}
Cancer estimates based on mouse studies			
Liver cancer			
Mechanism-based model[d]	Not applicable	8×10^{-4}	1.25×10^{-3}
Mechanism-based model[e]	Not applicable	8×10^{-2}	1.25×10^{-5}
Linear extrapolation	0.5–3.1	3×10^{-2}–2×10^{-1}	$0.5\text{–}3.1\times10^{-5}$
Nonlinear extrapolation	0.5–3.1	Not applicable	$(3\times10^{-4})^{f}$
Lung cancer[g]	1.7–4.8	Not applicable	(Not calculable)[f]
Cancer estimates based on rat studies			
Kidney cancer	33[h]	3×10^{-4}	3.3×10^{-3}
Testicular cancer	25	Not indicated	$(8\times10^{-4})^{f}$

From: EPA 2001 TCE report

References

Bronley-Delancey, A. et al. *Env Health Persp* 114: 1237–42, (2006).

Hoel, D. in *The Scientific Basis of Trichloroethylene Risk Assessment,* ISBN 0–9657650–0–8, (2004).

Lubin, J.H. and Boice, Jr., J.D. *JNCI* 89: 49–57, (1997).

National Research Council, *Assessing the Human Health Risks of Trichloroethylene: Key Scientific Issues.* The National Academies Press, (2006).

Wartenberg, D. et al. *Env Health Persp* 108 (Suppl 2): 161–176.

BIOGRAPHY FOR DAVID G. HOEL

Education:

1961—A.B. (Mathematics and Statistics) with highest honors, University of California at Berkeley

1966—Ph.D. (Statistics) University of North Carolina at Chapel Hill

1966–1967—U.S. Public Health Service Postdoctoral Traineeship in Preventative Medicine, Stanford University

Brief Chronology of Employment:

1997–date—Distinguished University Professor, Medical University of South Carolina, Charleston, South Carolina

2000–date—Clinical Professor, Department of Radiology, University of South Carolina, School of Medicine, Columbia, South Carolina

1993–1997—Professor and Chairman, Department of Biometry and Epidemiology and Associate Director for Epidemiology, Hollings Cancer Center, Medical University of South Carolina, Charleston, South Carolina

1981–1993—Director, Division of Biometry and Risk Assessment, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina

1990–1991—Acting Director, National Institute of Environmental Health Sciences and also the National Toxicology Program, Research Triangle Park, North Carolina

1984–1986—Associate Director, Radiation Effects Research Foundation, Hiroshima, Japan

1979–1980—Visiting Scientist, Epidemiology Department, Radiation Effects Research Foundation, Hiroshima, Japan

1977–1979—Acting Scientific Director, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina

1973–1981—Chief, Biometry Branch, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina

1970–1973—Mathematical Statistician, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina

1970–date—Adjunct Professor, Department of Biostatistics, University of North Carolina, Chapel Hill

1968–1970—Statistician, Oak Ridge National Laboratory, Oak Ridge, Tennessee

1967–1968—Senior Mathematician, Westinghouse Research Laboratories, Pittsburgh, Pennsylvania

Honors and Other Scientific Recognition:

Fellow, American Statistical Association, 1974

NIH Director's Award, 1977

Mortimer Spiegelman Gold Medal Award, American Public Health Association, 1977

Public Health Service Superior Service Award, 1980

Senior Executive Service Award, 1983, 1987–1991

Citation Classic, Institute for Scientific Information (Hoel et al. "Estimation of risks of irreversible delayed toxicity" *J. Toxicol. Env. Health* 1:133–51, 1975).

Member, Council of Fellows, Collegium Ramazzini, 1987

Member, Institute of Medicine, National Academy of Sciences, 1988

Council Member, National Council on Radiation Protection and Measurements (NCRP), 1992–1998 and 1999–2005

Westinghouse Distinguished Scientist, 1993–2004

Ramazzini 1994 Award Recipient for "Contributions to scientific knowledge on the oncogenic effects of nuclear radiation"

Fellow, American Association for the Advancement of Science, 1997

National Associate, National Academy of Sciences and National Research Council, 2001

Editorial—Books:

Methods for Estimating Risk of Chemical Injury: Human and Nonhuman Biota and Ecosystems, SCOPE /SGOMSEC 2, Proceedings of Workshop on Quantitative Estimation of Risk to Human Health from Chemicals, Rome, Italy, 1982 (co-editor with VB Vouk, GC Butler and DB Pekall).

Banbury Report 19: Risk Quantitation and Regulatory Policy, Proceedings of the Banbury Conference on Risk Quantitation and Regulatory Policy, (co-editor with R Merrill and F Perera). Cold Spring Harbor Laboratory, 1985.

Statistical Methods in Cancer Epidemiology, Proceedings of a Conference of the U.S.-Japan Cooperative Cancer Research Program, 1985 (co-editor with W Blot and T Hirayama).

Environmental and Occupational Health Sciences: A Series, Member, Editorial Advisory Board, 1986–date.

Trends in Cancer Mortality in Industrial Countries, (co-editor with D Davis), New York Academy of Sciences, 1990.

Biostatistics in Cancer Risk Assessment, (co-editor with T Yanagawa), Scientist, Inc., Tokyo, 1991.

2-Amino-N^6-hydroxyadenine: A collaborative study on the genetic toxicology of 2-amino-N^6-hydroxyadenine, (co-editor with FJ de Serres), Mutation Research, Vol. 253, 1991.

International Case Studies in Risk Assessment and Management, (co-editor with L Mohr and W Nixon), The Medical University of South Carolina Press, 1998.

Multimedia Modeling and Risk Assessment, (co-editor with J Regens and C Travis), The Medical University of South Carolina Press 1999.

Extrapolation of Radiation-Induced Cancer Risks from Non-human Experimental Systems to Human, (Chairman) Members include B Carnes, R Dedrick, RJM Fry, D Grahn, W Griffith, P Groer, RJ Preston) National Council on Radiation Protection and Measurements, NCRP Report No. 150, 2005.

Editorial—Journals:

Associate Editor, *Journal of Statistical Computation and Simulation,* 1972–1978

Associate Editor, *Journal of the American Statistical Association,* 1973–1979

Member, Editorial Board of the *Journal of Toxicology and Environmental Health,* 1975–1979

Member, Editorial Board of *Communications in Statistics, Part B—Simulation and Computation,* 1977–1979

Member, Editorial Board of the *Journal of Environmental Pathology and Toxicology,* 1979–1980

Member, Editorial Board of *Fundamental and Applied Toxicology,* 1981–1986

Member, Editorial Board of *Environmental Health Perspectives,* 1973–2000

Member, Editorial Advisory Board of *Journal of Statistical Computation and Simulation,* 1978–date

Member, Editorial Board of the *IMA Journal of Mathematics Applied in Medicine and Biology,* 1983–1988

Section Editor, *Journal of Environmental Pathology, Toxicology and Oncology,* 1986–date

Contributing Editor, *American Journal of Industrial Medicine,* 1987–date

Associate Editor, *Environmental Research,* 1987–date

Member, Editorial Board of *Risk Analysis,* 1987–1990

Associate Editor, *Journal of Communications in Statistics,* 1987–date

Associate Editor, *Biological Monitoring: An International Journal,* 1988–1990

Member, International Advisory Board, *Journal of Environmental Statistics,* 1992–1995

Section Editor, *Encyclopaedia of Biostatistics,* 1996–1997

Editorial Board, *Environmental and Ecological Statistics,* 2004–

Societies:

American Statistical Association

Biometric Society

Society for Risk Analysis

Collegium Ramazzini

American Association for the Advancement of Science

Radiation Research Society

Health Physics Society

Society for Epidemiological Research

Society Appointments:

Member, Regional Committee of the Biometric Society (ENAR), 1973–1975, 1978–1980

Biometrics Section Representative on the Council of the American Statistical Association, 1975–1976

Secretary, Biometrics Section, American Statistical Association, 1979

Representative of the Institute of Mathematical Statistics to the Biology Section of the AAAS, 1978–1981

Program Chairman, Biometric Society Spring Meetings, 1977

Member, Council of the Society for Risk Analysis, 1982–1985

Member/Chairman, American Statistical Association Awards Committee, 1991–1993

National Academy of Sciences Committees:

Member, Subcommittee on Margin of Safety and Extrapolation of the Safe Drinking Water Committee, 1976–1977

Member, Panel on Low Molecular Weight Halogenated Hydrocarbons of the Coordinating Committee for Scientific and Technical Assessments of Environmental Pollutants, 1976–1977

Chairman, Risk Assessment Subcommittee, Safe Drinking Water Committee, 1978–1979

Member, Committee on Chemical Environmental Mutagens, 1980–1983

Member, Board on Toxicology and Environmental Health Hazards, 1982–1985

Member, Committee on the Biological Effects of Ionizing Radiation (BEIR V), 1986–1989

Member, Committee to Provide Interim Oversight of the DOE Nuclear Weapons Complex, 1988–1990

Member, Committee on Environmental Epidemiology, 1990–1992

Member, Committee on Epidemiology and Veterans Follow-up Studies, 1990–

Member, Committee on Applied and Theoretical Statistics, 1991–1994

Member, Committee on The Health Effects of Mustard Gas and Lewisite, 1991–1992

Chairman, Committee to Study the Mortality of Military Personnel Present at Atmospheric Tests of Nuclear Weapons, 1993–1994

Member, National Toxicology Program's Science Advisory Board 1994–1996

Chairman, Committee on the Assessment of Wartime Exposure to Herbicides in Vietnam, 1996–2002

Member, Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, 1997–2003

Chairman, Board of the Medical Follow-up Agency, 1996–2001

Member, Commission on Life Sciences, 1999–2000

Advisor, Division on Earth and Life Studies (DELS), 2001–

Chairman, Medical Follow-up Agency, Patterns of Illness and Care before Deployment to the Persian Gulf War, 2001–2003

Member, Defense Threat Reduction Agency (DTRA), Committee to Review the Dose Reconstruction Program, 2002–2003

Member, National Research Council, National Academy of Sciences, Committee on California Agriculture Research Priorities—Pierce's Disease, 2003–2004

World Health Organization and Other International Activities:

Member, International Agency for Research on Cancer Working Group on the Evaluation of the Carcinogenic Risk of Chemicals to Man, 1977, 1981, 1982

Consultant, Subcommittee of International Commission for Protection against Environmental Mutagens and Carcinogens (ICPEMC) October, 1977–1982

Member, Environmental Mutagenesis and Carcinogenesis Panel, U.S.–Japan Cooperative Medical Science Program, NCI; 1987–1992

Member, Advisory Committee on The Radiation Protection of the Public from Radioactive Residues in Kazakhstan, International Atomic Energy Agency United Nations, 2003–2005

U.S. Government Advisory Committees:

Member, International Agency for Research on Cancer Working Group on the Use of Mechanistic Data to Evaluate the Carcinogenicity of Chemicals to Humans, 1991

Ex-officio member, Administrator's Pesticide Policy Advisory Committee, EPA, 1976

Chairman, Subcommittee on Estimation of Risks of Irreversible, Delayed Toxicity of the DHEW Committee to Coordinate Toxicology and Related Programs, 1975

Advisor, Carcinogen Assessment Group, EPA, 1977

Member, Scientific Advisory Board of the National Center for Toxicological Research, 1977–1980

Member, Ad Hoc Working Group to Develop Radioepidemiological Tables, NIH, 1984–1985

Member, Work Group on Health Effects Risks of the EPA Science Advisory Board's Committee on Research Strategies, 1987–1988

Chairman, Research Needs Subcommittee of the Committee to Coordinate the Environment and Related Programs, U.S. Public Health Service, 1990–1991

Member, Office of Technology Assessment Advisory Panel on Aging Nuclear Power Plants: Life Attainment, License Renewal, and Decommissioning. Congress of the United States, 1992

Member, EPA's FIFRA (pesticide) Science Advisory Panel, 1993–

Member, Interagency Staff Group for Development of OSTP Carcinogen Document, Office of Science and Technology Policy, 1983–1984 (Report: Chemical Carcinogens: A Review of Science and Its Associated Principles, *Environmental Health Perspectives,* Vol. 67, pp 201–282, 1986.)

Member, EPA's Science Advisory Board's Radiation Advisory Committee, 1993–1995

Member, DOD's Breast Cancer Research Program Integration Panel, 1995–1996

Panel Member, NIH Consensus Development Conference on Breast Cancer Screening in Women Ages 40–49, 1997

Member, FDA, Transmissible Spongiform Encephalopathies Advisory Committee, 1997–2000

Consultant, FDA's Center for Biologics Evaluation and Research (CBER), 2004–2008

Chairman, EPA's Expert Panel Review of Benzene Risk Assessment, 1997

Consultant, EPA's Science Advisory Board's Radiation Advisory Committee, 1996–

Member, EPA's Science Advisory Board's Environmental Health Committee, 1997–2004

Member, U.S. Consumer Product Safety Commission's Chronic Hazard Advisory Panel (CHAP), 1999–

Member, EPA's Science Advisory Board's Environmental Health Committee, TCE Health Risk Assessment: Synthesis and Characterization Review Panel, 2002

Member, EPA's Expert Panel Review of Perchlorate, 2002

Member, EPA's Expert Panel Review of Asbestos, 2003

Member, EPA's Expert Panel Review, Supplemental Guidance for Assessing Cancer Susceptibility from early-life Exposure to Carcinogens" (SGACS), 2003

Chairman, Committee to Study the Extrapolation of Radiation Risks from Animals to Humans, National Council on Radiation Protection and Measurements (NCRP), 1991–2005

Member, Scientific Advisory Committee of the Electric Power Research Institute's (EPRI) Environmental Risk Analysis Program, 1994–1995

Member, Scientific Committee 89 (non-ionizing radiation), National Council on Radiation Protection and Measurements (NCRP), 1994–1995

Member, Scientific Advisory Board, Environmental Health Foundation (EHF), 1994–1998

Member, Health Effects Institute (HEI) Diesel Epidemiology Project, 1998–1999

International Conferences Organized:

"Methods for Estimating Risk of Chemical Injury: Human and Non-Human Biota and Ecosystems" in Rome, Italy, July 12–16, 1982 (with G. Butler, D. Peakall, and N. Nelson)

"Conference on Risk Assessment and Statistical Methods" in Kyoto, Japan, August 30–31, 1984 (with A. Kudo and K. Wakimoto)

"The Third Japan-U.S. Conference on Biostatistics in the Study of Human Cancer" in Hiroshima, Japan, November 11–13, 1988 (with K. Aoki and T. Yanagawa)

"Trends in Cancer Mortality in Industrial Countries" in Carpi, Italy, October 21–22, 1989 (with D. Davis, J. Fox, and A. Lopez)

"International Biostatistics Conference in the Study of Toxicology" in Tokyo, Japan, May 23–25, 1992 (with A. Sakuma and T. Yanagawa)

"The Fourth Japan–U.S. Biostatistics Conference in the Study of Human Cancer" in Tokyo, Japan, November 9–11, 1992 (with R. Miller, H. Sugano, and T. Yanagawa)

"The Role of Environmental Factors in Breast Cancer: Collaborative Workshop" in Washington, DC, December 6–8, 1992 (with D. Davis)

"International Conference in Immunogenetic Risk Assessment in Human Disease" (MUSC) in Charleston, March 6–8, 1994 (with J. Pandey)

"The International Forum on Risk Assessment and Risk Management" (MUSC) in Charleston, March 5–7, 1996 (with L. Mohr and W. Nixon)

Congressional Testimony:

Senate Committee on Appropriations: Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Sen. Harkin)—March 14, 1991

House Committee on Appropriations: Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Cong. Natcher)—April 16, 1991

House Committee on Energy and Commerce: Subcommittee on Oversight and Investigations (Cong. Dingell)—May 8, 1991

Senate Committee on Appropriations: Subcommittee on Labor, Health and Human Services, Education, and Related Agencies (Sen. Specter)—February 5, 1997

Senate Committee on Environment and Public Safety (Sen. Boxer)—May 6, 2008

Bibliography:

Hoel DG: The number of k-simplices in the mth barycentric subdivision of an r-simplex. *American Mathematical Monthly* 74:819–820, 1967.

Hoel DG: Sequential testing of sample size. *Technometrics* 10:331–341, 1968.

Hoel DG: Closed sequential tests of an exponential parameter. *Biometrika* 55:387–391, 1968.

Hoel DG and Mazumdar M: An extension of Paulson's selection procedure. *Annals of Mathematical Statistics* 39:2067–2074, 1968.

Hoel DG: Discussion of engineering analysis of experimental data by Robert P. Benedict. *ASME Trans.* 91:130, 1969.

Hoel DG and Mazumdar M: A class of sequential tests for an exponential parameter. *Journal of American Statistical Association* 64:1549–1559, 1969.

Crump KS and Hoel DG: Some applications of renewal theory on the whole line. *Journal of Applied Probabilty* 7:734–746, 1970.

Gaver Jr. DP and Hoel DG: Comparison of certain small-sample Poisson probability estimates. *Technometrics* 12:835–850, 1970.

Hoel DG: On the Monotonicity of the OC of an SPRT. *Annals of Mathematical Statistics* 41:310–314, 1970.

Hoel DG: A simple two-compartmental model applicable to enzyme regulation. *Journal of Biological Chemistry* 245:5811–5812, 1970.

Hoel DG: Some modifications and applications of Wald's OC formula. *Annals of the Institute of Statistical Mathematics* 22:65–75, 1970.

Kastenbaum MA, Hoel DG and Bowman KO: Sample size requirements: One-way analysis of variance. *Biometrika* 57:421–430, 1970.

Kastenbaum MA, Hoel DG and Bowman KO: Sample size requirements: Randomized block designs. *Biometrika* 57:573–577, 1970.

Hoel DG: A method for the construction of sequential selection procedures. *Annals of Mathematical Statistics* 42:630–642, 1971.

Hoel DG and Mitchell TJ: The simulation, fitting, and testing of a stochastic cellular proliferation model. *Biometrics* 27:191–199, 1971.

Hoel DG and Sobel M: Comparisons of sequential procedures for selecting the best binomial population. *Proceedings of the Sixth Berkeley Symposium on Probability and Statistics* 4:53–69, 1971.

Hoel DG: A representation of mortality data by competing risks. *Biometrics* 28:475–488, 1972.

Hoel DG: An inverse stopping rule for play-the-winner sampling. *Journal of American Statistical Association* 67:148–151, 1972.

Hoel DG, Sobel M and Weiss GH: A two-stage procedure for choosing the better of two binomial populations. *Biometrika* 59:317–322, 1972.

Hoel DG and Walburg Jr. HE: Statistical analysis of survival experiments. *Journal of the National Cancer Institute* 49:361–372, 1972.

Hook GER, Bend JR, Hoel DG, Fouts JR and Gram,TE: Preparation of lung microsomes and a comparison of the distribution of enzymes between subcel-

lular fractions of rabbit lung and liver. *Journal of the Pharmocology Experimental Therapeutics* 182:474–490, 1972.

Beauchamp JJ and Hoel DG: Some investigations and simulation studies of canonical analysis. *J. Stat. Comput. Simul.* 2:197–209, 1973.

Hoel DG and Crump KS: Estimating the generation time distribution of an age-dependent branching process. *Biometrics* 30:125–135, 1973.

Patel KM and Hoel DG: A generalized Jonckheere K-sample test against ordered alternatives when observations are subject to arbitrary right censorship. *Communication in Statistics* 2:373–380, 1973.

Patel KM and Hoel DG: A nonparametric test for interaction in factorial experiments. *Journal of American Statistical Association* 68:615–620, 1973.

Chand N and Hoel DG: A comparison of models for determining safe levels of environmental agents. In Proschan F and Serfling RJ (Eds.): *Reliability and Biometry.* Philadelphia, SIAM, 1974, pp. 681–700.

Crump KS and Hoel DG: Mathematical models for estimating mutation rates in cell populations. *Biometrika* 61:237–252, 1974.

Haseman JK and Hoel DG: Tables of Gehan's generalized Wilcoxon test with fixed point censoring. *Journal of Statistics Comput. Simul.* 3:117–135, 1974.

Hoel DG: Some statistical aspects of experiments for determining the teratogenic effects of chemicals. In Pratt J (Ed.): *Statistical and Mathematical Aspects of Pollution Problems.* New York Marcel Dekker, Inc., 1974, pp. 375–381.

Hoel DG: Statistical models for estimating carcinogenic risks from animal data. In *Proceedings of the Fifth Annual Conference on Environmental Toxicology.* AMRL–TR–74–125 Washington, D.C., GPO, 1974, pp. 285–291.

Hoel DG and Weiss GH: A comparison of methods for choosing the better of two negative exponential lifetime distributions. In Proschan, F. and Serfling, R.J. (Eds.): *Reliability and Biometry.* Philadelphia, SIAM, 1974, pp. 619–636.

Chase GR and Hoel DG: Serial dilutions: Error effects and optimal designs. *Biometrika* 62:329–334, 1975.

Hoel DG: Human risk assessment based on laboratory animal studies. In *Second Joint U.S./USSR Symposium on the Comprehensive Analysis of the Environment.* U.S. Environmental Protection Agency, Washington, D.C., 1975, pp. 22–24.

Hoel DG, Gaylor DW, Kirschstein RL, Saffiotti U and Schneiderman MA: Estimation of risks of irreversible, delayed toxicity. *Journal of Toxicology Environmental Health* 1:133–151, 1975.

Hoel DG, Sobel M and Weiss GH: A survey of adaptive sampling for clinical trials. In Elashoff RM (Ed.): *Perspectives in Biometrics.* New York, Academic Press, 1975, pp. 29–61.

Hoel DG, Sobel M and Weiss GH: Comparisons of sampling methods for choosing the best binomial population with delayed observations. *J. Stat. Comput. Simul.* 3:299–313, 1975.

Hoel DG and Weiss GH: A clinical trial design with a fixed maximum number of failures. *Communication in Statistics* 4:429–436, 1975.

Simon R, Weiss GH and Hoel DG: Sequential analysis of binomial clinical trials. *Biometrika* 62:195–200, 1975.

Crump KS, Hoel DG, Langley CH and Peto R: Fundamental carcinogenic processes and their implications for low dose risk assessment. *Cancer Research* 36:2973–2979, 1976.

Hoel DG: Statistical extrapolation methods for estimating risks from animal data. *Annals of New York Academy Sciences* 271:418–420, 1976.

Hoel DG, Weiss GH and Simon R: Sequential tests for composite hypotheses with two binomial populations. *Royal Statistical Society* 38:302–308, 1976.

Guess HA and Hoel DG: The effect of dose on cancer latency period. *Journal of Environmental Toxicology* 1:279–286, 1977.

Hoel DG: Some problems in low dose extrapolation. In Hiatt HH, Watson JD and Winsten JA (Eds.): *Origins of Human Cancer,* Vol. 4, Book C. Cold Spring Harbor, NY, Cold Spring Harbor Laboratory, 1977, pp. 1391–1396.

Hoel DG and Weiss GH: Properties of noise emitted by vehicular queues. *Transportation Research* 11:39–44, 1977.

Simon R, Hoel DG and Weiss GH: The use of covariate information in the sequential analysis of dichotomous response experiments. *Communication in Statistics (A-Theory and Methods)* 6:777–788, 1977.

Haseman JK and Hoel DG: Statistical design of toxicity assays: Role of genetic structure of test animal population. *Journal of Toxicology Environmental Health* 5:89–101, 1979.

Hogan MD, Chi P, Hoel DG and Mitchell TJ: Association between chloroform levels in finished drinking water supplies and various site-specific cancer mortality rates. *Journal of Environmental Pathology and Toxicology* 2:873–887, 1979.

Hoel DG: Animal experimentation and its relevance to man. Proceedings from U.S.–Japan Conference on Biostatistics in the Study of Human Cancer, May 1978. *Environmental Health Perspective* 32:25–30, 1979.

Hoel DG: Low-dose and species-to-species extrapolation for chemically induced carcinogenesis. In McElheny VK and Abrahamson S (Eds): *Banbury Report 1: Assessing Chemical Mutagens: The Risk to Humans.* Cold Spring Harbor, NY, Cold Spring Harbor Laboratory, 1979, pp. 135–145.

Hoel DG: Sequential methods in genetic risk assessment. *Genetics* 92: s195-s198, 1979.

Hoel DG: Statistical approaches to toxicological data. Proceedings, 5th Symposium on Statistics and the Environment, NAS. *Environmental Health Perspective* 32:267–271, 1979.

Schoenfelder CA and Hoel DG: Properties of the Neyman-Scott carcinogenesis model at low dose rates. *Mathematical Biosciences* 45:227–246, 1979.

Anderson AW, Hoel DG and Kaplan NL: A general scheme for the incorporation of pharmacokinetics in low dose risk estimation for chemical carcinogenesis: Example—vinyl chloride. *Toxicology Applied Pharmacology* 55:154–161, 1980.

Hoel DG: Incorporation of background in dose-response models. Proceedings, Symposium on Extrapolation of Laboratory Toxicity Data to Man: Factors Influencing the Dose-Toxic Response Relationship, April 1979. *Federation Proceedings* 39:73–75, 1980.

Yanagimoto T and Hoel DG: Comparisons of models for estimation of safe doses using measures of the heaviness of tail of a distribution. *Annals of the Institute of Statistical Mathematics, Part B,* 32:465–480, 1980.

Yanagimoto T and Hoel DG: Measures of the heaviness of tail of estimation of safe doses. In Matusita K (Ed.): *Recent Developments in Statistical Inference and Data Analysis.* New York, North Holland Publishing Company, 1980, pp. 347–357.

Gaylor DW and Hoel DG: Statistical analysis of carcinogenesis data from chronic animal studies. In Sontag JM (Ed.): *Carcinogens in Industry and Environment.* New York, Marcel Dekker, 1981, pp. 97–111.

Haseman JK, Hoel DG and Jennrich RI: Some practical problems arising from the use of the gamma multi-hit model for risk estimation. *Journal of Toxicology Environmental Health* 8:379–386, 1981.

Hogan MD and Hoel DG: Estimated cancer risk associated with occupational asbestos exposure. *Risk Analysis* l:67–76, 1981.

Hoel DG: Carcinogenic Risk. *Risk Analysis* l:63–64, 1981.

Hoel DG: Extrapolation models of animal toxicity data to man. In Hoch RJ (Ed.): *Conference Proceedings: Environmental Risk Assessment: How New Regulations Will Affect the Utility Industry.* Palo Alto, Calif., Electric Power Research Institute, 1981, pp. 4–95 to 4–103.

Hoel DG: Statistical issues in toxicology. Selected Papers, Society for Industrial & Applied Mathematics. *Environmetrics* 81:248–257, 1981.

Hoel DG and Crump KS: Waterbourne Carcinogens: A Scientist's View. In Crandell R and Lave L (Ed.): *The Scientific Basis of Health in Safety Regulations.* The Brookings Institute, 173–195, 1981.

Hoel DG: Extrapolation of laboratory data to human health effects. *Environmental Science Research* 25:521–526, 1982.

Hoel DG: Statistical measures of risk. *Drug Metabolic Reviews* 13:829–838, 1982.

Hogan MD and Hoel DG: Extrapolation to man. In Hayes AW (Ed.): *Principles and Methods of Toxicology.* New York, Raven Press, 1982, pp. 711–731.

Kato H, Brown CC, Hoel DG and Schull WJ: Studies of the mortality of A-Bomb survivors. Report 7. Mortality, 1950–1978: Part II. Mortality from causes other

than cancer and mortality in early entrants. *Radiation Research* 91:243–264, 1982.

Brown KG and Hoel DG: Modeling time-to-tumor data: Analysis of the ED01 Study. *Fundamental Applied Toxicology* 3:458–469, 1983.

Brown KG and Hoel DG: Multistage prediction of cancer in serially dosed animals with application to the ED01 study. *Fundamental Applied Toxicology* 3:470–477, 1983.

Hoel DG: Conditional two sample tests with historical controls. In Sen PK (Ed.): *Contributions to Statistics: Essays in Honour of Norman L. Johnson.* Amsterdam, North Holland Publishing Company, 1983, pp. 229–236.

Hoel DG, Kaplan N and Anderson MW: Implication of nonlinear kinetics on risk estimation in carcinogenesis. *Science* 219:1032–1037, 1983.

Hoel DG, Wakabayashi T and Pike MC: Secular trends in the distributions of the breast cancer risk factors—menarche, first birth, menopause, and weight—in Hiroshima and Nagasaki, Japan. *American Journal of Epidemiology* 118:78–89, 1983.

Pike MC, Krailo MD, Henderson BE, Casagrande JT and Hoel DG: 'Hormonal' risk factors, 'breast tissue age' and the age-incidence of breast cancer. *Nature* 303:767–770, 1983.

Portier C and Hoel DG: Optimal bioassay design under the Armitage-Doll multistage model. *Journal of Toxicology Environmental Health* 12:1–19, 1983.

Portier C and Hoel DG: Low-dose rate extrapolation using the multistage model. *Biometrics* 39:897–906, 1983.

Poon AH and Hoel DG: Nonparametric estimation of the survival function when cause of death is uncertain. *Biometrics* 40:1151–1158, 1984.

Portier C and Hoel DG: Design of animal carcinogenicity studies for goodness-of-fit to multistage models. *Fundamental Applied Toxicology* 4:949–959, 1984.

Portier C and Hoel DG: Type 1 error of trend tests in proportions and the design of cancer screens. *Communication in Statistics (A-Theory and Methods)* 13:1–16, 1984.

Portier CJ, Hoel DG and Van Ryzin J: Statistical analysis of the carcinogenesis bioassay data relating to the risks from exposure to 2,3,7,8-tetrachlorodibenzo-p-dioxin. In Lowrance WW (Ed.): *Public Health Risks of the Dioxins.* New York, Rockefeller University, 1984, pp. 99–119.

Hoel DG: Epidemiology and the inference of cancer mechanisms. *National Cancer Institute Monograph* 67:199–203, 1985.

Hoel DG: Mathematical dose-response models and their application to risk estimation. In Vouk VB, Butler GC, Hoel DG and Pekall DB (Eds.): *Methods for Estimating Risk of Chemical Injury: Human and Nonhuman Biota and Ecosystems, Scope 1985/SGOMSEC 2.* New York, J. Wiley and Sons, 1985, pp. 347–359.

Hoel DG and Jennrich RI: Life table analysis with small numbers of cases: An example—multiple myeloma in Hiroshima and Nagasaki. *Journal of Statistics Comput. Simul.* 20:311–322, 1985.

Bernstein L, Gold LS, Ames BN, Pike MC and Hoel DG: Some tautologous aspects of the comparison of carcinogenic potency in rats and mice. *Fundamental Applied Toxicology* 5:79–86, 1985.

Hoel DG: The impact of occupational exposure patterns on quantitative risk estimation. In Hoel DG, Merrill RA and Perera FP (Eds.): *Risk Quantitation and Regulatory Policy, Banbury Report 19, 1984.* Cold Spring Harbor, NY, Cold Spring Harbor Laboratory, 1985, pp. 105–118.

Hoel DG: Dose-response in radiation carcinogenesis: Animal studies. In Castellani A (Ed.): *Epidemiology and Quantitation of Environmental Risk in Humans from Radiation and Other Agents: Potential and Limitations.* London, Plenum Press, pp. 93–103, 1985.

Hoel DG and Preston DL: Dose-response in radiation carcinogenesis: Human studies. In Castellani A (Ed.): *Epidemiology and Quantitation of Environmental Risk in Humans from Radiation and Other Agents: Potential and Limitations.* London, Plenum Press, pp. 105–122, 1985.

Yanagawa T and Hoel DG: Use of historical controls for animal experiments. *Environmental Health Perspective* 63:217–224, 1985.

Hoel DG: The incorporation of pharmacokinetics in low-dose risk estimation. In Clayton D, Krewski D and Munro I (Eds.): *Toxicological Risk Assessment (Volume I).* Boca Raton, Fla., CRC Press, 1985, pp. 205–214.

Bernstein L, Gold LS, Ames BN, Pike MC and Hoel DG: Toxicity and carcinogenic potency. *Risk Analysis* 5:263–264, 1985.

Gold LS, Bernstein L, Kaldor J, Backman G and Hoel DG: An empirical comparison of methods used to estimate carcinogenic potency in long-term animal bioassays: Lifetable vs. summary incidence data. *Fundamental Applied Toxicology* 6:263–269, 1986.

Brown KG and Hoel DG: Statistical modeling of animal bioassay data with variable dosing regimens: Example—vinyl chloride. *Risk Analysis* 6:155–166, 1986.

Hoel DG and Yanagawa T: Incorporating historical controls in testing for a trend in proportions. *Journal of American Statistical Association* 81:1095–1099, 1986.

Portier CJ, Hedges JC and Hoel DG: Age-specific models of mortality and tumor onset for historical control animals in the National Toxicology Program's carcinogenicity experiments. *Cancer Research* 46:4372–4378, 1986.

Hogan M and Hoel DG: Utilizing scientific data in assessing human cancer risk associated with chemical exposure. In Report: Chemical Carcinogens: A Review of the Science and Its Associated Principles by U.S. Intergency Staff Group on Carcinogens, *Environmental Health Perspectives,* Vol. 67, pp. 253–258, 1986.

Hoel DG: Statistical aspects of chemical mixtures. In Vouk VB, Butler GC, Upton AC, Parke DV and Asher SC (Eds.): *Methods for Assessing the Effects of Mixtures of Chemicals, SGOMSEC3.* New York, J. Wiley & Sons Limited, 1987, pp. 369–377.

Hoel DG and Landrigan PJ: Comprehensive evaluation of human data. In Tardiff RG and Rodricks JV (Eds.): *Toxic Substances and Human Risk, Principles of Data Interpretation.* New York, Plenum Press, 1987, pp. 121–129.

Portier CJ and Hoel DG: Issues concerning the estimation of the TD50. *Risk Analysis* 7:437–447, 1987.

Kaplan N, Hoel DG, Portier CJ and Hogan MD: An evaluation of the safety factor approach in risk assessment. In Pratt RM, McLachlan JA and Markert CL (Eds.): *Developmental Toxicology: Mechanisms and Risk, Banbury Report 26.* Cold Spring Harbor, NY, Cold Spring Harbor Laboratory, 1987, pp. 335–346.

Hoel DG: Radiation risk estimation models. *Environmental Health Perspective* 75:105–107, 1987.

Weinberg CR, Brown KG and Hoel DG: Altitude, radiation, and mortality from cancer and heart disease. *Radiation Research* 112:381–390, 1987.

Hoel DG: Cancer risk models for ionizing radiation. *Environmental Health Perspective* 76:121–124, 1987.

Hoel DG, Haseman JK, Hogan MD, Huff JE and McConnell EE. The impact of toxicity on carcinogenicity studies: Implications for risk assessment. *Carcinogenesis* 9:2045–2052, 1988.

Pedersen LG, Darden TA, Deerfield DW, Anderson MW and Hoel DG: A theoretical study of the effect of methylation or ethylation at 06-guanine on the structure and energy of DNA double strands. *Carcinogenesis* 9:1553–1562, 1988.

Piegorsch WW and Hoel DG: Exploring relationships between mutagenic and carcinogenic potencies. *Mutation Research* 196:161–175, 1988.

Bailer AJ and Hoel DG: Metabolite-based internal doses used in a risk assessment of benzene. *Environmental Health Perspective* 82:177–184, 1989.

Bailer AJ and Hoel DG: Benzene risk assessments: Review and update. In Mehlman MA (Ed.): *Benzene: Occupational and Environmental Hazards Scientific Update (Vol. 16, Advances in Modern Environmental Toxicology).* Princeton, NJ, Princeton Scientific Publishing Co., Inc., 1989, 131–140. and *Cell Biology and Toxicology* 5(3):287–295, 1989.

Yanagawa T, Hoel DG and Brooks G: A conservative use of historical data for a trend test in proportions. *Journal of Japan Statistical Society* 19(1):83–94, 1989.

Hoel DG and Dinse GE: Using Mortality Data to Estimate Radiation Effects on Breast Cancer Incidence. *Environmental Health Perspective* 87:123–129, 1990.

Portier CJ, Hoel DG, Kaplan NL and Koop A: Biologically Based Models for Risk Assessment. In Vannio H, Sora M, and McMichael AJ (Eds.): *Complex Mixtures and Cancer Risk.* Lyon, France, International Agency for Research on Cancer Scientific Publications, 1990, No. 104.

Hoel DG: An Overview of the Probable Consequences of Prolonged Inhibition of Gastric Acid Secretion. In Elder J (Ed.): Profound Gastric Acid Suppression: Long-Term Safety Risk? *Research and Clinical Forums* 12(1):169–176, 1990.

Davis DL, Hoel DG, Fox J and Lopez A: International Trends in Cancer Mortality in the France, West Germany, Italy, Japan, England and Wales, and the USA. *Lancet* 336:474–481, 1990.

Davis DL, Hoel DG, Fox J and Lopez A: International Trends in Cancer in France, West Germany, Italy, Japan, England and Wales, and the United States. *Annals of the New York Academy of Sciences* 609:5–48, 1990.

Hoel DG: Assumptions of the HERP Index. *Risk Analysis* 10:623–624, 1990.

Ellett WH, Hoel DG and Cooper RD: BEIR V Estimates of Excess Cancer Mortality. Conference Proceedings: Statistics of Human Exposure to Ionizing Radiation Workshop. Oxford, England, *1990 Radiation Protection Dosimetry* 36:309–314, 1991.

Hoel DG: A Balanced Approach to Risk Assessment. In Tsuchiya K, Lee SD, Grant LD and Mehlman MA (Eds.): *Conference Proceedings: Toxicology and Industrial Health,* Vol. 7, Number 5/6, IXth UOEH International Symposium and First Pan Pacific Cooperative Symposium. Kitakyushu, Japan, 1991, pp. 305–311.

deSerres FJ and Hoel DG: Collaborative Study on the Genetic Toxicology of 2-Amino-N6-Hydroxadenine (AHA): An Exercise in Genetic Risk Assessment. *Mutation Research* 253:1–3, 1991.

Swenberg JA, Hoel DG and Magee PN: Mechanistic and Statistical Insight into the Large Carcinogenesis Bioassays on DEN and DMN. *Cancer Research* 51:6409–6414, 1991.

Davis DL, Ahlbom A, Hoel DG and Percy C: Is Brain Cancer Mortality Increasing in Industrial Countries? *American Journal of Industrial Medicine* 19:421–431, 1991.

Hoel DG, Davis DL, Miller AB, Sondik EJ and Swerdlow AJ: Trends in Cancer Mortality in 15 Industrial Countries 1969–1986. *Journal of the National Cancer Institute* 84:313–320, 1992.

Huff J and Hoel DG: Perspective and Overview of the Concepts and Value of Hazard Identification as the Initial Phase of Risk Assessment for Cancer and Human Health. *Scandinavian Journal of Work Environmental Health* 18(1):83–89, 1992.

Piegorsch WW, Carr GJ, Portier CJ and Hoel DG: Concordance of Carcinogenic Response between Rodent Species: Potency Dependence and Potential Underestimation. *Risk Analysis* 12:115–121, 1992.

Hoel DG: Multistage Models of Carcinogenesis and Their Implications for Dose-Response Models and Risk Projections. Conference Proceedings: International Conference on Radiation Effects and Protection. Mito, Japan, March 18–20, pp 123–126, 1992.

Shimizu Y, Kato H, Schull WJ and Hoel DG: Studies of the Mortality of A-Bomb Survivors. Mortality, 1950–8: Part 3. Non-cancer mortality in the years 1950-85 based on the recently revised doses (DS86). *Radiation Research* 130:249–266, 1992.

Dinse GE and Hoel DG: Exploring Time Trends in Cancer Incidence. *Cancer Causes and Control* 3:409–417 1992.

Davis DL and Hoel DG: Figuring Out Cancer. *International Journal of Health Services* 22(3):447–453, 1992.

Davis DL, Blair A, and Hoel DG: Agricultural Exposures and Cancer Trends in Developed Countries. *Environmental Health Perspective* 100:39–44, 1992.

Fung VA, Huff JE, Weisburger EK and Hoel DG. Predictive Strategies for Selecting 379 NCI/NTP Chemicals Evaluated for Carcinogenic Potential: Scientific and Public Health Impact. *Fundamentals and Applied Toxicology* 20:413–436, 1993.

Portier C, Clark G, Edler L, Greenlee W, Hoel D, Tritscher A and Lucier G: Ligand/Receptor Binding for 2,3,7,8–TCDD: Implication for Risk Assessment. *Fundamentals and Applied Toxicology* 12:48–56, 1993.

Hoel DG, Carter R, Ron E and Mabuchi K: The Influence of Death Certificate Errors on Cancer Mortality Trends. *Journal of the National Cancer Institute* 85:1063–1068, 1993.

Hoel DG: Questions about Radiation and Risk Estimates that Remain After BEIR–V. *Radiation Research* 136:137–139, 1993.

Davis DL, Bradlow HL, Wolff M, Woodruff T, and Hoel DG, Anton-Culver H: Medical Hypothesis: Xeno-estrogens as Preventable Causes of Breast Cancer. *Environmental Health Perspectives* 101:372–377, 1993.

Yanagawa T and Hoel DG: Incorporating Geographic Distribution into the Expected Number of Deaths in a Comparative Study. *Statistical Science and Data Analysis,* Matsusita K et al., Eds. 25–32, 1993.

Hoel DG and Portier CJ: Nonlinearity of Carcinogenesis Dose. *Environmental Health Perspective* 102:109–113, 1994.

Davis DL, Dinse GE, and Hoel DG: Decreasing Cardiovascular Disease and Increasing Cancer Among Whites in the United States from 1973 to 1987. *JAMA* 271:431–437, 1994.

Mori H, Nakamura T, Mine M, Kondo H, Okumura Y, and Hoel DG: Early Mortality of Atomic Bomb Survivors based on House Reconstruction Survey. *International Journal of Radiation Biology* 65: No. 2, 267–275, 1994.

Hoel DG: Ionizing Radiation and Cancer Prevention. *Environmental Health Perspective* 103 (Suppl 8):241–243, 1995.

Daniel DM, Lackland DT, Baron LF, Nixon DW, Garr DR, Gross AJ, O'Brien and Hoel DG. Comparison of White and African-American Barriers to Mammography: A Need for a Barrier-Specific Approach to Care. *Cancer Prevention International* 2:3–21, 1995.

Gordis L, Berry DA, Chu SY, Fajardo LL, Hoel DG, Laufman LR, Rufenbarger CA, Scott, JR, Sullivan DC, Wasson JH, Westhoff CL and Zern RT. National Institutes of Health Consensus Development Conference Statement: Breast Cancer Screening for Women Ages 40–49, January 21–23, 1997. (Special Article) *Journal of National Cancer Institute* 89(14):1015–1026, 1997.

Radivoyevitch T, Hoel DG, Hahnfeldt PJ, Rydberg B and Sachs RK. Recent Pulsed Fields Gel Electrophoresis Data Suggest Two Types of DSBs [4409–R]. *Radiation Research* 149:52–58, 1998.

Radivoyevitch T, Hoel DG, Chen AM, Sachs RK. Double-Strand Break Misrejoining After X–Irradiation: Relating Moderate to Very High Doses by a Markov Model [4437–R]. *Radiation Research* 149:59–67, 1998.

Nietert P, Sutherland SE, Silver RM, Pandey JP, Knapp R, Hoel DG and Dosemeci, M. Is Occupational Organic Solvent Exposure a Risk Factor for Scleroderma? *Arthritis and Rheumatism* 41:1111–1118, 1998.

Radivoyevitch T, Hoel, DG, Hahnfeldt, Sachs RK. Size Distribution of Misrejoining DNA Fragments in Irradiation Cells. *Mathematical Biosciences* 149:107–136, 1998.

Hoel DG and Li P. Threshold Models in Radiation Carcinogenesis. *Health Physics* 75(3):241–250, 1998.

Nicholas JS, Lackland DT, Dosemeci M, Mohr L, Dunbar JB, Grosche B and Hoel DG. Mortality among United States Commercial Pilots and Navigators. *Journal of Occupational and Environmental Medicine* 40:980–985, 1998.

Nicholas JS, Lackland DT, Butler GC, Mohr LC, Dunbar JB, Kaune WT, Grosche B and Hoel DG. Cosmic Radiation and Magnetic Field Exposure to Airline Flight Crews. *American Journal of Industrial Medicine* 34:574–580, 1998.

Dinse GE, Umbach DM, Sasco AJ, Hoel DG and Davis DL. Unexplained Increase in Cancer Incidence in the United States from 1975 to 1994: Possible Sentinel Health Indicators? *Annual Review of Public Health* Vol. 20, 1999.

Grosche B, Lackland D, Mohr L, Dunbar J, Nicholas J, Burkart W and Hoel D. Leukemia in the vicinity of two Tritium releasing nuclear facilities: a comparison of the Kruemmel Site, Germany, and the Savannah River Site, South Carolina, USA. *Journal of Radiological Protection* 19:243–252, 1999.

Radivoyevitch T and Hoel, DG. Modeling the Low-LET Dose-Response of BCR–ABL Formation: Predicting Stem Cell Numbers from A-bomb Data. *Mathematical Biosciences* 162:85–101, 1999.

Radivoyevitch T and Hoel D. Biologically-Based Risk Estimation for Radiation-Induced Chronic Myeloid Leukemia. *Radiation & Environmental Biophysics* 39(3):153–159, 2000.

Nicholas JS, Butler GC, Lackland DT, Hood WC, Hoel DG and Mohr LC. Flight deck magnetic fields in Commercial Aircraft. *American Journal of Industrial Medicine* 38(5):548–554, 2000.

Nicholas JS, Butler GC, Lackland DT, Tessier GS, Mohr LC and Hoel DG. Health among commercial airline pilots. *Aviation, Space, and Environmental Medicine* 72(9);821–826, 2001.

Tessier GS, Lam C, Nakamura T and Hoel DG, Two-Stage Cancer Models Applied to Gamma and Neutron Exposed Mice. *European J. of Oncology* 6(3):297–301, 2001.

Schubauer-Berigan MK, Frey GD, Baron L andHoel DG. Mammography Dose in Relation to Body Mass Index, Race, and Menopausal Status. *Radiation Protection Dosimetry* 98(4):425–432, 2002.

McGreevy KM, Baron LF and Hoel DG. Clinical Breast Examination Practices Among Women Undergoing Screening Mammography. *Radiology* 224(2):555–559, 2002.

Schubauer-Berigan MK, Baron L, Frey GD and Hoel DG. Breast Dose Variability in a Biracial Population Undergoing Screening Mammography. *Radiation Protection Dosimetry* 98(4):417–424, 2002.

Baker GS and Hoel DG. Corrections in the Atomic bomb Data to Examine Low Dose Risk. *Health Physics* 85(6):709–720, 2003.

Carnes BA, Grahn D, Hoel D. Mortality of Atomic Bomb Survivors Predicted from Laboratory Animals. *Radiation Research,* 160:159–167, 2003.

Nicholas J, Butler G, Davis S, Bryant E, Hoel D and Mohr L. Stable Chromosome Aberrations and Ionizing Radiation in Airline Pilots. *Aviation, Space and Environmental Medicine* 74:953–956, 2003.

Nakamura T and Hoel DG. Comparing Risks between Radiation and Dioxin Exposure Based on Two-Stage Model. *Environmetrics* 14:203–211, 2003.

Creasman WT, Hoel DG and DiSaia PJ. WHI: Now that the Dust has settled. A Commentary. *American Journal of Obstetrics and Gynecology* 189:621–626, 2003.

Heath, Jr. CW, Bond PD, Hoel DG and Meinhold CB. Residential Radon Exposure and Lung Cancer Risk: Commentary on Cohen's County-based Study. *Health Physics* 87(7):647–655, 2004.

McGreevy KM, Hoel B, Lipsitz SR, Bissada, NK and Hoel DG. Racial and Anthropometric Differences in Insulin-Like Growth Factor I (IGF–I) and Insulin-Like Growth Factor Binding Protein-3 (IGFBP–3) Levels. *Urology 2004* (in press).

McGreevy KM, Hoel B, Lipsitz SR and Hoel DG. Impact of Nutrients on Insulin-like Growth Factor-I, Insulin-like Growth Factor Binding Protein-3 and their Ratio in Black and White Males. *Public Health Nutrition,* 2004 (accepted).

Hoel, DG, Carnes B. Cancer Dose-Response Analysis of the Radium Dial Workers. Proceedings from the HEIR 2004 9th International Conference on Health Effects of Incorporated Radionuclides—Emphasis on Radium, Thorium, Uranium and their Daughter Products. GSF–National Research Center, Neuherberg, Germany, November 29–December 1, 2004. 2005 (in press)

○