AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

S. HRG. 115–102

HEARING ON THE NOMINATIONS OF MICHAEL DOURSON, MATTHEW LEOPOLD, DAVID ROSS, AND WILLIAM WEHRUM TO BE ASSISTANT ADMINISTRATORS OF THE ENVIRONMENTAL PROTECTION AGENCY, AND JEFFERY BARAN TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION

HEARING

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

OCTOBER 4, 2017

Printed for the use of the Committee on Environment and Public Works



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

HEARING ON THE NOMINATIONS OF MICHAEL DOURSON, MATTHEW LEOPOLD, DAVID ROSS, AND WILLIAM WEHRUM TO BE ASSISTANT ADMINISTRATORS OF THE ENVIRONMENTAL PROTECTION AGENCY, AND JEFFERY BARAN TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION

S. HRG. 115–102

HEARING ON THE NOMINATIONS OF MICHAEL DOURSON, MATTHEW LEOPOLD, DAVID ROSS, AND WILLIAM WEHRUM TO BE ASSISTANT ADMINISTRATORS OF THE ENVIRONMENTAL PROTECTION AGENCY, AND JEFFERY BARAN TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION

HEARING

BEFORE THE

COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS UNITED STATES SENATE

ONE HUNDRED FIFTEENTH CONGRESS

FIRST SESSION

OCTOBER 4, 2017

Printed for the use of the Committee on Environment and Public Works

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

U.S. GOVERNMENT PUBLISHING OFFICE

27–172 PDF WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing 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 ENVIRONMENT AND PUBLIC WORKS

ONE HUNDRED FIFTEENTH CONGRESS
FIRST SESSION

JOHN BARRASSO, Wyoming, *Chairman*

JAMES M. INHOFE, Oklahoma	THOMAS R. CARPER, Delaware
SHELLEY MOORE CAPITO, West Virginia	BENJAMIN L. CARDIN, Maryland
JOHN BOOZMAN, Arkansas	BERNARD SANDERS, Vermont
ROGER WICKER, Mississippi	SHELDON WHITEHOUSE, Rhode Island
DEB FISCHER, Nebraska	JEFF MERKLEY, Oregon
JERRY MORAN, Kansas	KIRSTEN GILLIBRAND, New York
MIKE ROUNDS, South Dakota	CORY A. BOOKER, New Jersey
JONI ERNST, Iowa	EDWARD J. MARKEY, Massachusetts
DAN SULLIVAN, Alaska	TAMMY DUCKWORTH, Illinois
RICHARD SHELBY, Alabama	KAMALA HARRIS, California

RICHARD M. RUSSELL, *Majority Staff Director*
GABRIELLE BATKIN, *Minority Staff Director*

C O N T E N T S

Page

OCTOBER 4, 2017

OPENING STATEMENTS

Barrasso, Hon. John, U.S. Senator from the State of Wyoming 1
Carper, Hon. Thomas R., U.S. Senator from the State of Delaware 3
Inhofe, Hon. James M., U.S. Senator from the State of Oklahoma 410

WITNESSES

Chabot, Hon. Steve J., U.S. Representative from the State of Ohio 410
Prepared statement 412
Dunn, Hon. Neal P., U.S. Representative from the State of Florida 414
Prepared statement 415
Dourson, Michael, Professor, Risk Science Center, Department of Environmental Health, University of Cincinnati, College of Medicine 419
Prepared statement 422
Response to an additional question from Senator Barrasso 426
Responses to additional questions from:
Senator Carper 427
Senator Booker 445
Response to an additional question from:
Senator Capito 447
Senator Cardin 448
Responses to additional questions from:
Senator Duckworth 449
Senator Ernst 450
Senator Fischer 451
Senator Markey 452
Senator Merkley 454
Senator Sanders 456
Senator Whitehouse 460
Leopold, Matthew, Counsel, Carlton Fields Jordan Burt, P.A. 478
Prepared statement 480
Responses to additional questions from:
Senator Carper 484
Senator Cardin 489
Response to an additional question from Senator Markey 489
Responses to additional questions from:
Senator Sanders 490
Senator Whitehouse 491
Ross, David, Assistant Attorney General, State of Wisconsin, and Director, Wisconsin Department of Justice Environmental Protection Unit 495
Prepared statement 497
Responses to additional questions from:
Senator Carper 501
Senator Booker 509
Senator Cardin 510
Response to an additional question from Senator Ernst 512
Responses to additional questions from:
Senator Markey 513
Senator Sanders 514
Senator Whitehouse 519
Wehrum, William, Partner, Hunton & Williams LLP 527

Page

Wehrum, William, Partner, Hunton & Williams LLP—Continued
Prepared statement 529
Responses to additional questions from Senator Carper 532
Response to an additional question from Senator Cardin 556
Responses to additional questions from:
Senator Duckworth 557
Senator Ernst 560
Senator Fischer 561
Senator Markey 562
Senator Merkley 563
Senator Sanders 569
Senator Whitehouse 572
Senator Wicker 587
Baran, Jeffery, (Reappointment) Commissioner, U.S. Nuclear Regulatory Commission 591
Prepared statement 593

ADDITIONAL MATERIAL

Letter to Senators Barrasso and Carper from Audubon Florida, September 19, 2017 961
News Release from the Office of the Administrator, EPA, Widespread Praise for Matt Leopold, Leopold Nominated as EPA General Counsel, September 2, 2017 962
News Release from the Office of the Administrator, EPA, Widespread Praise From Environmental Officials for David Ross, Ross Nominated to Head EPA Office of Water, September 2, 2017 964

HEARING ON THE NOMINATIONS OF MICHAEL DOURSON, MATTHEW LEOPOLD, DAVID ROSS, AND WILLIAM WEHRUM TO BE ASSISTANT ADMINISTRATORS OF THE ENVIRONMENTAL PROTECTION AGENCY, AND JEFFERY BARAN TO BE A MEMBER OF THE NUCLEAR REGULATORY COMMISSION

WEDNESDAY, OCTOBER 4, 2017

U.S. SENATE,
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS,
Washington, DC.

The Committee met, pursuant to notice, at 10:03 a.m. in room 406, Dirksen Senate Office Building, Hon. John Barrasso (Chairman of the Committee) presiding.

Present: Senators Barrasso, Carper, Inhofe, Capito, Boozman, Wicker, Fischer, Rounds, Ernst, Sullivan, Cardin, Whitehouse, Merkley, Gillibrand, Booker, Markey, Duckworth, and Harris.

OPENING STATEMENT OF HON. JOHN BARRASSO, U.S. SENATOR FROM THE STATE OF WYOMING

Senator BARRASSO. Good morning. I call this hearing to order.

Today we are going to be considering the nomination of four individuals to serve as Assistant Administrators of the U.S. Environmental Protection Agency and one individual to serve as a member of the Nuclear Regulatory Commission, the NRC.

First, I am going to address the four nominees before us today to be Assistant Administrators of the EPA. Each one is a well qualified individual who will bring a wealth of experience and expertise to a critically important role in protecting America's public health and safety. I applaud the President's nomination of such accomplished Americans and dedicated public servants.

President Trump has nominated Michael Dourson to lead the EPA's Office of Chemical Safety and Pollution Prevention. The Office of Chemical Safety and Pollution Prevention protects the American people and the environment from potential risks posed by pesticides and toxic chemicals.

Dr. James Klaunig, who has served on numerous EPA scientific advisory panels, stated of Dr. Dourson, "Dr. Dourson is a leader in the field of risk assessment. He has been instrumental in bringing scientists of different disciplines and representing different constituents together to address current and future approaches to the risks of humans to exogenous chemicals."

President Trump also nominated Matthew Leopold to lead the EPA's Office of the General Counsel. The Office of General Counsel serves as the EPA's chief legal advisor. John Cruden, former Obama Justice Department Assistant Attorney General, said this of Mr. Leopold: "He is committed to the rule of law and can be counted on to give sound and candid advice to EPA decision-makers."

President Trump nominated David Ross to lead EPA's Office of Water. The Office of Water ensures drinking water is safe. The Office also restores and maintains oceans, watersheds, and their aquatic ecosystems to protect human health, to support economic and recreational activities, and to provide healthy habitat for fish, wildlife, and plants.

Todd Parfitt, the Director of Wyoming's Department of Environmental Quality, said this of Mr. Ross. He said, "Mr. Ross possesses the necessary tools to effectively and appropriately oversee EPA's water program in a fair, balanced, and practical way."

When we get to the witness introductions, I will be introducing Mr. Ross and will say more about his accomplishments in the time he spent in the State of Wyoming.

President Trump also nominated William Wehrum to lead the EPA's Office of Air and Radiation. The Office of Air and Radiation develops national programs, policies, and regulations for controlling air pollution and radiation exposure. Former environmental Obama Justice official John Cruden said of Mr. Wehrum, "I believe he is committed to achieving clean air for all citizens and carefully following sound and current science."

I believe we must act quickly to confirm all these EPA nominees so the Agency will be even better prepared to protect human health and the environment, enforce our environmental laws, and respond effectively when disasters strike.

It is deeply unfortunate that blind opposition to all of these Administration EPA nominees, including the well respected Susan Bodine to be EPA's Enforcement Chief, has stalled the confirmation process. Susan was reported in July and has been held up by the minority ever since.

I want to be clear. The EPA's Office of Enforcement and Compliance Assurance, the office whose vital mission is to hold polluters accountable, is without a confirmed leader. It is without its confirmed leader because the minority feels compelled to block all nominees to the EPA, regardless of all the pollution and environmental needs of our communities, including those communities struggling to recover from the hurricanes that have ravaged our shores.

A primary complaint of the minority that they cite is that blocking all nominees to the EPA is that the EPA is not being responsive to minority's oversight requests. The EPA has already sent the minority over 2,800 pages in response to its seemingly never ending requests. And I have those responses here. Twenty-eight hundred pages. And these are printed on both sides of the pages throughout. Two thousand eight hundred pages in response to its seemingly never ending requests of the minority. These from the EPA. Claiming the EPA is not responsive as an excuse for not confirming important nominees does not pass the smell test.

Now, I regret that I can't strike the same positive note that I have for the EPA nominees for the nomination of Jeffery Baran to serve on another term as member of the Nuclear Regulatory Commission. Mr. Baran is currently on the NRC and though his term does not expire until June 2018, he has been nominated at the request of the Senate Democrats. Senate Democrats have refused to advance the nominations of Annie Caputo and David Wright to the NRC until Commissioner Baran is confirmed to a new 5-year term.

Let me be clear. Mr. Baran's nomination is a big ask. Mr. Baran has been nominated for a term that is effectively 3 years longer than the term for which Mr. Wright has been nominated and 2 years longer than the term for which Ms. Caputo has been nominated. If Mr. Baran is confirmed, his term would outlast those of all Republican nominees to the NRC, including Chairman Svinicki.

In December 2014, the last time the Senate confirmed Mr. Baran, only one Republican voted in favor of his confirmation. I, along with many Republicans on this Committee, have voted against his nomination on six separate occasions. Since then Commissioner Baran has given me little reason to reconsider my vote. I hope this hearing gives us an opportunity to hear from Commissioner Baran and get more clarity regarding his record at the NRC.

I will now turn to the Ranking Member for his statement.

Thank you, Senator Carper.

OPENING STATEMENT OF HON. THOMAS R. CARPER, U.S. SENATOR FROM THE STATE OF DELAWARE

Senator CARPER. Thanks, Mr. Chairman.

I want to welcome our witnesses today, our nominees. I want to welcome your family members—spouses, parents, children, sisters-in-law, brothers-in-law. We are happy that you are here, and we thank you for your willingness to share with our country those that you love.

Let me just say our Chairman has stacked up here answers that he explains are answers to requests and inquiries that we have made on the minority side. Senate Democrats on this Committee have sent Mr. Pruitt, the Administrator of the EPA, some 26 letters. To seven of them we have received generally full responses. Seven out of 26.

I have stacked up right here the pages of the responses for the other 19 requests, the other 19 requests. I have said more than a few times if the shoe were on the other foot, and we had a Democrat in the White House, and we had a Democrat majority in the House and the Senate, and the Republicans on this Committee or any committee were trying to do oversight and get the kind of responses from EPA and from an Administrator from EPA, you would be pulling your hair out, and ours, too. This is just unacceptable.

I am seen in the Senate, and before that as Governor of Delaware, as a fair and impartial person. I like to work with my Republican colleagues. I have gone to bat for my Republican colleagues when we did have a Democrat in the White House and the responses to them and to us were not what I thought they should be.

But we can do better than that. EPA needs to do better than that. They need to show us more progress, and when we do we will

be happy to move these nominations forward. I don't think that is asking too much.

And with respect to the nomination of Jeff Baran to serve another term on the Nuclear Regulatory Commission, if he is confirmed, I hope that he will be, there will be—get this—three Republicans on the Nuclear Regulatory Commission—three—and there will be two Democrats. And they are all good nominees, and I look forward to supporting them all.

Having said that, fast forward to the present to today's hearing. We are 4 days into the new fiscal year and our EPA Administrator, Scott Pruitt, has yet to appear before this Committee to discuss EPA's proposed budget. Since Mr. Pruitt was confirmed, I mentioned a number of letters that we submitted and the responses that we have gotten, or not gotten.

Let me just say the idea that we are 9 months into a new Administration, an Administration that has proposed deep cuts in the budget for EPA, deep cuts to the number of people who work there, deep cuts to the programmatic support of clean water, clean air, cleanups for brownfields, hazardous waste sites, and we have yet to see the EPA Administrator sit at this table and talk to us to defend this budget. That is just unheard of. I have never seen anything like this.

Turning to today's hearing, we have five nominees before us. For the most part, I believe that Presidents, Governors, mayors, and other elected CEOs should generally be allowed to assemble their leadership teams. As Governor, I used to say to the legislature, I have been elected to serve as Governor of our State; allow me to at least nominate the people that I think would enable me to serve well, and they did. And that is why I find it hard, though, I have always tried to find a way to support Democrat or Republic administrations with their nominees, and I am certainly trying to do that in this Administration, too. They don't always make it easy. They don't always make it easy.

But I have some serious and unresolved concerns with two of our nominees today. The majority of our nominees I expect to support, but two I am troubled by, and I know a number of my colleagues are as well.

Just over a year ago members of this Committee celebrated a rare bipartisan achievement when Congress almost unanimously enacted comprehensive reform of the Toxic Substances Control Act. Jim Inhofe provided great leadership. Others on this Committee did as well. From Jim Inhofe all the way to Ed Markey, that covers a pretty broad spectrum here.

And we are trying to get that legislation implemented now, and all of us want to see it implemented well. And it was enacted because of a decades old lawsuit that made it all but impossible for EPA to otherwise regulate some of the most dangerous chemicals known to humankind. And we all share a strong bipartisan interest in seeing the new law implemented in an impartial, credible, and responsible way.

Regrettably, I am concerned that Dr. Dourson is not the leader that we need for that job. Never in the history of the EPA has a nominee to lead the Chemical Safety Office had such deep ties to industry. Never has a nominee had such a long record of recom-

mending chemical safety standards that are as much as thousands of times less protective, thousands of times less protective than those recommended by regulators. Never has a nominee, to my knowledge, so consistently underestimated the risks of chemical exposures to the most vulnerable among us.

And I would like to recognize the presence of a number of people who are here in this hearing today who have suffered greatly due to exposure to harmful chemicals. These people traveled all the way from across the country to be here today. I am not going to ask them to stand, but we know you are here. We appreciate your presence.

Having said that, Dr. Dourson did make a good faith effort to respond to a number of the prehearing questions that I sent him and others sent to him. That is the good news.

Now, Mr. Chairman, I ask unanimous consent to place those materials in the record.

Senator BARRASSO. Without objection.

[The referenced information follows:]

JOHN BARRASSO, WYOMING, CHAIRMAN
JAMES M. INHOFE, OKLAHOMA
SHELLEY MOORE CAPITO, WEST VIRGINIA
JOHN BOOZMAN, ARKANSAS
ROGER WICKER, MISSISSIPPI
DEB FISCHER, NEBRASKA
JERRY MORAN, KANSAS
MIKE ROUNDS, SOUTH DAKOTA
JONI ERNST, IOWA
DAN SULLIVAN, ALASKA
RICHARD SHELBY, ALABAMA
THOMAS R. CARPER, DELAWARE
BENJAMIN L. CARDIN, MARYLAND
BERNARD SANDERS, VERMONT
SHELDON WHITEHOUSE, RHODE ISLAND
JEFF MERKLEY, OREGON
KIRSTEN GILLIBRAND, NEW YORK
CORY A. BOOKER, NEW JERSEY
EDWARD J. MARKEY, MASSACHUSETTS
TAMMY DUCKWORTH, ILLINOIS
KAMALA HARRIS, CALIFORNIA
RICHARD M. RUSSELL, MAJORITY STAFF DIRECTOR
GABRIELLE BATKIN, MINORITY STAFF DIRECTOR

United States Senate
COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS
WASHINGTON, DC 20510-6175

August 4, 2017

Dr. Michael L. Dourson
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati, OH 45267-0056

Dear Dr. Dourson:

The Senate Environment and Public Works Committee has received your nomination to serve as the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention at the Environmental Protection Agency (EPA). Your record is extensive, particularly your work with the Toxicology Excellence for Risk Assessment (TERA) that you founded[1]. So the Committee can more fully assess your record, I request that you provide the following supplemental materials and responses to questions prior to the Committee's hearing on your nomination.

1) Please provide copies of the 2014, 2015 and 2016 annual reports for TERA, as the last publicly available report on the TERA website is from 2013[2]

2) TERA's website states that "TERA provides significant pro bono support to local and state governments, NGOS and others to help them address important human health and risk issues[3]." For each of the past ten years, please list a) the name of each entity to whom TERA provided such support and the duration of such efforts, b) the purpose of such support, and c) copies of any documents, presentations or other work products that were provided to the entity as part of such support.

3) TERA's website states that "We are transparent about who our funders are and what role they had, if any, in commenting on the TERA scientific opinions or results." Specific information necessary to determine TERA's transparency about this funding is neither included in the materials that were provided to the Committee nor available in either the publicly available annual reports for TERA or on the TERA website(s)[4]. For each of the past ten years, please provide a list that names each entity that provided grant, contract or other financial support to TERA (or directly to you), the amount and type of such funding, the purpose(s) for which it was provided and a specific description (name of

[1] For purposes of this letter, references to TERA include its successor entity, the Risk Science Center
[2] http://www.tera.org/about/AnnualReports.html
[3] http://www.tera.org/about/mission_history.html
[4] https://med.uc.edu/eh/centers/rsc/about-us/funding

PRINTED ON RECYCLED PAPER

research publication, expert testimony, or white paper, etc.) of any outcome developed or provided as a result of such funding.

4) TERA's website states that "TERA can provide a variety of litigation support services from review and analysis of data, to written opinions, to expert witness testimony" and that this work has included "testimony as expert witness on U.S. EPA's chromium risk assessment for Defendant in groundwater contamination case." For each of the past ten years, please identify each case in which TERA or any of its employees provided 'litigation support' and the party to which such support was provided, and the amount and type of compensation received. In responding, please include the caption of the case, the court in which the case was heard and the case number, and include copies of all materials produced as part of its litigation support services, including expert witness testimony, analysis of data and written opinions provided by TERA or any of its employees, as well as transcripts of depositions of TERA or any of its employees.

5) TERA's website states that "TERA's work organizing peer input, peer consultation and peer review is intended to meet the needs of public and private sponsors who have developed risk assessment documentation." For each of the past ten years, please provide a) a list naming and describing the purpose of each peer input, peer consultation or peer review activity conducted by TERA, b) the entity(ies) that provided the funding for the peer activity and the amount of such funding, and c) a list of the individuals who participated in the peer activity, along with who chaired the project and which individuals were paid for their participation by TERA or the funding party.

6) The CV you provided to the Committee lists dozens of invited presentations you delivered. Please provide copies of the slides, speech or other briefing materials for the presentations given on the following dates: June 14, 2017, March 21, 2017, March 14, 2017, March 14, 2016, June 24, 2015, April 20, 2015, January 21, 2015, November 18, 2010, November 4, 2010, December 3, 2004, September 29, 2003, September 26, 2003, July 25, 2002, and April 30, 1996.

7) The Public Financial Disclosure Report that was provided to the Committee indicates that you served as a member of the North American Flame Retardant Alliance (NAFRA) until June 2017, and lists that entity as a non-profit. According to its website[5], that entity "was formed in March 2011 to serve as the lead advocacy organization in North America for flame retardant producers and users." Does NAFRA receive any funding from any entity that is not itself a manufacturer, user, distributor of or trade association for flame retardant chemicals? If so, for each of the past two years, please list each such entity and the amount of funding it provided to NAFRA.

[5] https://flameretardants.americanchemistry.com/About-North-American-Flame-Retardant-Alliance-NAFRA-/

8) The Public Financial Disclosure Report that was provided to the Committee indicates that you serve as the President of the Toxicology Education Foundation, and lists that entity as a non-profit. For each of the past two years, please provide a) a list naming each corporate entity or industry trade association that provided funding to the Foundation, along with the amount of the funding and b) the total amount of funding provided to the Foundation.

9) The Public Financial Disclosure Report that was provided to the Committee indicates that you served as the Secretary of the Toxicology Forum until June 2017, and lists that entity as a non-profit. That entity's website does not list any non-corporate sponsors.[6] Does the Toxicology Forum receive any funding from any entity that is not a corporation or trade association representing corporations? If so, for each of the past two years, please list each such entity and the amount of funding it provided to the Toxicology Forum.

10) Your Ethics Agreement states that "I will not participate personally and substantially in any particular matter in which I know that I have a financial interest directly and predictably affected by the matter, or in which I know that a person whose interests are imputed to me has a financial interest directly and predictably affected by the matter, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2)." Please provide a list of persons and particular matters (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) about which you plan to consult with the Designated Agency Ethics Official in order to determine whether you will recuse yourself or require a written exemption or waiver prior to your participation.

11) Your Ethics Agreement states that "Upon confirmation, I will resign from my positions with the following entities: University of Cincinnati, and the Toxicology Education Foundation. I resigned from my position with the North American Flame Retardant Alliance, and the Toxicology Forum in June 2017. For a period of one year after my resignation from each of these entities, I will not participate personally and substantially in any particular matter involving specific parties in which I know that entity is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d)." Please provide a list of particular matters involving specific parties (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) about which you plan to consult with the Designated Agency Ethics Official in order to determine whether you will recuse yourself or require advance authorization prior to your participation.

---

[6] http://dialogue.toxforum.org/page/become-a-sponsor

12) Your Ethics Agreement also states that you will sign the Trump Ethics Pledge[7]. The Trump Ethics Pledge states "I will not for a period of 2 years from the date of my appointment participate in any particular matter involving specific parties that is directly and substantially related to my former employer or former clients, including regulations and contracts." The Pledge additionally notes that (d) "Directly and substantially related to my former employer or former clients" shall mean matters in which the appointee's former employer or a former client is a party or represents a party" and (i) "Former client" is any person for whom the appointee served personally as agent, attorney, or consultant within the 2 years prior to the date of his or her appointment, but excluding instances where the service provided was limited to a speech or similar appearance. It does not include clients of the appointee's former employer to whom the appointee did not personally provide services." Please provide a list of particular matters involving specific parties (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) that you plan to recuse yourself from participating in for 2 years. If you plan to request waivers from the Trump Ethics Pledge for any such matter, please also list those.

Thank you very much for your consideration of this important matter. If you have any questions or concerns, please contact [redacted] my staff at 202-224-8832 or [redacted] I look forward to meeting with you.

With best personal regards, I am,

Sincerely yours,

Tom Carper
Ranking Member

[7] https://www.whitehouse.gov/the-press-office/2017/01/28/executive-order-ethics-commitments-executive-branch-appointees

UNIVERSITY OF Cincinnati

Risk Science Center
Department of Environmental Health
University of Cincinnati College of Medicine
PO Box 670056
Cincinnati, Ohio 45267-0056

160 Panzeca Way
Kettering Lab Building, Suite G-24
http://med.uc.edu/eh/centers/tera

Dear Senator Carper

September 6th, 2017

I appreciate your interest in Toxicology Excellence for Risk Assessment (TERA). As you may know, TERA is a nonprofit 501c3 organization with a mission to support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues. TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion. One-third of TERA's effort has been for industry; 2/3rds of its effort has been for government.

In 21 years as an independent and science neutral group, TERA published numerous reports, manuscripts, presentations and education courses, created 5 freely accessible websites, and garnered the sponsorship of over 50 government groups and as many industry and nonprofit organizations. We were often the go-to group for government-industry collaborations such as the perchlorate research program in the late 1990s, the West Virginia PFOA contamination in the early 2000's, and EPA's Voluntary Children's Chemical Evaluation Program in the mid 2000's. TERA also conducted the independent peer review of the 9-government report on the world trade center disaster and the recent Elk River spill in West Virginia. TERA has received many accolades and hundreds of scientists and managers from both government and industry can attest to its independent and science-neutral approach. Even staff of NRDC has commented privately that TERA websites were visited often since they contained so much valuable information.

Please find attached responses to you questions, including a disk of related information. I would be more than happy to answer additional questions from you or your hard-working staff, either before or after the tentatively scheduled committee meeting later this month.

Cheers!

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Professor of Environmental Health

An affirmative action/equal opportunity institution

Michael L. Dourson, Ph.D., DABT, FATS, FSRA

Responses to Thomas Carper letter to Michael Dourson dated August 4, 2017

Question 1) Please provide copies of the 2014, 2015 and 2016 annual reports for TERA, as the last publicly available report on the TERA website is from 2013.

> Response: Annual reports for 2014 and 2015 are now available on the TERA website as well as a financial summary for 2015. These two annual reports with financial summaries are also attached.

Question 2) TERA's website states that "TERA provides significant pro bono support to local and state governments, NGOS and others to help them address important human health and risk issues." For each of the past ten years, please list a) the name of each entity to whom TERA provided such support and the duration of such efforts, b) the purpose of such support, and c) copies of any documents, presentations or other work products that were provided to the entity as part of such support.

> Response: Please see the list of hours for pro bono, nonprofit, and profit tasks for the years 1995 to 2015. These hours were devoted to either:
>
> - Participation in scientific societies---e.g., see attached resume under appointments starting on page 27,
> - State Hazard Evaluation and Lending Program (State HELP) program---e.g., see reports at www.allianceforrisk.org, which is currently being reconfigured and found at www.archive.org,
> - Corporate science development---e.g., work on projects not otherwise funded, such as the 2004 publication by Strawson et al. on perchlorate, and
> - Miscellaneous answering of phone calls and other generally quick email responses to the public.
>
> Detailed records of this activity were maintained by individual TERA staff for general reporting purposes and corporate records of such efforts were not retained Several scientific publications resulted from such efforts, as generally described in the acknowledgement section of the publication and available on one or more of our websites.

Question 3) TERA's website states that "We are transparent about who our funders are and what role they had, if any, in commenting on the TERA scientific opinions or results." Specific information necessary to determine TERA's transparency about this funding is neither included in the materials that were provided to the Committee nor available in either the publicly available annual reports for TERA or on the TERA website(s). For each of the past ten years, please provide a list that names each entity that provided grant, contract or other financial support to TERA (or directly to you), the amount and type of such funding, the purpose(s) for which it was provided and a specific description (name of 1 research publication, expert testimony, or white paper, etc.) of any outcome developed or provided as a result of such funding.

Response: TERA's work is independent and science-neutral. In some cases, TERA allowed scientific comments from its sponsors on draft work products. These comments, if any, were considered during the internal quality assurance review prior to finalizing any report. In all cases, the final report reflected the opinions of the TERA scientists, and not necessarily those of the sponsor. All of the TERA reports included explanations for our scientific opinions, particularly for controversial or uncertain scientific decisions when we perceived our opinions or results were at odds with what sponsors may have desired. TERA's approach to accepting and conducting its work is discussed at http://www.tera.org/about/mission_history.html.

TERA maintains a document retention policy of 7 years for files; with the exception of those involved with litigation efforts, which are retained indefinitely. Therefore, details of sponsors other than summary information prior to 2010 are not generally available (note, however, that some reports from projects may be found on the TERA web page). A summary of the extent of either government or industry work can be found at: http://www.tera.org/about/FundingSources.html. Beginning in 2010, this summary information also included a list of those sponsors that represented a 2% or greater part of TERA's efforts for that year.

A list of sponsors and projects from January 2010 through June 2015[1] are attached. From July 2015 to now, TERA's work has been minimal as the corporation winds down. For information regarding the sponsors during this wind-down phase, please contact Dr. Patricia McGinnis, the acting President for Toxicology Excellence for Risk Assessment (TERA) at: mcginnis *at* tera.org.

Not all of TERA's work resulted in publications or other immediately available public information. For example, many of the tasks done for both government and industry sponsors resulted in reports delivered to the sponsor that were subsequently used by or submitted to a government organization. The immediately available public information is posted or noted on TERA's website. Presentations made on TERA's work may not have always been retained in the corporation's files, particularly presentations and those made at scientific society meetings beyond the 7-year retention policy.

The specific type of compensation is not listed in the attachments, but TERA was primarily paid through contracts, with some government grants, and private gift letters. As noted above, if the work exceeded 2% of TERA's overall effort in any one year, the sponsor is listed on the on-line financial summaries.

Question 4) TERA's website states that "TERA can provide a variety of litigation support services from review and analysis of data, to written opinions, to expert witness testimony" and that this work has included "testimony as expert witness on U.S. EPA's

[1] In July 2015, I and most of the TERA staff joined the University of Cincinnati, College of Medicine

chromium risk assessment for Defendant in groundwater contamination case." For each of the past ten years, please identify each case in which TERA or any of its employees provided 'litigation support' and the party to which such support was provided, and the amount and type of compensation received. In responding, please include the caption of the case, the court in which the case was heard and the case number, and include copies of all materials produced as part of its litigation support services, including expert witness testimony, analysis of data and written opinions provided by TERA or any of its employees, as well as transcripts of depositions of TERA or any of its employees.

Response: Please see the table below. Requests for details of the materials and opinions should be directed to the given contact, as I am uncertain of the existing status of the litigation. Compensation is not listed, but if the work exceeded 2% of TERA's effort in anyone year from 2010 to 2015, it was listed on the financial summaries referred to above.

Case	Issue	Contact
No. CIV MSC 05-01725; IN THE SUPERIOR COURT OF THE STATE OF CALIFORNIA IN AND FOR THE COUNTY OF CONTRA COSTA: RON BLOCK, et al., Plaintiff; DANIEL HELIX, et al., Defendant.	Contaminated site regarding comparison of levels of contaminant exposure and health benchmarks. TCE and other solvents were involved.	Richard Bowles; 925 935 3300 Bowles and Verna LLP 2121 N. California Blvd., Suite 875 P.O. Box 8180 Walnut Creek, CA 94596-8180 Representing the plaintiff.
Case No. BC435759 SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF LOS ANGELES, CENTRAL CIVIL WEST; COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS, a California corporation, acting as a private attorney general in the public interest. Plaintiff; STARBUCKS CORPORATION, et al., Defendants	Review of toxicology information for acrylamide in coffee and potential mixtures risk assessment for various constituents.	ROBIN STAFFORD (BAR NO. 200950) RStafford@mofo.com MORRISON & FOERSTER LLP 425 Market Street San Francisco, CA 94105-2482 Telephone: 415.268.7000 Representing the defendants
Case: BC 337618 SUPERIOR COURT OF THE STATE OF CALIFORNIA COUNTY OF LOS ANGELES,	Review of toxicology information for acrylamide in french fries and snacks and development of a No	Gary Roberts 601 South Figueroa Street Suite 1500 Los Angeles, California 90017

Environmental World Watch Inc., Plaintiff McDonald's Corporation, Defendants	Significant Risk Level. Three publications resulted: one of them funded by the sponsor. The other two publications were TERA funded.	213-892-5005 Representing the defendants

Question 5) TERA's website states that "TERA's work organizing peer input, peer consultation and peer review is intended to meet the needs of public and private sponsors who have developed risk assessment documentation." For each of the past ten years, please provide a) a list naming and describing the purpose of each peer input, peer consultation or peer review activity conducted by TERA, b) the entity(ies) that provided the funding for the peer activity and the amount of such funding, and c) a list of the individuals who participated in the peer activity, along with who chaired the project and which individuals were paid for their participation by TERA or the funding party.

Response: This information is available for all major peer reviews or peer consultations on TERA website at: http://www.tera.org/Peer/index.html. Less intense peer reviews are done for government, industry and NGOs on a routine basis and are described in response to question 3 above. Compensation is not listed, but if the work exceeded 2% of TERA's effort in anyone year from 2010 to 2015, it was listed on the financial summaries referred to above.

Question 6) The CV you provided to the Committee lists dozens of invited presentations you delivered. Please provide copies of the slides, speech or other briefing materials for the presentations given on the following dates: June 14, 2017, March 21, 2017, March 14, 2017, March 14, 2016, June 24, 2015, April 20, 2015, January 21, 2015, November 18, 2010, November 4, 2010, December 3, 2004, September 29, 2003, September 26, 2003, July 25, 2002, and April 30, 1996.

Response: The titles of my presentations and groups to which I spoke are shown below. The presentations are attached, except the last one, which cannot be located.

"Health risk assessment for perchlorate: New direction in EPA's modeling approach for establishing standards" **American Water Works Association.** Annual Conference. Philadelphia, PA. June 14, 2017.

Managing the non-cancer risks a hazardous waste sites: Trichloroethylene (TCE) as a case study" **Association for Environmental Health and Sciences (AEHS) Foundation**. San Diego, California March 21, 2017.

"The concept of hormesis and application in risk assessment" **Society of Toxicology**, Baltimore, Maryland, March 14, 2017.

"Yes, 'Thresholdable' Carcinogens Are Still Delaney Carcinogens" Roundtable Session: Is a "Thresholdable" Carcinogen Still a Delaney Carcinogen? **Society of Toxicology**, New Orleans, Louisiana, March 14, 2016.

"Defining the range of the reference dose: imprecision versus uncertainty" **The TCE Revolution and its Permanent Impact on Environmental Due Diligence,** EDR Insight, National Teleconference/Webinar, June 24, 2015.

"Assessment and management of Elk River, West Virginia drinking water contamination incident, 2014" **British Toxicology Society Annual Congress**, Birmingham, UK, April 20, 2015.

"Practical Guidance on the Development of a Non-cancer Hazard Range for Effective Risk Assessment and Risk Management of Contaminated Sites: A Case Study with Trichloroethylene and Other Chemicals" **Tri-Service Environmental Risk Assessment Work Group,** Naval Medical Center, Portsmouth, VA, Jan. 21, 2015

"Draft Toxicological Review of Hexavalent Chromium" **Environmental Protection Agency's** IRIS listening session. Washington, D.C. November 18, 2010.

"Perspectives of Air Pollutants: Health Effects Research Update Session: Risk Assessment...*in the 21st Century*" **Clean Air Forum**. Houston, TX, Nov. 4, 2010.

"Mercury Regulation: Fishing For The Facts About Risk"
States and Nation Policy Summit. **American Legislative Exchange Council.** Washington D.C. December 3, 2004.

"History of *TERA* Coordinated Public/Private Partnership on Perchlorate Research" Perchlorate State-of-the-Science Symposium. **University of Nebraska, Center for Environmental Toxicology**, Omaha, Nebraska. September 29, 2003.

"Perchlorate Reference Dose (RfD)" **California Environmental Protection Agency**. September 26, 2003.

"Modeling Of Population Variability" Midwestern States Risk Assessment Symposium. **Indiana Department of Environmental Management.** Indianapolis, IN. July 25, 2002.

"Dose Response Class Exercise: Aroclor" In: Risk assessment. **University of Cincinnati, College of Medicine**. April 30, 1996. [presentation could not be located]

Question 7) The Public Financial Disclosure Report that was provided to the Committee indicates that you served as a member of the North American Flame Retardant Alliance (NAFRA) until June 2017, and lists that entity as a non-profit. According to its website, that entity "was formed in March 2011 to serve as the lead advocacy organization in North America for flame retardant producers and users." Does NAFRA receive any

funding from any entity that is not itself a manufacturer, user, distributor of or trade association for flame retardant chemicals? If so, for each of the past two years, please list each such entity and the amount of funding it provided to NAFRA.

> Response: I was a member of the NAFRA Science Advisory Committee and as such was not privy to this information. Please feel free to contact Dr. Kimberly White at Kimberly_White@americanchemistry.com.

Question 8) The Public Financial Disclosure Report that was provided to the Committee indicates that you serve as the President of the Toxicology Education Foundation, and lists that entity as a non-profit. For each of the past two years, please provide a) a list naming each corporate entity or industry trade association that provided funding to the Foundation, along with the amount of the funding and b) the total amount of funding provided to the Foundation.

> Response: The following contributions were received:
> - Avon, 6/9/16, $300
> - Avon, 12/16/16, $1000
> - Experimur, 1/13/17, $2500

Question 9) The Public Financial Disclosure Report that was provided to the Committee indicates that you served as the Secretary of the Toxicology Forum until June 2017, and lists that entity as a non-profit. That entity's website does not list any non-corporate sponsors. Does the Toxicology Forum receive any funding from any entity that is not a corporation or trade association representing corporations? If so, for each of the past two years, please list each such entity and the amount of funding it provided to the Toxicology Forum.

> Response: Please find attached a funding list from the Toxicology Forum.

Question 10) Your Ethics Agreement states that "I will not participate personally and substantially in any particular matter in which I know that I have a financial interest directly and predictably affected by the matter, or in which I know that a person whose interests are imputed to me has a financial interest directly and predictably affected by the matter, unless I first obtain a written waiver, pursuant to 18 U.S.C. § 208(b)(1), or qualify for a regulatory exemption, pursuant to 18 U.S.C. § 208(b)(2)." Please provide a list of persons and particular matters (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) about which you plan to consult with the Designated Agency Ethics Official in order to determine whether you will recuse yourself or require a written exemption or waiver prior to participation.

> Response: In connection with the nomination process, I have consulted with the Office of Government Ethics and the EPA's designated agency ethics official to identify potential conflicts of interest. Any potential conflicts of interest will be resolved in accordance with the terms of an ethics agreement that I have entered

into with the Agency's designated agency ethics official and that has been provided to this Committee.

The entities from which I expect to be recused under 18 U.S.C. § 208 are:

- Dourson, Dourson and Fowler (until such time that the financial interest is transferred)
- Martha C. Dourson, LLC

Question 11) Your Ethics Agreement states that "Upon confirmation, I will resign from my positions with the following entities: University of Cincinnati, and the Toxicology Education Foundation. I resigned from my position with the North American Flame Retardant Alliance, and the Toxicology Forum in June 2017. For a period of one year after my resignation from each of these entities, I will not participate personally and substantially in any particular matter involving specific parties in which I know that entity is a party or represents a party, unless I am first authorized to participate, pursuant to 5 C.F.R. § 2635.502(d)." Please provide a list of particular matters involving specific parties (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) about which you plan to consult with the Designated Agency Ethics Official in order to determine whether you will recuse yourself or require advance authorization prior to your participation.

Response: In connection with the nomination process, I have consulted with the Office of Government Ethics and the EPA's agency ethics officials to identify potential impartiality concerns. Any such concerns will be resolved in accordance with the terms of an ethics agreement that I have entered into with the Agency's designated agency ethics official and that has been provided to this Committee.

Pursuant to 5 C.F.R. § 2635.502, I expect to be recused from participation in any specific party particular matter in which any of the following is or represents a party:

- University of Cincinnati
- Toxicology Education Foundation
- North American Flame Retardant Alliance
- Toxicology Forum
- CreateSpace Independent Publishing Platform
- Dourson, Dourson, and Fowler (for one year following the financial transfer)
- Any client of my spouse's firm, Martha C. Dourson, LLC

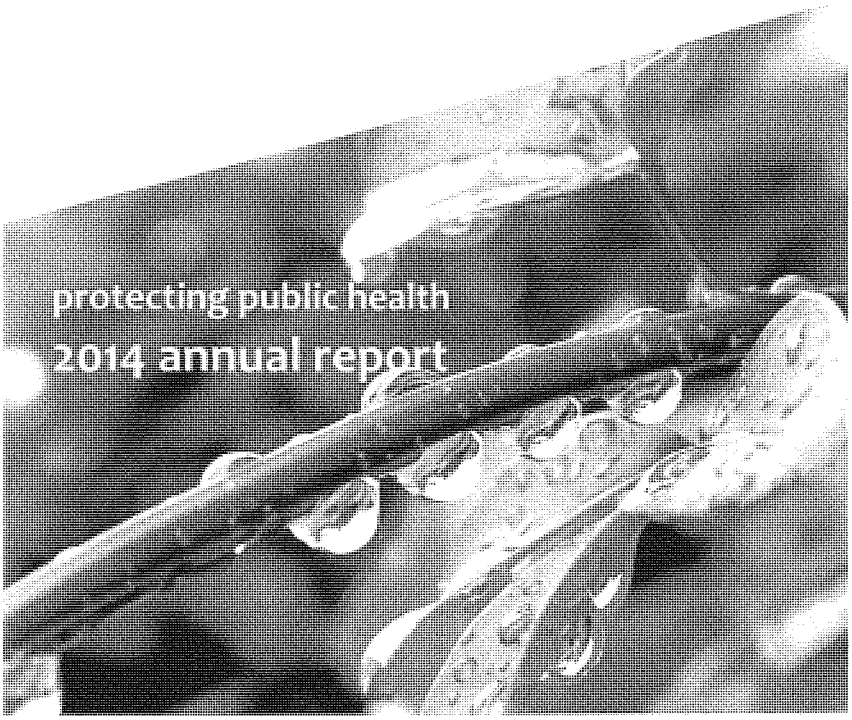
Question 12) Your Ethics Agreement also states that you will sign the Trump Ethics Pledge. The Trump Ethics Pledge states that "I will not for a period of 2 years from the

date of my appointment participate in any particular matter involving specific parties that is directly and substantially related to my former employer or former clients, including regulations and contracts." The Pledge additionally notes that (d) "Directly and substantially related to my former employer and former clients" shall mean matters in which the appointee's former employer or former client is a party or represents a party" and (i) "Former client" is any person for whom the appointee served personally as agent, attorney, or consultant within the 2 years prior to the date of his or her appointment, but excluding instances in which the service provided was limited to a speech or similar appearance. It does not include clients of the appointee's former employer to whom the appointee did not personally provide services." Please provide a list of particular matters involving specific parties (including a list of specific chemical substances, pesticides, regulations, regulatory decisions, risk evaluations, assessments or determinations, or topics) that you plan to recuse yourself from participating in for 2 years. If you plan to request waivers from the Trump Ethics Pledge for any such matter, please also list those.

Response: In connection with the nomination process, I have consulted with the Office of Government Ethics and the EPA's agency ethics officials and been advised that my former employer for the past 2 years has been the University of Cincinnati, which is a local university. As set forth in Section 2(j) of Executive Order 13,770, the term "former employer" does not include any State or local government. I am advised that, for the purposes of the Ethics Pledge, the Office of Government Ethics has determined that this exclusion "does extend to a state or local college or university."[2] Therefore, my only former client/former employer is the University of Cincinnati, which is addressed in my ethics agreement that has been provided to this Committee. I do not intend to seek any waiver from the Trump Ethics Pledge.

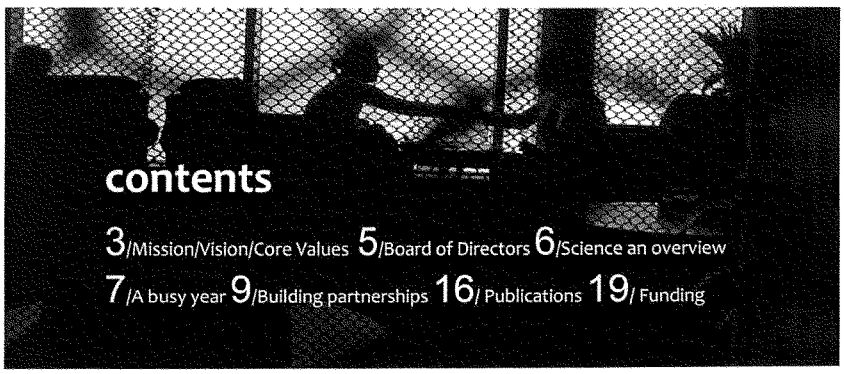
[2] *See* Office of Government Ethics (OGE), "Ethics Pledge: Revolving Door Ban – All Appointees Entering Government," DO-09-011 (March 26, 2009). OGE affirmed in its "Guidance on Executive Order 13770," LA-17-03 (March 20, 2107) that the terms used in Pledge paragraph 2 are applicable to Executive Order 13770, sec. 1, par. 6.

Toxicology Excellence For Risk Assessment (TERA)



Independent

NonProfit

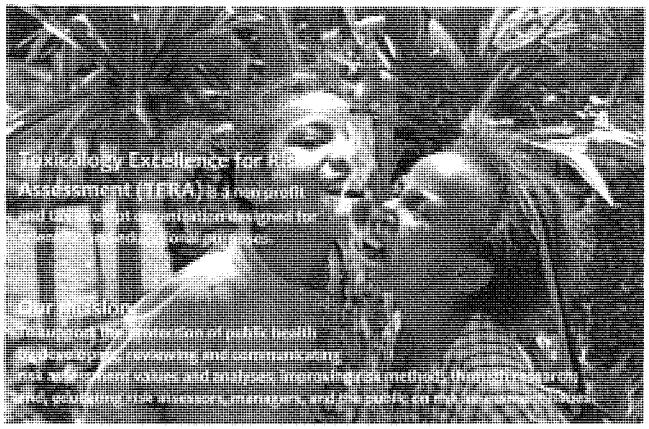


contents

3/Mission/Vision/Core Values 5/Board of Directors 6/Science an overview
7/A busy year 9/Building partnerships 16/ Publications 19/ Funding

Mission/Vision/Core Values

Mission



Vision

TERA was founded on the belief that an independent **non-profit** organization can provide a unique function **to protect** human health by conducting scientific research **and development** on risk issues in a transparent and **collaborative** fashion, and communicating these results **widely.**

Core Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations, from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

- Honesty and integrity
- Independence
- Transparency
- Collaboration

Board of Directors

DATE INDICATES YEAR OF CURRENT ENDING TERM

Michael Dourson, PhD (perpetual)[2]
President
Toxicology Excellence for Risk Assessment

Gail Charnley Elliott, PhD (2015)
HealthRisk Strategies

Mike Fremont, PhD (2014)
Rivers Unlimited

Jennifer L.S. Knaack, PhD (2015)
Department of Pharmaceutical Sciences
College of Pharmacy & Health Sciences
Mercer University

Laurie Kraus, PhD (2016)

James Rock, PhD (2016)

Gregery S. Romshe, CMA (2015)
VICE CHAIR and FINANCE COMMITTEE CHAIR
The Procter & Gamble Company

Jon L. Seymour, PhD (2014)
AUDIT COMMITTEE MEMBER

Martin L. Stephens, PhD (2016)
Johns Hopkins Center for Alternatives to Animal Testing

Philip E. Tobin, PA-C, MPAS (2016)
NOMINATING COMMITTEE MEMBER
Department of Physician Assistant Studies

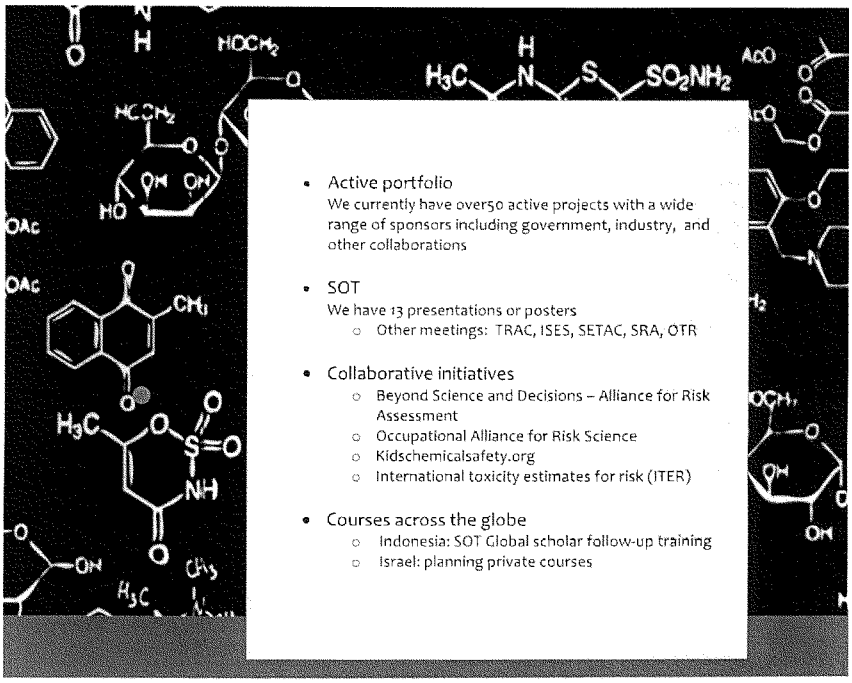
James D. Wilson, PhD (2016)
CHAIR

Chase D. Wright, CPA (2016)
AUDIT COMMITTEE CHAIR

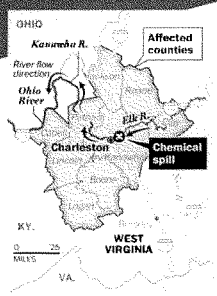
[1] Directors serve 3 year term; date indicates ending year of current term, [2] Michael is an *ad hoc* member of the Board of Directors as the President of TERA.

SCIENCE

an overview



a busy year...



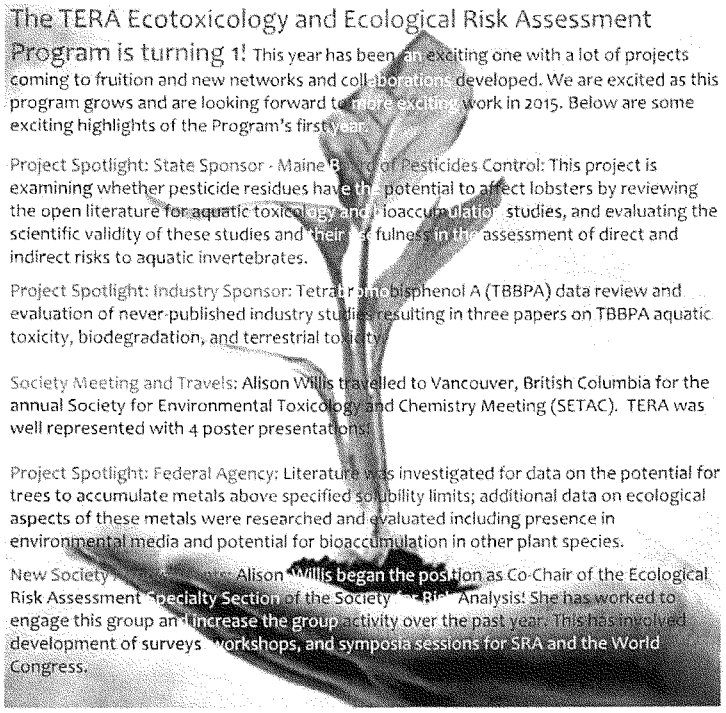
WV TAP Peer Review of the MCHM Screening Level

Last winter the people of Charleston West Virginia complained of a licorice odor from their water. A coal-cleaning chemical, MCHM, had spilled from a storage tank into the Elk River and contaminated the community's water supply. With very limited health effects data, the Centers for Disease Control and Prevention (CDC) provided the state with a screening value of 1 ppm for 4-methyl-1-cyclohexanemethanol (MCHM). One month after the spill, measurements were below the detection limit yet some people could still smell the chemical's characteristic licorice odor, leading the Governor of West Virginia to fund an independent group - the West Virginia Testing Assessment Project (WV TAP) - to conduct research to address the inconsistent results and convene an independent panel to evaluate the health protection of the CDC screening level.

TERA was asked to organize and convene an independent peer review panel to review the available data and determine whether the screening value that the CDC provided the State was protective of public health. The TERA panel of five experts (Shai Ezra, Mekorot, Israel National Water Company Ltd.; James Jacobus, Minnesota Department of Health; Stephen Roberts, University of Florida; Paul Rumsby, National Centre for Environmental Toxicology at WRc plc, UK; and Michael Dourson, TERA) met in Charleston to review the toxicological literature and screening values. The Panel derived a short-term health advisory of 120 ppb for MCHM based on a NOEL of 100 mg/kg-day from a 4 week study (Eastman, 1990). This study and effect level were the same as that used by CDC for its advisory. However, the panel differed from CDC in several regards, including adjusting the experimental dose for the five days per week dosing regimen and accounting for the public's exposure via other routes.

See http://www.tera.org/Peer/index.html for a copy of the panel's report.

Ecotoxicology



The TERA Ecotoxicology and Ecological Risk Assessment Program is turning 1!

This year has been an exciting one with a lot of projects coming to fruition and new networks and collaborations developed. We are excited as this program grows and are looking forward to more exciting work in 2015. Below are some exciting highlights of the Program's first year:

Project Spotlight: State Sponsor - Maine Board of Pesticides Control: This project is examining whether pesticide residues have the potential to affect lobsters by reviewing the open literature for aquatic toxicology and bioaccumulation studies, and evaluating the scientific validity of these studies and their usefulness in the assessment of direct and indirect risks to aquatic invertebrates.

Project Spotlight: Industry Sponsor: Tetrabromobisphenol A (TBBPA) data review and evaluation of never-published industry studies resulting in three papers on TBBPA aquatic toxicity, biodegradation, and terrestrial toxicity.

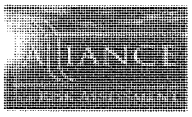
Society Meeting and Travels: Alison Willis travelled to Vancouver, British Columbia for the annual Society for Environmental Toxicology and Chemistry Meeting (SETAC). TERA was well represented with 4 poster presentations.

Project Spotlight: Federal Agency: Literature was investigated for data on the potential for trees to accumulate metals above specified solubility limits; additional data on ecological aspects of these metals were researched and evaluated including presence in environmental media and potential for bioaccumulation in other plant species.

New Society [illegible]: Alison Willis began the position as Co-Chair of the Ecological Risk Assessment Specialty Section of the Society for Risk Analysis! She has worked to engage this group and increase the group activity over the past year. This has involved development of surveys, workshops, and symposia sessions for SRA and the World Congress.

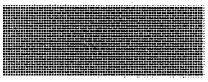
We are pleased to announce our expanded suite of ecological and environmental science services, complementing our strong historical reputation in health risk assessment and industrial hygiene. Our staff now includes scientists with broad experience in ecotoxicology, environmental fate, and ecological risk and hazard assessment of chemical ingredients, products and by-products.

Building partnerships

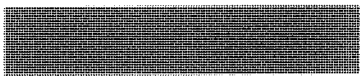


Alliance for Risk Assessment (ARA)

The Alliance for Risk Assessment (ARA) is a collaboration of diverse organizations representing government, academic, industry, environmental and consulting perspectives, teaming to protect public health. Working together, the ARA pools resources, information, and expertise to address chemical risk assessment issues that individual organizations cannot resolve on their own. State risk assessors have formed coalitions within the ARA to develop guidance methods, to peer review risk assessments, and to find funding for risk projects.
> ALLIANCEFORRISK.ORG



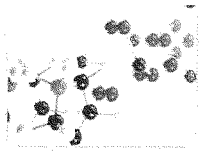
Risk Information Exchange (RISKIE) RiskIE contains over 4700 in-progress human health risk assessment projects from 35 organizations in 13 countries around the world. RiskIE offers a view into the risk science work of other organizations, in an effort to bridge communication gaps among risk assessors of government, industry, academic, and environmental organizations. State risk assessors can use RiskIE to find soon to be released risk values, find potential partners on an upcoming assessment, or publicize their own risk work.
> ALLIANCEFORRISK.ORG/RISKIE.HTM



State Environmental Agency Collaboration for Harmonization (SEARCH) SEARCH is a free online interactive tool designed to help create a collaborative network among state agencies to aid in efficiently sharing information and resources, and to work toward the harmonization of risk values used by state agencies. SEARCH is intended to help state risk agencies communicate, share information, and collaborate.

> ALLIANCEFORRISK.ORG/SEARCH/INDEX.HTML

Guidance for Contaminated Sites A coalition of organizations was formed to develop guidance on how to interpret the non-cancer endpoint when it is used for deciding clean-up standards or acceptable exposure levels when closing sites, using trichloroethylene as a case study. The group sought to clarify the issues surrounding the potential developmental cardiac malformations for use in understanding clean-up standards and short term exposure levels. A webinar will be held this fall to discuss lessons learned and to develop a path forward. State risk assessors working in remediation, or site closure may find the guidance developed by this effort particularly useful.
> ALLIANCEFORRISK.ORG/PROJECTS/TCE.HTML



BEYOND SCIENCE & DECISIONS

From Problem Formulation to Dose-Response Assessment

May 21 and 22, 2014 at the Texas Commission on Environmental Quality in Austin, Texas

The workshop series, Beyond Science and Decisions: From Problem Formulation to Dose-Response continues and expands upon the discussion initiated by the National Academy of Science report: *Science and Decisions: Advancement of Risk Assessment* (NRC, 2009). The workshops utilize a multi-stakeholder format to support the development of a practical and solution-oriented compendium of risk assessment methods. Conducted under the aegis of the Alliance for Risk Assessment (ARA), the workshop series explores both currently available and evolving methodologies, through the development and application of case studies. The workshop series is based on the fundamental premise that the appropriate methodologies for dose-response assessment need to be based on objectives specific to the intended application; this will include varying levels of analysis.

The workshop series continues to advance the framework of ARA (2012) on problem formulation and dose-response analysis (beta version available at http://chemicalriskassessment.org/methods/).

The purpose of this workshop report is to document and communicate the workshop results to the workshop participants and interested others. The report contains summaries of the Science Panel discussions with the authors of invited presentations, as well as the Science Panel review of case studies presented at the workshop.

Keeping up with Evolving Risk Methods – the ARA Dose Response Framework The ARA Dose Response Framework is a library of risk methods, with tools to help you find the method you are looking for, and case studies to illustrate real work applications.

Search by key term, or browse by problem formulation, the Framework offers an overview of how the method works, when it's applicable, and a discussion of limitations.

The ARA Dose Response Framework 2.0 is available in beta at www.chemicalriskassessment.org.

Multi-stakeholder Experts Working Together to Advance Risk Assessment: Recent Reports and Publications

Multi-stakeholder Workshop on Lessons Learned, Challenges, and Opportunities: The U.S. Endocrine Disruptor Screening Program

Workshop report is available now online on the ALTEX website at :http://www.altex.ch/Online-first.95.html and in PubMed PMID:24114257

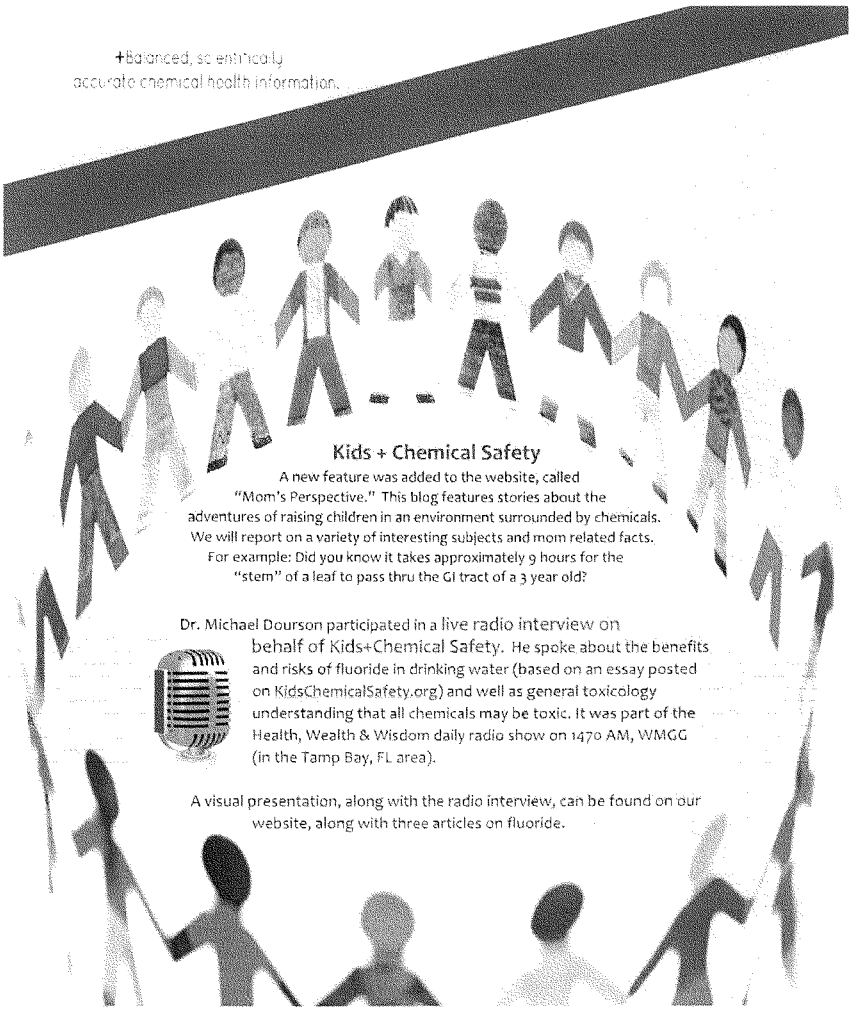
Workshop on Mode of Action for Nuclear Receptor Mediated Liver Cancer

The report is available at http://www.tera.org/peer/nuclearreceptor/.

Peer Consultation Workshop on the Relationship between PAC Profile and Toxicity of Petroleum Substances

Assessing the mammalian toxicity of high-boiling point petroleum substances, Reg. Tox and Pharm (Volume 67, Issue 2, Supplement - pp. S1-S94 (1 November 2013).





Kids + Chemical Safety

A new feature was added to the website, called "Mom's Perspective." This blog features stories about the adventures of raising children in an environment surrounded by chemicals. We will report on a variety of interesting subjects and mom related facts. For example: Did you know it takes approximately 9 hours for the "stem" of a leaf to pass thru the GI tract of a 3 year old?

Dr. Michael Dourson participated in a live radio interview on behalf of Kids+Chemical Safety. He spoke about the benefits and risks of fluoride in drinking water (based on an essay posted on KidsChemicalSafety.org) and well as general toxicology understanding that all chemicals may be toxic. It was part of the Health, Wealth & Wisdom daily radio show on 1470 AM, WMGG (in the Tamp Bay, FL area).

A visual presentation, along with the radio interview, can be found on our website, along with three articles on fluoride.

OARS WEEL

New OARS-WEEL Values Available Occupational Alliance for Risk Science initiative (OARS) is an initiative to facilitate sharing of information with workers and occupational health and safety professionals.

Five new WEEL values have been developed and finalized since the transfer of WEELs to OARS. WEEL documentation is now available for

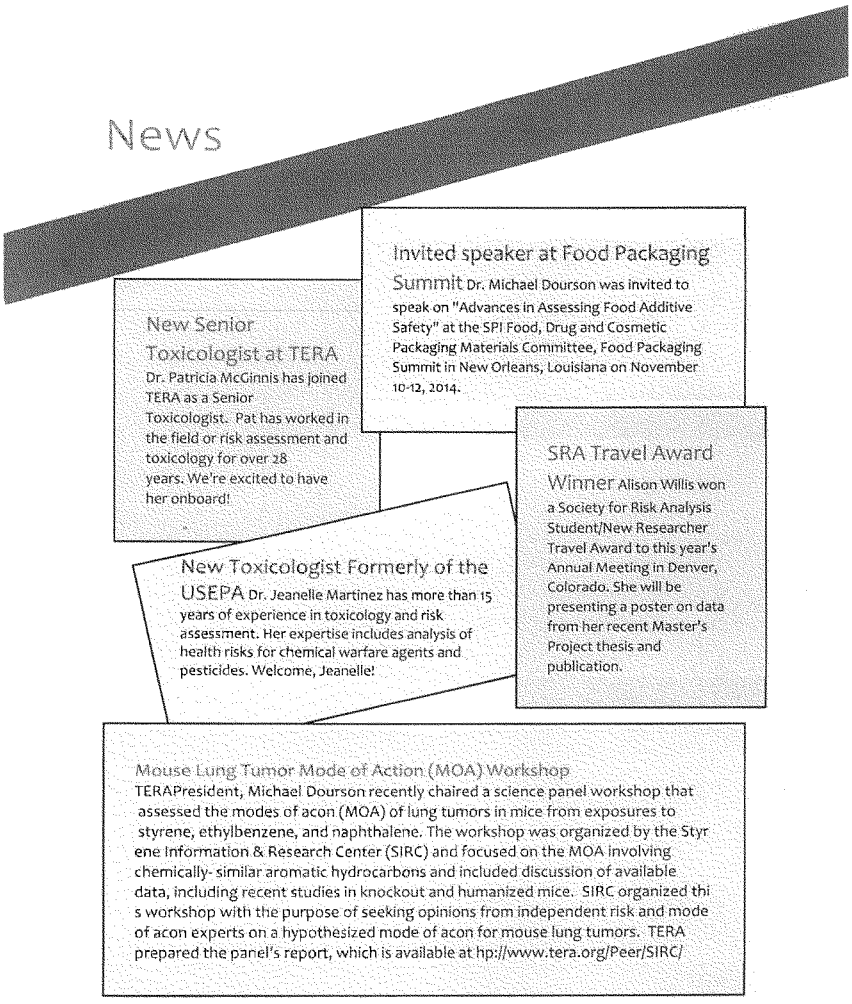
- trans-1-Chloro-3,3,3-trifluoropropylene (HCFO-1233zd(E))
- Menthol
- 2,4-Dinitroanisole (DNAN),
- cis-1,1,1,4,4,4-Hexafluoro-2-butene (HFO-1336mzz-Z)
- 3-Nitro-1,2,4-triazol-5-One (NTO)

Revision of additional WEELs is currently in progress. All current AIHA and TERA WEEL values are available in a tabular format at www.tera.org/OARS/WEEL.html.

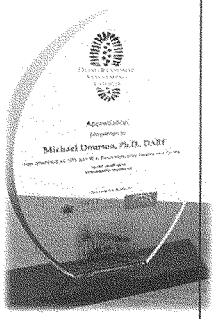
iter

What's new with The International Toxicity Estimates for Risk (ITER) ITER is growing in content and usage, and is proud to announce major enhancements to benefit the international risk community:

- New interface to help you find the information you need.
- Over 90 Concise International Chemical Assessment Documents (CICADs) from the World Health organization (WHO) have been added to ITER
- With the help of Summit Toxicology, ITER now includes Biomonitoring Equivalents (BEs) for over 40 chemicals. BEs present an entirely new type of content for ITER users, and can be used to help interpret NHANES data.


News
Invited speaker at Food Packaging Summit Dr. Michael Dourson was invited to speak on "Advances in Assessing Food Additive Safety" at the SPI Food, Drug and Cosmetic Packaging Materials Committee, Food Packaging Summit in New Orleans, Louisiana on November 10-12, 2014.
New Senior Toxicologist at TERA Dr. Patricia McGinnis has joined TERA as a Senior Toxicologist. Pat has worked in the field or risk assessment and toxicology for over 28 years. We're excited to have her onboard!
SRA Travel Award Winner Alison Willis won a Society for Risk Analysis Student/New Researcher Travel Award to this year's Annual Meeting in Denver, Colorado. She will be presenting a poster on data from her recent Master's Project thesis and publication.
New Toxicologist Formerly of the USEPA Dr. Jeanelle Martinez has more than 15 years of experience in toxicology and risk assessment. Her expertise includes analysis of health risks for chemical warfare agents and pesticides. Welcome, Jeanelle!
Mouse Lung Tumor Mode of Action (MOA) Workshop
TERAPresident, Michael Dourson recently chaired a science panel workshop that assessed the modes of acon (MOA) of lung tumors in mice from exposures to styrene, ethylbenzene, and naphthalene. The workshop was organized by the Styr ene Information & Research Center (SIRC) and focused on the MOA involving chemically- similar aromatic hydrocarbons and included discussion of available data, including recent studies in knockout and humanized mice. SIRC organized thi s workshop with the purpose of seeking opinions from independent risk and mode of acon experts on a hypothesized mode of acon for mouse lung tumors. TERA prepared the panel's report, which is available at hp://www.tera.org/Peer/SIRC/

training



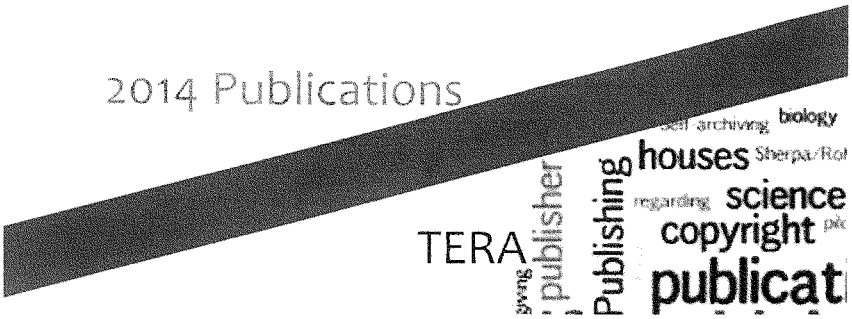
Making progress in developing countries

TERA, in conjunction with Dr. Noegrohati and the Pharmaceutical Chemistry Department (Faculty of Pharmacy, Gadjah Mada University, Yogjakarta, Indonesia), conducted its first ever, 5-day intensive training in Indonesia, tailored to the needs of the local region and including local teachers. This course was partly sponsored by the Society of Toxicology (SOT) Global Senior Scholar Exchange Program (GSSEP), the Faculty of Pharmacy and the Graduate School of Gadjah Mada University, and the Indonesia Ministry of Agriculture, and was endorsed by the Society for Risk Analysis. The course was taught by Drs. Michael Dourson and Bernard Gadagbui, with local presentations by Dr. Sri Noegrohati (Gadjah Mada University) and Yayah Rodiana (M.Sc., Ministry of the Environment, Jakarta, Indonesia).

Dr. Dourson also gave a lecture on the importance of toxicology and risk assessment to students at the Faculty of Pharmacy, Gadjah Mada University.

The crowning event of this training was the formation and inauguration of the Indonesian Society for Toxicological Sciences (ISTS) on June 20, 2014.

Dose-Response Boot Camp TERA has partnered with the University of Cincinnati, College of Medicine (UC) to offer existing TERA courses and develop new courses. TERA's well-known Dose-Response Assessment Boot Camp has evolved into two new courses: a basic dose-response course for those new to formal risk assessment methods and an advanced dose-response framework and modeling course. The Boot Camp Basics course will include a new component on introduction to toxicology for risk assessors, while also covering the fundamental approaches used in developing most current human health risk assessment with an introduction to complex concepts and modeling. The Boot Camp Advanced Framework and Modeling course will introduce the student to the application of advanced concepts and models, including mode of action evaluation techniques, use of dosimetry and PBPK models, benchmark dose modeling, structure activity evaluation tools and methods, and other tools that are an essential part of the advanced risk assessment practice.



Andersen, ME; Preston, RJ; Maier, A; **Willis, A; Patterson, J.** 2014. Dose-Response Approaches for Nuclear Receptor-Mediated Modes of Action for Liver Carcinogenicity: Results of a Workshop. Crit Rev Toxicol. 44(1):50-63 (doi:10.3109/10408444.2013.835785).

> Downloads of this and other papers coming out of the nuclear receptor workshop published in *Critical Reviews in Toxicology* are being made available for a limited time free of charge. Please go to http://www.tera.org/Peer/NuclearReceptor/index.html to download a copy. **The paper on the CAR MOA by Elcombe and Lake, et al. was selected as a top 10 risk assessment paper published in 2013 by the Risk Assessment Specialty Section of SOT.**

Budinsky, RA; Schrenk, D; Simon, T; Van den Berg, M; **Reichard, JF;** Silkworth, JB; Aylward, LL; Brix, A; Gasiewicz, T; Kaminski, N; Perdew, G; Starr, TB; Walker, NJ; Rowlands, JC. 2014. Mode of action and dose-response framework analysis for receptor-mediated toxicity: The aryl hydrocarbon receptor as a case study. Crit Rev Toxicol 44(1):83-119 (PMID: 24245878).

Chen, J; Hu, Z; Phatak, M; **Reichard, J;** Freudenberg, JM; Sivaganesan, S; Medvedovic, M. 2013. Genome-wide signatures of transcription factor activity: connecting transcription factors, disease, and small molecules. PLoS Comput Biol. 9(9):PMC3764016.

Dourson, M; Reichard, J; Nance, P; Burleigh-Flayer, H; **Parker, A; Vincent, M;** McConnell, EE. 2014. Mode of Action Analysis for Liver Tumors from Oral 1,4-Dioxane Exposures and Evidence-Based Dose Response Assessment. Regul Toxicol Pharmacol (in press).

Dourson, M; Becker, RA; **Haber, LT;** Pottenger, LH; Bredfeldt, T; Fenner-Crisp, P. 2013. Advancing Human Health Risk Assessment: Integrating Recent Advisory Committee Recommendations. Crit Rev Toxicol. 43(6):467-92 (doi: 10.3109/10408444.2013.807223).

Dourson, M; **Gadagbui,** B; Griffin, S.; Garabrant, D.H.. Haws, L.C.; Kirman, C.; and Tohyama, C. 2013. The importance of problem formulations in risk assessment: A case study involving dioxin-contaminated soil. Reg Toxicol Pharmcol. 66(2):208-216.

Effio, DC; **Kroner, O;** Maier, A; Hayes, W; **Willis, A; Strawson J.** 2013. A Look at State-Level Risk Assessment in the United States: Making Decisions in the Absence of Federal Risk Values. Risk Analysis. 33(1):54-67.

Hasegawa, R; Hirata-Koizumi, M; **Dourson, ML; Parker, A**; Ono, A; Hirose, A. 2013. Safety assessment of boron by application of new uncertainty factors and their subdivision. Regul Toxicol Pharmacol 65(1):108-114 (doi: 10.1016/j.yrtph.2012.10.013).

Hertzberg, RC; Pan, Y; Li, R; **Haber, LT**; Lyles, RH; Herr, DW; Moser, VC; Simmons, JE. 2013. A four step approach to evaluate mixtures for consistency with dose addition. Toxicology. (doi: S0300-483X(12)00368-X. 10.1016/j.tox.2012.10.016).

Juberg, DR; Borghoff, SJ; Becker, RA; Casey, W; Hartung, T; Holsapple, MP; Marty, SM; Mihaich, EM; Van Der Kraak, G; Wade, MG; Willett, CE; Andersen, ME; Borgert, CJ; Coady, KK; **Dourson, ML**; Fowle, JR; Gray, LE; Lamb, JC; Ortego, LS; Schug, TT; Toole, CM; Zorrilla, LM; **Kroner, OL; Patterson, J**; Rinckel, LA; Jones, BR. 2014. *t4Workshop Report, Lessons Learned, Challenges, and Opportunities: The U.S. Endocrine Disruptor Screening Program. ALTEX.*. ALTEX, 31:63-78, January http://www.tera.org/Peer/EDSP/altex_2014_1_063_078_T4Juberg.pdf

Maier, A; **Vincent, MJ**; Hack, E; **Nance, P**; Ball, W. 2014. Derivation of an Occupational Exposure Limit for Inorganic Borates Using a Weight of Evidence Approach. Regul Toxicol Pharmacol. 68(3):424-437. doi: 10.1016/j.yrtph.2014.02.001

Meek, ME;., Bolger, M; Bus, JS; Christopher, J; Conolly, RB; Lewis, RJ; Paoli, G; Schoeny, R; **Haber, LT**; Rosenstein, AB; **Dourson, ML**. 2013. A Framework for Fit-for-Purpose Dose Response Assessment. Regul Toxicol Pharmacol 66(2):234-40 (doi: 10.1016/j.yrtph.2013.03.012). **Available open access.**

Moser, VC; Padilla, S; Simmons, JE; **Haber, LT**; Hertzberg, RC. 2012. Impact of Chemical Proportions on the Acute Neurotoxicity of a Mixture of Seven Carbamates in Preweanling and Adult Rats. Toxicol Sci 129(1):126-34 (doi: 10.1093/toxsci/kfs190).

Patterson, J; Maier, A;, **Kohrman-Vincent, M; Dourson, ML**. 2013. Peer consultation on relationship between PAC profile and toxicity of petroleum substances. Regul Toxicol Pharmacol 67: S86–S93. **Available open access.**

Parsons, BL; Manjanatha, MG; Myers, MB; McKim, KL; Shelton, SD; Wang, Y; Gollapudi, BB; Moore, NP; **Haber, LT**; Moore, MM. 2013. Temporal changes in K-ras mutant fraction in lung tissue of big blue B6C3F, mice exposed to ethylene oxide. Toxicol Sci 136(1):26-38 (doi: 10.1093/toxsci/kft190).

Sweeney, LM; **Parker, A; Haber, LT**; Tran, CL; Kuempel, ED. 2013. Application of Markov chain Monte Carlo analysis to biomathematical modeling of respirable dust in US and UK coal miners. Regul Toxicol Pharmacol 66:47–58.

Book Chapters

toxicology journal PBPK modeling benchmark dose

Haber, LT; Strawson, JE; Maier, A; Baskerville-Abraham, IM; **Parker, A; Dourson, ML**. 2013. "Noncancer Risk Assessment: Principles and Practice in Environmental and Occupational

Settings." In: Bingham, E., and B. Cohrssen, eds. *Patty's Toxicology, 6th Edition, Volume 5*. John Wiley and Sons Inc.

York, RG; Parker, RM; **Haber, LT.** 2014. "Test Methods for Assessing Female Reproductive and Developmental Toxicology." In: Hayes, A.W., ed. Principles and Methods of Toxicology, 6th Edition, In press.

In *Encyclopedia of Toxicology*: **Gadagbui, B; Vincent, M; Willis, A.,** Methyl isothiocyanate; **Haber, L; Willis, A; Nance, P.** Mode of Action; Abdollahi, M., Karami-Mohajeri, S., **Gadagbui, B.** Oral/Dermal Reference Dose (RfD)/Inhalation Reference Concentration.

TERA Reports

Report of a Workshop to Assess the Modes of Action of Lung Tumors in Mice from Exposures to Styrene Ethylbenzene, and Naphthalene. Prepared by TERA for the Workshop Panel. http://www.tera.org/Peer/SIRC/index.htm

Workshop Report, Lessons Learned, Challenges, and Opportunities: The U.S. Endocrine Disruptor Screening Program. http://www.tera.org/Peer/EDSP/. Also published in ALTEX (See Juberg et al., above).

Report of Workshop for the Industry Sponsored Asthma Science Forum. http://www.cleaninginstitute.org/assets/1/Page/AsthmaScienceForumReport.pdf



Funding

Proportion of Work by Project Sponsor

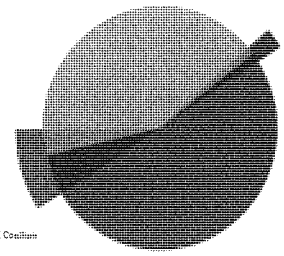
2014 TERA Project Time by Sponsor

43%
For Profit
Projects/Sponsors

- American Cleaning Institute
- Amgen
- Eli Lilly
- Genentech
- Morrison & Foerster
- Quinn

9%
Collaborations
Projects/Sponsors

- Alliance for Risk Assessment TCE Coalition
- Beyond Science & Decisions
- Kidschemicalsafety.org
- Occupational Alliance for Risk Assessment

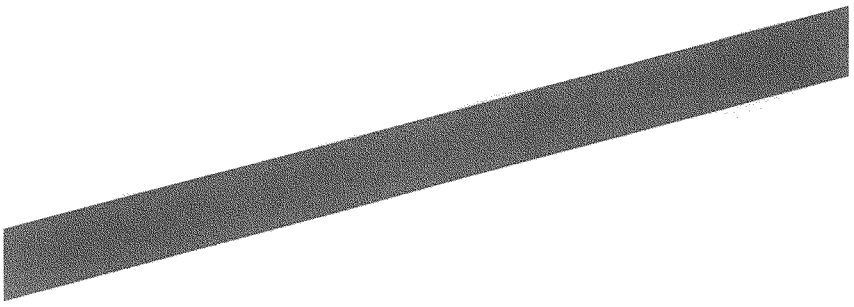


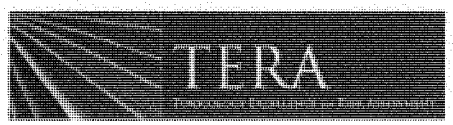
2%
Training
Projects/Sponsors

- Dose Response Boot Camp
- FDA Training Course

57%
Government/ Nonprofit
Projects/Sponsors

- Consumer Product Safety Commission
- ERM- Alaska Sulfolane
- Health Canada
- West Virginia Spill - MCHM

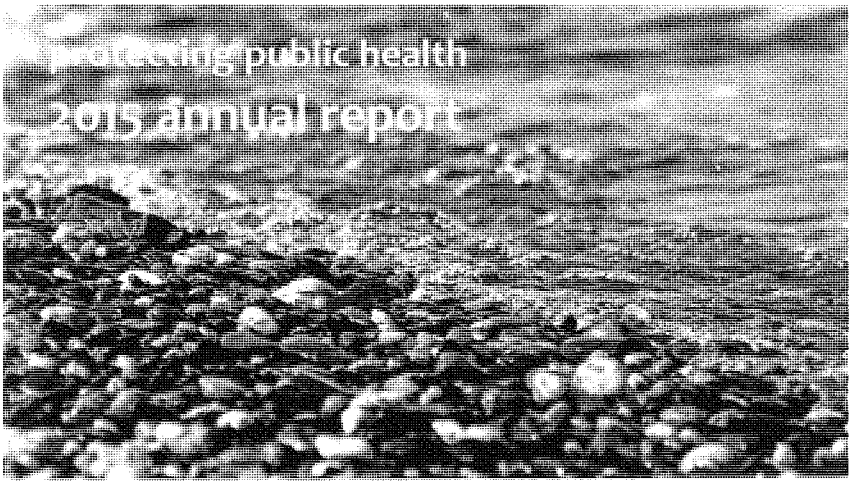




TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT
Address: 2300 Montana Avenue, Suite 409, Cincinnati, Ohio 45211
Tel : (513) 542-7475
Fax : (513) 542-7487
Email : tera@tera.org

www.tera.org

Toxicology Excellence For Risk Assessment (TERA)



contents



3/Mission/Vision/Core Values 4/Board of Directors 5/News 6/Global impact 7/A busy year 12/Building partnerships 18/ Training 23/ Publications 25/ Funding

Mission/Vision/Core Values

Toxicology Excellence for Risk Assessment (TERA) is a non-profit and tax-exempt organization designed for scientific and educational purposes.

Mission

To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and, educating risk assessors, managers, and the public on risk assessment issues.

Vision

TERA was founded on the belief that an independent non-profit organization can provide a unique function to protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion, and communicating these results widely.

Core Values

TERA is an independent non-profit and as such we embrace our core principles and values in all our activities. These core principles guide day-to-day TERA operations - from our consideration of new projects and sponsors, to our scientific evaluations and communication of results.

- Honesty and integrity
- Independence
- Transparency
- Collaboration

Board of Directors

DATE INDICATES YEAR OF CURRENT ENDING TERM.

Michael Dourson, PhD
President Toxicology Excellence for Risk Assessment
(1/1/2015 – 8/1/2015)

Patricia McGinnis, PhD (2017)
Interim President Toxicology Excellence for Risk Assessment

Gail Charnley Elliott, PhD (2015)
HealthRisk Strategies

Mike Fremont, PhD (2014)
Rivers Unlimited

Jennifer L.S. Knaack, PhD (2015)
Department of Pharmaceutical Sciences College of Pharmacy & Health Sciences Mercer University

Laurie Kraus, PhD (2016)

James Rock, PhD (2016)

Gregery S. Romshe, CMA (2015)
VICE CHAIR and FINANCE COMMITTEE CHAIR
The Procter & Gamble Company

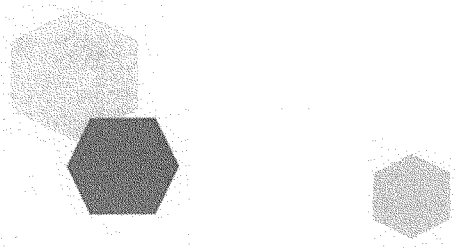
Jon L. Seymour, PhD (2014)
AUDIT COMMITTEE MEMBER

Martin L. Stephens, PhD (2016)
Johns Hopkins Center for Alternatives to Animal Testing

Philip E. Tobin, PA-C, MPAS (2016)
NOMINATING COMMITTEE MEMBER
Department of Physician Assistant Studies

James D. Wilson, PhD (2016)
CHAIR

Chase D. Wright, CPA (2016)
AUDIT COMMITTEE CHAIR



News from TERA's President and Board of Directors

TERA Joins the University of Cincinnati

Toxicology Excellence for Risk Assessment joined the Department of Environmental Health, at the University of Cincinnati's (UC), College of Medicine on July 6, 2015. TERA will be known as the Toxicology Excellence for Risk Assessment Center (or TERA Center).

TERA was organized in 1995 as a nonprofit with a mission to support the protection of public health through the best use of toxicity data. Now as a Center with the Department of Environmental Health at the University of Cincinnati's College of Medicine, we continue to accomplish this mission through independent evaluation of toxicity data and by interpreting and communicating risk assessment information through assessments and websites, organizing peer reviews and consultations, improving risk methods through research, and educating risk managers, assessors, and the public on risk assessment issues. TERA has a strong history of enhancing the use of chemical-specific data to increase the rigor and transparency of evaluations aimed at the prevention of potential human health risks.

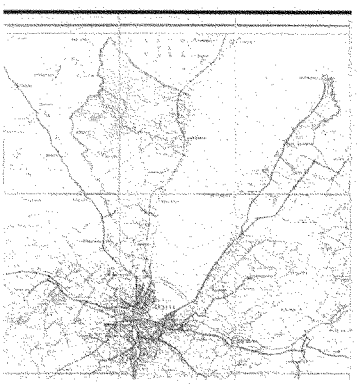
The TERA Center will maintain this rigor and transparency, but will also mesh its work with the research findings of UC investigators in order to develop the next generation of risk assessment methods based on Toxicology 21 principles.

SUPPORTING MISSIONS

TERA Center: To support the protection of public health by developing, reviewing and communicating risk assessment values and analyses; improving risk methods through research; and educating risk assessors, managers, and the public on risk assessment issues.

UC-DEH: To improve the quality of life by identifying the mechanisms of disease and injury due to environmental exposures and genetic factors, and by developing effective methods of preventions and interventions.

Global impact



Geneva

9/14/2015 – 9/25/2015

Dr. Michael Dourson served on the 2015 Joint Meeting of the Pesticide Review panel to determine the appropriate acceptable daily intakes and exposures for up to 20 pesticides.

The meeting was highly interactive and impactful.

A report is available at the World Health Organization website.

Philippines

8/25/2015-8/31/2015

Dr. Michael Dourson served as a US delegate to the Asian Pacific Economic Conference held in Cebu, Philippines, where he gave several lectures on metal toxicity, and led a small study group on methyl mercury contamination of fish.

This organization meets periodically to share technology among member states.



A busy year...

TERA brings RISK ASSESSMENT PERSPECTIVE *to* Nutrition Science

In a novel approach

to addressing the effect of consumption of a macronutrient, TERA has conducted an evaluation of the relationship between the intake of trans fatty acids (TFAs), particularly industrially-produced TFAs (iTFAs), and changes in plasma low density lipoprotein cholesterol (LDL-C), particularly in the low intake region.

A key issue was evaluating the shape of the dose-response curve in the low-dose region. TERA took a two-pronged approach to address the issue. First, the mode of action (MOA) for the impact of TFA on plasma LDL-C was evaluated. Second, TERA conducted a meta-regression of the controlled clinical trial data on iTFAs, using (MCMC) modeling, in collaboration with Bruce Allen for the modeling, and DeAnn Liska of Biofortis for the nutritional perspective.

This approach was unique in nutritional literature, in rigorously considering a variety of flexible curves, including both linear and nonlinear models. The MOA analysis concluded that, although there are several data gaps precluding a rigorous application of the evolved Hill Criteria for evaluation of MOA, the feedback loops and homeostatic controls responsible for maintaining homeostasis of cholesterol and triglyceride levels result in a less than linear relationship between TFA and LDL-C. Consistent with the MOA evaluation, the meta-regression found that an S-shaped curve fit by the Hill model is clearly better than linear model, and linear model is not acceptable.

This novel analysis has generated much interest in the nutrition and risk assessment communities. It has been presented at several venues, including the ToxForum, and SOT-FDA Joint Colloquium; publications are in preparation.

This work was sponsored by the ILSI North America PHO Task Force.

Ozone NAAQS Science and Policy Workshop Report Now Available

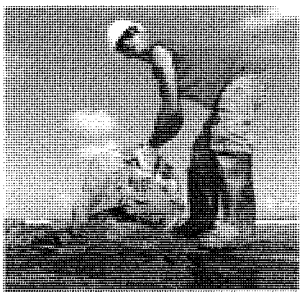
Working with the Texas Commission on Environmental Quality (TCEQ) and others, TERA organized a public workshop in April 2015 to provide an independent evaluation and synthesis of key considerations for EPA's November 2014 proposal to lower the primary National Ambient Air Quality Standard (NAAQS) for ozone. A diverse group of well-known and respected science and policy experts engaged in robust discussions on key issues, so that TCEQ and other attendees could gain a better understanding of the issues and implications. This multi-disciplinary group of science and policy experts deliberated on the nexus between scientific findings and implications for public health. The focus was on science related to the level (concentration) of the primary NAAQS and an independent evaluation and synthesis of key policy and other considerations for approaching the difficult and important ozone NAAQS decision.

Presentations, background materials and a summary report are available at http://www.tera.org/Peer/ozone/index.html.

Framework for Addressing Less-than-Chronic and Intermittent Exposures

How does one identify an exposure limit (toxicity reference value, or TRV) for an intermittent exposure (e.g., one day/month for 40 years)? Should one use an acute or a chronic limit for this sort of scenario? How does one decide?

Intermittent exposures such as these are common in many sectors, including manufacturing, waste site cleanup, food safety, and consumer product exposures. Led by Lynne Haber and in collaboration with Bette Meek and Health Canada scientists, the TERA team developed a framework for addressing such scenarios. The framework presents an integrated, tiered approach that assists the user in identifying when existing TRVs can be applied directly, and the adaptations needed to assess the acceptability of short-duration or intermittent exposure scenarios. A manuscript based on the framework is nearing publication, and Dr. Haber shared the framework in a Risk Assessment Specialty Section webinar.



See http://www.toxicology.org/groups/ss/RASS/downloads.asp.

TERA Scientists Assist With Harmonization Effort in Pharmaceutical Industry Like other industries, the pharmaceutical industry has to manage chemical safety issues—both for workers and consumers. The TERA Center has been working with toxicologists and risk assessment scientists from pharmaceutical industries, consulting groups and academia to discuss current practices for exposure limits, evaluate inconsistencies across guidance documents, identify key areas for harmonization, and document best practices for risk assessment of pharmaceuticals.

"Harmonization doesn't necessarily mean standardization," says Andrew Maier, PhD, an associate professor in the Department of Environmental Health and TERA Center co-director. "It's more a matter of understanding the basis for safety so that we enable savvy users of the risk assessment materials.

Maier and Alison Pecquet were key organizers and facilitators for an October 2014 workshop that was convened in New Brunswick, New Jersey, to identify and address further opportunities for advancing harmonization and best practices in deriving and applying acceptable daily exposures (ADE) in pharmaceutical manufacturing operations. The workshop effort was spurred from a benchmarking assessment to compare current methods in risk assessment for pharmaceuticals.

> "During our benchmarking work, we found that the international guidance documents and methods being used were clearly not harmonized in a number of areas," Pecquet says. "The workshop, which involved most of the top global pharmaceutical companies, was an effort to discuss some of the ways that we could harmonize efforts across agencies so that all of these health-based limits for pharmaceuticals are based on consistent methodologies."

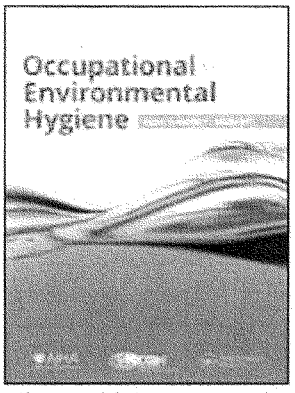
Following the workshop, an article summarizing key workshop findings was published in the September 2015 issue of Contract Pharma, a trade magazine.

The article concluded that a "harmonized set of recognized scientific principles is needed to inform individual efforts in calculating, interpreting, and implementing pharmaceutical risk assessments."

"We are currently working on a series of 10 articles associated with each workshop topic that will appear in a Special Issue of Regulatory Toxicology and Pharmacology in early 2016," Pecquet says. "Our goal is for these reports to shed light on inconsistencies and data needs, lead to further research of the knowledge gaps and contribute to informing decision making among risk assessors in the pharmaceutical industry by providing a 'guide to best practices.'"

"Ultimately, we aim to have one publication that summarizes key issues in this area to help users harmonize and use best practices, all in one place."

SPECIAL ISSUE: State of the Science of Occupational Exposure Limit (OEL) Methods and Guidance



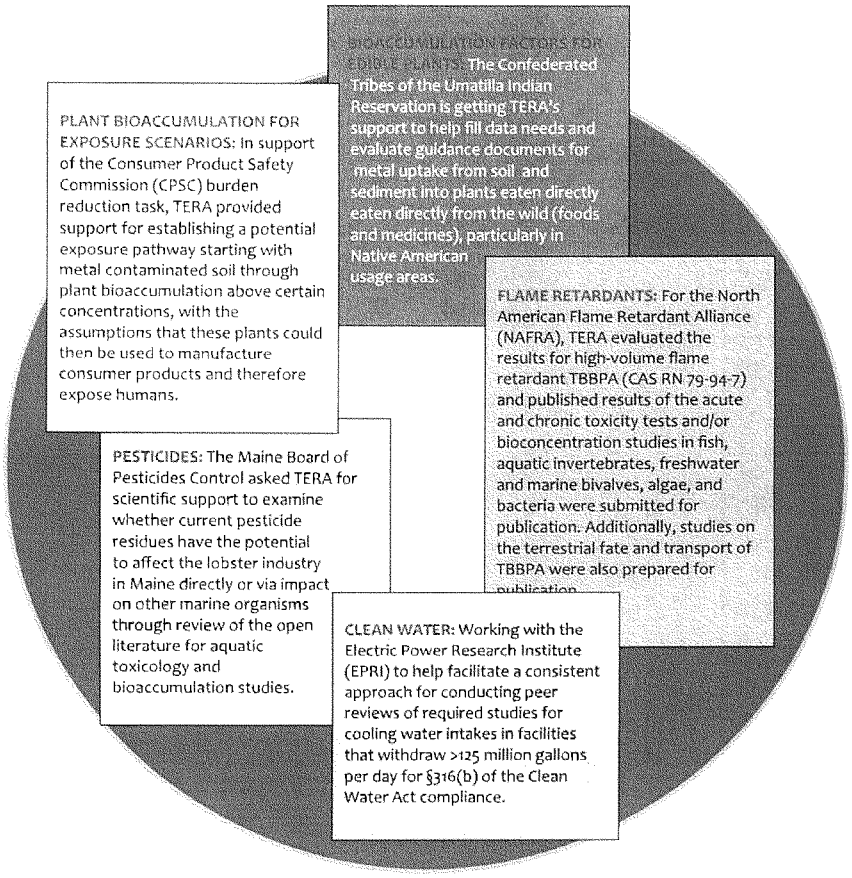
The National Institute for Occupational Safety and Health (NIOSH) conducted an effort to identify and characterize leading issues pertaining to OELs and their development through research, which culminated in a collection of articles focused on each key issue. Those articles and the key issues they explore comprise a Special Issue of the *Journal of Occupational and Environmental Hygiene*. The goal of this effort is to describe the issues related to education and communication of science principles and to understand how they can be incorporated into (and thereby impact) the practices of OEL development and interpretation. Focusing specifically on the state-of-the-science in the fields of exposure science, occupational hygiene, risk assessment, and toxicology this effort sought to provide a clear description of how advances in these research areas can contribute to the practice of OEL setting—by reviewing the methods used for most OELs that are currently available as well as new methods that are actively being incorporated in the OEL process. An essential topic included within the set of complementary and interrelated articles dedicated to this pursuit is the consideration and interpretation of OELs in the context of evolving risk management practices. The articles are intended to serve as a current critical review of occupational risk assessment methods that will enable occupational hygiene professionals to have a clear understanding of the science methods incorporated in the OELs they develop or use.

The ten articles in the supplement resulted from collaborations among scientists at NIOSH, Toxicology Excellence for Risk Assessment (TERA) Center (Dr. Andrew Maier, Dr. Lynne Haber, Dr. Michael Dourson, Dr. Bernard Gadagbui), and other organizations.

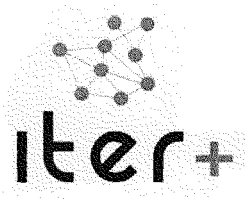
While the list of topics for OELs covered in this supplement is in no way exhaustive, it does represent some of the most relevant, promising, and readily applicable scientific advances that can be integrated into risk assessment and management of occupational hazards. The purpose of this collection of article is to inform the practitioner, stimulate the researcher, and provide a basis for more protective and scientifically sound guidance and policy.

TERA's Eco Risk Assessment portfolio is growing!

Ms. Alison Pecquet, M.Sc. and Dr. Charles Pittinger, TERA Fellow, along with additional TERA staff and external collaborators are working to provide support for environmental risk-related services.



Partnerships



A collaborative effort to organize the world's risk data

Through the Alliance for Risk Assessment, a group of organizations have come together to build the world's premiere database of human health risk values. Building from TERA's *International Toxicity Estimates for Risk (ITER)*, this effort has been dubbed *ITER+* and seeks to first expand the database offerings to include the European Union's Derived No Effect Levels (DNELS), and then additional values to be determined. *ITER* is currently available via the National Library of Medicine, and includes risk values from EPA, ATSDR, IARC, IPCS, and more. The *ITER+* Advisory Committee is responsible for prioritizing the addition of risk values from new sources.

Situation: Exposure analysis requires the use of reference values to qualitatively understand exposure data. Currently, these values are developed by a number of researchers and/or authoritative bodies and reside in a variety of locations. Searching for these values can be time-intensive, values identified can be of varying scientific quality, and often additional expertise is needed to conduct a screening level exposure assessment.

Proposal: Build upon the existing data housed within the International Toxicity Estimates for Risk Assessment (*ITER*) database to include additional values needed for exposure and risk assessment. *ITER* includes peer-reviewed human-health risk values and is searchable using the Toxicology Data Network (TOXNET) on the National Library of Medicine's website (**http://toxnet.nlm.nih.gov/newtoxnet/iter.htm**).

The Alliance for Risk Assessment is organizing a collaborative public/private partnership for the systematic addition of credible values to *ITER+*. The new additions will include the health basis of the value and any assessment or uncertainty factors needed for the lack of key data. These additions will be for chemical ingredients that are known to be used or are found in consumer products. As the initial start for a systematically-phased project, REACH data for derived no effect levels (DNEL) for about 600 chemicals will be added, followed by derived minimal effect levels (DMEL), and the values for the 100 most commonly found

chemical ingredients in consumer products. This focus could encourage analysts to use *ITER+* as their initial 'go to library' site prior to undertaking a full literature search.

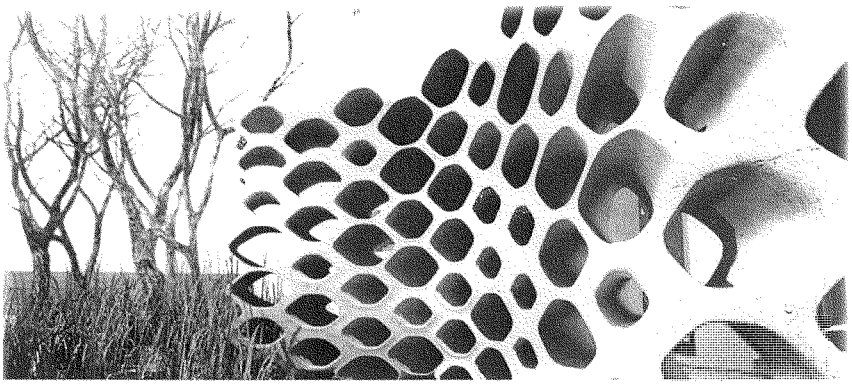
Value: Centralizing authoritative reference values from global organizations in a curated database will streamline the risk assessment process, and foster the consideration of exposure for consumer products by removing one of the current barriers to the use of screening level exposure analysis.

The Alliance welcomes additional partners interested in helping to build ITER+, whether through financial or in-kind support. Additional information can be found at www.allianceforrisk.org.



Turning Big Data to Knowledge (BD2K): A discussion of the NIH BD2K initiative and how it might advance the practice of Toxicology and Risk Assessment: The fields of toxicology, pharmacology and risk assessment are undergoing a revolution in the use of pathway-based approaches to evaluate the biological effects of chemicals. These fields would benefit from accessible tools that make big data convenient and intuitive to integrate, analyze, query and visualize. The aim of this ancillary meeting is to reach out to toxicological scientists and introduce them to the NIH big data programs. A panel of researchers provided short overviews of the BD2K and LINCS initiative and thoughts on how big data can be leveraged for protection of people and the environment.

This discussion was held March 23, 2015 Society of Toxicology (SOT) Outreach Meeting in San Diego, California.



Beyond Science & Decisions: *From Problem Formation to Dose-Response Assessment*

9

Workshops
the Workshop series has now completed 9 workshops, bringing scientists of various affiliations and expertise together.

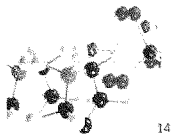
60+

Over 60 organizations
government, industry scientific societies and nonprofits— have contributed to the Workshop's mission to advance the science of risk assessment.

40+

Case Studies
the Workshop series has now reviewed over 40 case studies focusing on a range of risk topics.

Preparation for 2016 Workshop 10 is in underway.



ARA Coalition

1,4-Dioxane Reanalysis of a Regenerative Hyperplasia Mode of Action

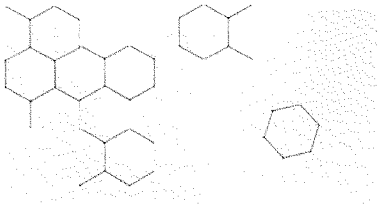
EPA's IRIS 2012 external reviewers of the 1,4-dioxane assessment suggested that the histopathology slides from the NCI 1978 dioxane cancer bioassay in mice be reviewed to ascertain whether non cancer pathology was evident. If evident, this finding would support the conclusion that the cancer MOA is regenerative hyperplasia. TERA scientists worked with Dr. Gene McConnell and staff of the NTP to reevaluate these mouse liver slides and found extensive non cancer pathology, thus supporting the regenerative hyperplasia MOA.

This evaluation also suggested the need to re-evaluate the mouse liver slides from a series of Japanese studies on 1,4-dioxane. Five US states and TERA scientists requested the full unpublished reports (including the relevant micrographs) from the study authors. These reports have been reviewed and a draft analysis was prepared.

As described in our draft analysis, the additional information and translations are also supportive of a regenerative hyperplasia MOA but with one exception, specifically, the reported findings from the histopathology and clinical chemistry of the mouse liver in the Japanese studies are contradictory. This may be due in part to the investigators changing the criteria for liver histopathology scoring during the course of reporting their results.

The State of Kentucky petitioned the Alliance for Risk Assessment (ARA) Steering Committee to obtain additional histopathology documentation from the Japanese studies to inform 1,4-dioxane's cancer Mode of Action (MOA). The intent of this project is to use this additional information, together with the earlier re-evaluations, in order to reach a conclusion regarding the hypothesized MOA for 1,4-dioxane's liver tumor formation (and potentially other tumors). The coalition includes 5 groups and others are welcomed to participate. An evaluation of the data is being done by 3 pathologists and will be used in the final publication.

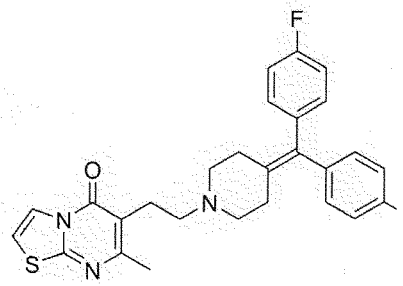
More information, including a project timeline, can be found on the project website at http://allianceforrisk.org/14-dioxane-analysis/



What is *ITERate*?

ITERate is a new program from TERA to review chemical risk values from published peer-reviewed journals for loading onto the International Toxicity Estimates for Risk (*ITER*) (www.tera.org/iter; http://toxnet.nlm.nih.gov/) Through *ITERate*, TERA convenes a small group of toxicology and risk assessment experts to evaluate the Enter *ITERate*. This process will help fill data gaps for missing values or outdated assessments. TCDD example: This controversial chemical has no risk guidance from EPA. The *ITER* database contains data from ATSDR for noncancer endpoints only. The *ITERate* process was utilized to upload an independently derived cancer value for TCDD. Now, states needing to act to protect human health regarding TCDD have access to this newly derived value.

How to Participate Experts in risk assessment are invited to volunteer for review panels. Authors of risk value papers are invited to submit to *ITERate*.

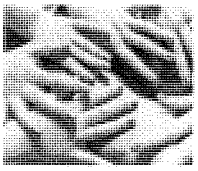


Kids + Chemical Safety



+ Balanced, scientifically accurate chemical health information.

Latest Updates:



Is Nail Polish A Health Risk?



Fluoride in Drinking Water Too Much of a Good Thing?



A new resource addressing the needs of parents and families by providing balanced and scientifically accurate health information on chemical hazards and safe use of chemicals around children.

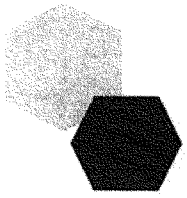
Partnerships:

Superfund Research Program, Harvard University

Cincinnati Children's

Drug and Poison Information Center (DPIC)

NSF



Training



Workshops, Courses, and Webinars. Off-the-shelf or Customized

Dose-Response Assessment Boot Camp continues to be our most popular course. Our original 5-day course which is an intensive hands-on training in hazard characterization and dose-response assessment.

Boot Camp Basics begins with an introduction to toxicology for risk assessors. It addresses the fundamental approaches used in hazard characterization and dose-response assessment, as well as introducing complex concepts and modeling.

Boot Camp Advanced Framework and Modeling provides applications of advanced concepts and models, including mode of a provides applications of advanced concepts and models, including mode of action evaluation techniques, use of dosimetry and PBPK models, benchmark dose modeling, structure activity evaluation tools and methods, systems biology and other tools essential to the advanced risk assessment practice.

Practitioner's Guide to Development & Reproductive Toxicology (DART) A 4 hour webinar intended for health scientists and product stewardship professionals, addressing key issues for understanding and interpreting reproductive and developmental toxicity assays, as well as how such data are interpreted in a risk assessment context.

Non-Cancer and Cancer Risk Assessment A 6 hour course providing key concepts of non-cancer and cancer risk assessment followed by a detailed discussion of the methods for hazard characterization and dose-response.

Dosimetric Adjustments in Dose-Response Assessment A 4 hour course designed to provide basic training in dosimetric adjustments for oral and inhalation exposures in dose-response assessment.

Use of Chemical Specific Adjustment Factors A 6 hour course teaching participants methods for refining interspecies and intraspecies uncertainty factors based on toxicokinetic or toxicodynamic data, using chemical-specific adjustment factors (CSAFs)/ data-derived extrapolation factors (DDEFs).

Benchmark Dose Modeling An 8 hour course designed to give an overview of benchmark modeling software for cancer and non-cancer dose-response assessment. This course also provides hands-on experience in using the EPA BMDS software.

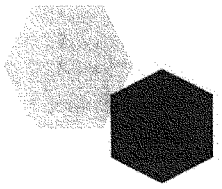
Children's Risk Issues A 1.5 day course discussing the major issues relating to risk assessment for children, such as toxicokinetic differences between adults and children, consideration of windows of susceptibility, and adequacy of the database uncertainty factor.

Mixtures A 2 day course helping scientists to understand and apply methods for risk assessment for multiple exposures or multiple routes ("mixtures risk assessment" or "combined exposures" or "cumulative and aggregate exposure"). Topics include additivity approaches, consideration of interactions, and strategies for addressing complex exposures scenarios.

Occupational Exposures Limit (OEL) Course A 4 day course similar to the Dose-Response Assessment Boot Camp, but focuses on the development of occupational exposure limits (OELs). The training covers the development of OELs, appropriate safety factors, exposure assessment, and hands-on activities to engage all participants.

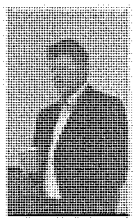
Globally Harmonized System (GHS) Training A training tailored to corporate needs and circumstances. TERA provides firms with written certification as proof of meeting OSHA requirements. We are familiar with GHS as it relates to the Environmental, Health and Safety (EHS) needs and interests of private corporations and public agencies alike.

Emergency Management and Response Training A 3 day course touching on key toxicology and risk assessment concepts, with an in-depth focus on tools for preventing and responding to chemical emergencies including CAMEO, ALOHA, and MARPLOT. This course is offered onsite to members of your ERM team. CEU credits are available from the University of Cincinnati.





Risk Assessment Lecture Series



TERA is sponsoring a new monthly Risk Assessment Lecture Series within the Department of Environmental Health, University of Cincinnati. The lecture series will be on a range of "risk assessment" topics from a variety of risk assessment experts from various organizations and fields of study.

Dr. Charles Menzie, Global Executive Director for the Society of Environmental Toxicology and Chemistry (SETAC) and a principal with Exponent Inc., a science and engineering consulting company, was the inaugural speaker Friday, November 20th. He presented on *"Using Causal Analysis for Evaluating Environmental and Health Issues."* Since then, topics covered have ranged from issues on hazard & dose response assessment, TOXCAST/TOX21, epidemiology-based risk assessment, and asthma. Speakers have volunteered from various organizations and agencies, such as National Institute of Occupational Safety and Health (NIOSH), U.S. Environmental Protection Agency (EPA), University of Cincinnati, and many others.

The Seminar series is held every third Friday of the month. Anyone outside of the Cincinnati area can participate via webinar. Details on the seminars and how to register can be found on the website at http://eh.uc.edu/tera/seminars/

Posters & Presentations

Sunday, 12:00 PM - 1:00 PM, Marriott Marquis Miramar Room: Alliance for Risk Assessment - "Beyond Science and Decisions"	
"Beyond Science and Decisions": Updates and New Developments	L. Haber and M. Dourson, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 9:30 AM to 12:30 PM, CC Exhibit Hall: Poster Session: Risk Assessment I (L. Patterson, Chair)	
Alkylated Lipids in the Food Chain: Toxicology and Risk Assessment (#219)	J. Patterson, M. L. Dourson, J. Rowan, and A. Jonnalagadda, Toxicology Excellence for Risk Assessment, Cincinnati, OH; Corona Environmental Consulting, Boston, MA; and Purdue University, West Lafayette, IN
Mode of Action and Meta-Regression Analysis of the Effect of Trans Fatty Acids (TFAs) on LDL-Cholesterol (#220)	L. T. Haber, J. F. Reichard, M. J. Vincent, R. C. Allen, Leidos, Inc., and M. L. Dourson, Toxicology Excellence for Risk Assessment, Cincinnati, OH, and BCS Associates, Chapel Hill, NC, Ruskin, FL
Monday, 12:15 PM - 1:30 PM, Marriott Marquis, Del Mar Room: Turning Big Data to Knowledge (BD2K) Session	
Data Science and 21st Century Toxicology (12:15 PM)	J. Reichard, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Monday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Genetic Toxicology I	
Evaluation of the Mutations in Lungs of Mice Big Blue Mice Exposed to Lymphan Pentoxide by Inhalation for Up to 4 Weeks (#233)	M. G. Manjanatha, S. D. Shelton, L. T. Haber, A. Aidoo, and M. M. Moore, Genetic and Molecular Toxicology, FDA/NCTR, Jefferson, AR; Toxicology Excellence for Risk Assessment, Cincinnati, OH; Center for Toxicology and Mechanistic Biology, Excerpt Inc., Midland, MI; and TEVEN Bioinnovation Consortium, Little Rock, AR
Quantification of Mutations in Lungs of Mice Big Blue Mice Exposed to Lymphan Pentoxide by Inhalation for Up to 4 Weeks (#234)	M. Bahadori, R. L. Mellick, L. T. Haber, J. A. Manjanatha, B. Gollapudi, and G. A. Kimmel, Division of Genetic and Molecular Toxicology, National Center for Toxicological Research, US FDA, Jefferson, AR; Toxicology Excellence for Risk Assessment, Cincinnati, OH; Toxicology Consulting Services, Arnold, MD; and Exponent, Chicago, IL
Monday, 3:15-4:15, Room 24A: Chemical Risk Assessment Best Practices Session	
Risk Assessment Education: Dissemination & Communication of Methods & Risk Values	M. Dourson, P. Nance, O. Kroner, Toxicology Excellence for Risk Assessment, Cincinnati, OH
Tuesday, 9:00 AM to 11:45 AM, CC Ballroom 6E: Workshop Session: Understanding and Communicating Uncertainty in Hazard Assessment and Dose Response	
Presenting Health Assessments to Understand and Improve Confidence (#T3-A.1, 9:30AM)	K. L. Gaylor, S. L. Sargent, M. L. Dourson, S. Storey, R. H. Lee, and Z. K. Lewis and N. B. Beck, Regulatory and Technical Affairs, American Chemistry Council, Washington, DC; Texas Commission on Environmental Quality, Austin, TX; TCEQ/OPIC/RRP Risk Communication and Environmental Management Consultant, Medford, MA; Toxicology Excellence for Risk Assessment (TERA), Cincinnati, OH and ToxStrategies, Bioanalytics Sciences, Inc., Knoxville, TN
Promoting Understanding of the Context of Biological Monitoring and Exposure Biomarkers (#W1-A.1, 10:15AM)	N. B. Beck, R. H. Lee, S. L. Sargent, P. Nance, and T. Simon, Environmental and Radiological Health Sciences, Colorado State University, Fort Collins, CO; Regulatory and Technical Affairs, American Chemistry Council, Arlington, DC; Toxicology Excellence for Risk Assessment, Cincinnati, OH; and TetraTech, EC, Inc., Atlanta, GA
Tuesday, 4:30 PM – 6:30 PM, Hard Rock Hotel, Satisfaction Room, OTR Planning Meeting	
Occupational Toxicology Roundtable (OTR) Planning Meeting	R. Sandhu, P. Nance, R. Adler, R. Subramani, Toxicology Excellence for Risk Assessment, Cincinnati, OH; Sahmidge Consultants, Inc., New York, NY; Bayer
Wednesday, 1:00 PM to 4:30 PM, CC Exhibit Hall: Poster Session: Bioinformatics	
Big Data to Knowledge (BD2K) – An Adverse Approach to Data Discovery, Use and Integration (#23)	J. F. Reichard, M. Medvedovic, and S. Hogan, Toxicology Excellence for Risk Assessment, (TERA), Cincinnati, OH; and Department of Environmental Health, University of Cincinnati, Cincinnati, OH
Thursday 8:30 AM –12:00 PM, Sails Pavilion: Late-Breaking Poster Session II: Developmental Basis of Adult Disease and Developmental Toxicology	
Developmental Toxicity of Chromium (+3) Picolinate Administered Orally to Sprague Dawley Rats (#277)	R. York, B. Gallaghar, J. Maier, A. Charlton, Rivalry, Rye, NH and Brooklyn, Manhasset, NY; Toxicology Excellence for Risk Assessment, Cincinnati, OH; University Cincinnati College of Medicine, Cincinnati, OH; ISOM Industries, Inc., Akron, OH

Presented at the 2015 SOT Annual Meeting

Presented at the 2015 SRA Annual Meeting

	Monday				
	Monday				
M3-A	Monday	M3-A.1	B	Haber; Reichard; Vincent; Allen; Leidos; Dourson	Mode of action and meta-regression analysis of the effect of trans fatty acids (TFAs) on LDL-cholesterol
P	Monday	P.27		Lenger; Tan; Rhomberg; Goodman; Dourson; Honeycutt	Dose response curves derived from clinical ozone exposures can inform public policy
P	Monday	P.118		Willis, Dvorsen, Reichard, Sandhu, Maier	Using pharmacokinetic data to replace default adjustment factors in assessing risk from non-clinical exposures to pharmaceuticals
P	Monday	P.189		Kroner; Haber; Dourson	The Dose-Response Framework: An online compendium of risk methods organized by problem formulation
P	Monday	P. 207		Nance, Dourson	Alliance for Risk Assessment Project: 1,4-Dioxane Reanalysis in Support of a Regenerative Hyperplasia Mode of Action (MOA)
T3-A	Tuesday	T3-A.3	A	Willis; Dvorsen; Reichard; Sandhu; Maier	How does setting an Acceptable Daily Exposure (ADE) for pharmaceutical risk assessment differ from the U.S. EPA Reference Dose (RfD) approach?
W1-A	Wednesday	W1-A.2	A	Devesa; Maier; Mees; Krewski	Incorporation of chemical-specific data in dose-response assessments for occupational and environmental exposure limits
W4-D	Wednesday	W4-D.3	DE	Patterson; Kroner; Lee; Willis	A Tiered Approach to Investigate Metal Contamination in Unfinished Natural Materials Used in Children's Products
W1-C	Thursday 8:30AM-12:00PM	Workshop		Haber	Developments in Risk Assessment: State of the Science for Evaluating Toxicity Data for Human Health Risk Assessment

Special Issue Articles

- State-of-the-Science: The Evolution of Occupational Exposure Limit Derivation and Application
- Historical Context and Recent Advances in Exposure-Response Estimation for Deriving Occupational Exposure Limits
- Advances in Inhalation Dosimetry Models and Methods for Occupational Risk Assessment and Exposure Limit Derivation
- Systems Biology and Biomarkers of Early Effects for Occupational Exposure Limit Setting
- The Scientific Basis of Uncertainty Factors Used in Setting Occupational Exposure Limits
- Considerations for using Genetic and Epigenetic Information in Occupational Health Risk Assessment and Standard Setting
- Setting Occupational Exposure Limits for Chemical Allergens—Understanding the Challenges
- Exposure Estimation and Interpretation of Occupational Risk: Enhanced Information for the Occupational Risk Manager
- Aggregate Exposure and Cumulative Risk Assessment—Integrating Occupational and Non-occupational Risk Factors
- The Global Landscape of Occupational Exposure Limits—Implementation of Harmonization Principles to Guide Limit Selection

Publications

Allen, B.C., **M.K. Vincent**, D. Liska, and **L.T. Haber**. Meta-regression analysis of the effect of *trans* fatty acids on LDL-C. Accepted with minor revisions.

Banda, M., K.L. McKim, **L.T. Haber**, J.A. MacGregor, B.B. Gollapudi, and B.L. Parsons. 2015. Quantification of *Kras* mutant fraction in the lung DNA of mice exposed to aerosolized particulate vanadium pentoxide by inhalation. Mutat Res Genet Toxicol Environ Mutagen. 789-790:53-60

Beck, N., R. Becker, N. Erraguntla, W. Farland, R. Grant, G. Gray, C. Kirman; J. LaKind, J. Lewis, **P. Nance**; L. Pottenger, S. Santos, T. Simon, **M. Dourson**. 2016. Approaches for Communicating Overall Uncertainty in Toxicity Characterizations: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) as a Case Study. Environment International, 89-90:110-128.

Cope RB, Kacew S, **Dourson M**. 2015. A reproductive, developmental and neurobehavioral study following oral exposure of tetrabromobisphenol A on Sprague-Dawley rats. Toxicology. 2015 Mar 2;329:49-59.

Dotson GS, Hudson NL, **Maier A**. 2015. A decision support framework for characterizing and managing dermal exposures to chemicals during Emergency Management and Operations. J Emerg Manag. 13(4):359-80.

Dourson ML, Chinkin L, MacIntosh D, Finn JA, Brown KW, Reid SB, **Martinez JM**. 2016. A Case Study of Potential Human Health Impacts from Petroleum Coke Transfer Facilities, Journal of the Air & Waste Management Association. (*Submitted*)

Greenberg M, Goldstein BD, Anderson E, **Dourson M**, Landis W, North DW. 2015. Whither Risk Assessment: New Challenges and Opportunities a Third of a Century After the Red Book. Risk Anal. 35 (11):1959-1968.

Haber, L.T., R. Sandhu, A. Li-Muller, A. Mohapatra, S. Petrovic, and M.E. Meek. 2015. Framework for Human Health Risk Assessment of Noncancer Effects Resulting from Short-Duration and Intermittent Exposures to Chemicals. Accepted with minor revisions.

Maier, A; Ovesen, J; Allen, C; York, R; Gadagbui, B; Kirman, C; Poet, T; and Quiñones-Rivera, A. 2015. Safety Assessment for Ethanol-Based Topical Antiseptic Use by Health Care Workers: Evaluation of Developmental Toxicity Potential. Regul Toxicol Pharmacol. 73(1):248-64.

Maier A, Vincent MJ, Parker A, Gadagbui BK, Jayjock M. 2015. A tiered asthma hazard characterization and exposure assessment approach for evaluation of consumer product ingredients. Regul Toxicol Pharmacol. doi: 10.1016/j.yrtph.2015.09.028. [Epub ahead of print]

Manjanatha, M.G., S. D. Shelton, **L. Haber**, B. Gollapudi, J.A. MacGregor, and M.M. Moore. 2015. Evaluation of *cII* mutations in lung of male Big Blue mice exposed by inhalation to vanadium pentoxide for up to 8 weeks. Mutat Res Genet Toxicol Environ Mutagen. 789-790:46-52.

Manjanatha, M.G., S. D. Shelton, Y. Chen, B.L. Parsons, M.B. Myers, B.B. Gollapudi, N.P. Moore, **L.T. Haber**, B.C. Allen, and M.M. Moore. Ethylene oxide is a weak mutagen at the *cII* locus as evaluated in the lung of male Big Blue mice exposed for up to 12 weeks by inhalation. Accepted with revisions.

McAvoy, D., **Pittinger, C. Willis, A.** 2015. Biotransformation of Tetrabromobisphenol A (TBBPA) in Freshwater Sediments, Agricultural Soils, and Anaerobic Digester Sludge. *Ecotoxicol Environ Safety.* [Epub ahead of print]

Pittinger, C.A., **Pecquet (Williz), A.M.** 2016. Aquatic Toxicity and Bioconcentration of Tetrabromobisphenol A in Aqueous and Spiked Sediment Exposures to Fish, Algae, and Invertebrates. *[Submitted]*

Rothenbacher, K., **Pecquet (Willis) A.M.** 2016. Effects of the brominated flame retardant tetrabromobisphenol-A (TBBPA) on soil microorganisms, earthworms, and seedling emergence. *[Submitted].*

Reichard, J. and L.T. Haber. 2016. Mode of action evaluation for the effect of *trans* fatty acids on LDL-C. Accepted with minor revisions.

Sweeney, L.M., L. MacCalman, **L.T. Haber**, E.D. Kuempel, C.L. Tran. 2015. Bayesian Evaluation of a Physiologically-Based Pharmacokinetic (PBPK) Model of Long-Term Kinetics of Metal Nanoparticles in Rats. Reg. Toxicol. Pharmacol. 73:151-163

Waters M, McKernan L, **Maier A**, Jayjock M, Schaeffer V, Brosseau L. 2015. Exposure Estimation and Interpretation of Occupational Risk: Enhanced Information for the Occupational Risk Manager. J Occup Environ Hyg. 12 Suppl 1:S99-S111.

Weideman P., Bercu J.P., Callis C., Dolan D.G., Faria E., Flueckiger A., Gould J., Hayes E.P., Jolly R., Lovsin Barle E., Luo W., Molnar L.R., Morinello E., Naumann B.D., Olson M., Pfister T., **Sandhu R.**, Sargent E.V., Seaman C., Sehner C., Shipp B.K., Stanard B., Streeter A.J., Sussman R., Walsh A., **Willis A.M., Maier A**, 2015. Deriving Health-Based Exposure Limits in the Pharmaceutical Industry. Contract Pharma, September, 74-80.

Book Chapters

Nance, P., O. Kroner, L. Haber and M. Dourson. 2015. Assessing Risks to Human Health. In Reference Module in Biomedical Sciences (Online). In-Press.

Nance, P., O. Kroner, L. Haber and M. Dourson. 2015. Assessing Risks to Human Health. In Reference *Comprehensive Toxicology, Third Edition, In-Press*

Special Issue in Journal of Occupational and Environmental Hygiene: State of the Science of Occupational Exposure Limit Methods and Guidance, available at http://www.tandfonline.com/toc/uoeh20/12/sup1

DeBord, D.G., L. Burgoon, S.W. Edwards, **L.T. Haber**, M.H. Kanitz, E.D. Kuempel, R.S. Thomas, B. Yucesoy. 2015. Systems Biology and Biomarkers of Early Effects for Occupational Exposure Limit Setting. J Occup Environ Hyg. 12 Suppl 1:S41-54.

Dankovic DA, Naumann BD, **Maier A, Dourson ML,** Levy LS. 2015. The Scientific Basis of Uncertainty Factors Used in Setting Occupational Exposure Limits. J Occup Environ Hyg. 2015 Nov 25;12 Suppl 1:S5-68

Deveau M, Chen CP, Johanson G, Krewski D, **Maier A**, Niven KJ, Ripple S, Schulte PA, Silk J, Urbanus JH, Zalk DM, Niemeier RW. 2015. The Global Landscape of Occupational Exposure Limits-Implementation of Harmonization Principles to Guide Limit Selection. J Occup Environ Hyg. 2015;12 Suppl 1:S127-44.

Dotson GS, **Maier A**, Siegel PD, Anderson SE, Green BJ, Stefaniak AB, Codispoti CD, Kimber I. 2015. Setting Occupational Exposure Limits for Chemical Allergens-Understanding the Challenges. J Occup Environ Hyg. 12 Suppl 1:S82-98.

Lentz, T; Dotson, S; Williams, P; **Maier, A; Gadagbui, B**; Pandalai, S P; Lamba, A; Hearl, F; Mumtaz, M. 2015. Aggregate Exposure and Cumulative Risk Assessment – Integrating Occupational and Non-occupational Risk Factors. J Occup. Environ. Hyg. 12 Suppl 1:S112-26

Maier A, Lentz TJ, MacMahon KL, McKernan LT, Whittaker C, Schulte PA. 2015. State-of-the-Science: The Evolution of Occupational Exposure Limit Derivation and Application. J Occup Environ Hyg. 2015;12 Suppl 1:S4-6

Sargent EV, Flueckiger A, Lovsin Barle E, Luo W, Molnar L, **Sandhu R**, Weideman P. 2016. The Regulatory Framework for Preventing Cross-Contamination of Pharmaceutical Products: History and Considerations for the Future. *In preparation for Regulatory Toxicology and Pharmacology.*

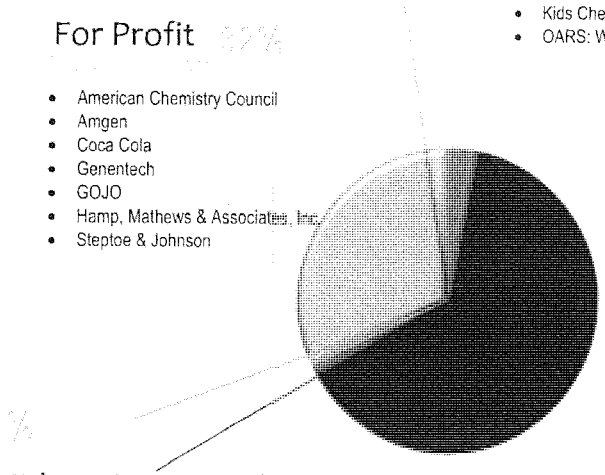
Olson M, Faria E, Hayes EP, Jolley R, Lovsin Barle E, Molnar L, Naumann BD, **Pecquet AM,** Shipp B, Sussman R, Weideman P. 2016. A Harmonization Effort for Acceptable Exposure Methodology Applied to Pharmaceutical Cleaning Validation -- Communication with External Stakeholders. *In preparation for Regulatory Toxicology and Pharmacology.*

Hayes EP, Faria E, Jolly R, Lovsin Barle E, Molnar L, Naumann B, Olson M, **Pecquet AM,** Shipp B, Sussman R, Weideman P. 2016. A Harmonization Effort for Acceptable Exposure Methodology Applied to Pharmaceutical Cleaning Validation -- Operational Aspects. *In preparation for Regulatory Toxicology and Pharmacology.*

Faria EC, Bercu J, Dolan DG, Morinello E, **Pecquet AM,** Seaman C, Sehner C, Weideman, P. 2016. Using Default Methodologies to Derive an Acceptable Daily Exposure (ADE). *In preparation for Regulatory Toxicology and Pharmacology.*

Reichard JF, Maier MA, Naumann BD, **Pecquet AM,** Pfister T, **Sandhu R,** Sargent EV, Streeter AJ, Weideman P. 2016. Pharmacokinetic and Pharmacodynamic Considerations when Deriving Health-Based Exposure Limits for Pharmaceuticals. *In preparation for Regulatory Toxicology and Pharmacology.*

2015 TERA Project Time by Sponsor



Collaborators

- Alliance for Risk Assessment
- Beyond Science and Decisions: From Problem Formation to Dose Response
- Kids Chemical Safety Webpage
- OARS: WEEL

For Profit

- American Chemistry Council
- Amgen
- Coca Cola
- Genentech
- GOJO
- Hamp, Mathews & Associates, Inc.
- Steptoe & Johnson

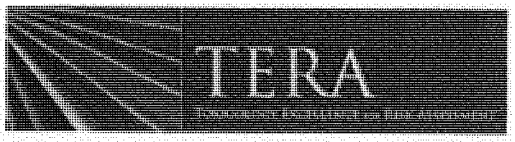
Education Training

- Dose-Response Boot Camp

Government/Non-Profit

- Consumer Product Safety Commission
- Health Canada
- International Life Sciences International
- Texas Commission on Environmental Quality

The sponsors listed above are sponsors that each comprise 2% or more of our work.



TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT
Address: 2300 Montana Avenue, Suite 409, Cincinnati, Ohio 45211
Tel : (513) 542-7475
Fax : (513) 542-7487
Email : tera@tera.org

www.tera.org

CURRICULUM VITAE

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

michael.dourson@uc.edu
513-558-7949
419-892-2502 (Fridays)
2017

EMPLOYMENT

2017-	Professor, Risk Science Center (aka TERA Center), Department of Environmental Health, University of Cincinnati, College of Medicine, Cincinnati, Ohio
2015-16	Professor and Director, Toxicology Excellence for Risk Assessment Center, Department of Environmental Health, University of Cincinnati, College of Medicine, Cincinnati, Ohio
1995-15	Director/President, Toxicology Excellence for Risk Assessment, Cincinnati, Ohio
1991-94	Chief, Systemic Toxicants Assessment Branch, Environmental Criteria & Assessment Office (ECAO), U.S. Environmental Protection Agency (EPA), Cincinnati, Ohio
1990-91	Associate Director, ECAO, Cincinnati, Ohio
1989-90	Chief, Pesticides and Toxics Team, EPA, Washington, D.C.
1986-89	Chief, Methods Evaluation and Development Staff, ECAO, Cincinnati, Ohio
1985	Leader, Acceptable Daily Intake (ADI) Group, ECAO, Cincinnati, Ohio
1980-84	Staff Toxicologist, ECAO, Cincinnati, Ohio

EDUCATION

1988-89	Executive Potential Program, U.S. Office of Personnel Management
1986-87	Zenger Miller Supervision Course
1985-2015	Diplomate of the American Board of Toxicology
1975-80	University of Cincinnati, College of Medicine, Ph.D. degree in toxicology
1970-74	Wittenberg University, B.A. degree in biology

TEACHING

I have lectured in courses at the graduate level in several universities and institutes; have lectured high school students on the general principles of toxicology over several years; and have talked with grade school students on several occasions about careers in science and my experiences in Africa. I participated as a member of the Ph.D. thesis committee of Dr. Natalia Foronda of the Ministry of Health, New Zealand.

RESEARCH: INVITED PRESENTATIONS (Selected)

"Current status of Benchmark Dose Modeling for 3-Monochloropropane-1,2-diol (3-MCPD)"
German Fat Scientists Association and the German Federation for Food Law and Food Science. Berlin, Germany, June 20, 2017.

"Health risk assessment for perchlorate: New direction in EPA's modeling approach for establishing standards"
American Water Works Association. Annual Conference. Philadelphia, PA. June 14, 2017.

"Hazard identification"
"Dose response assessment"
"Exposure assessment"
"Risk characterization"
Atenco School of Medicine and Public Health. Makati City, Philippines. June 1-2, 2017.

"Risk Assessor Certification"
Taiwan Chapter of the Society for Risk Analysis. Taichung City, Taiwan. May 24, 2017.

"Overview of risk assessment"
"Hazard identification II: Cancer"
"Dose response assessment II: Cancer"
"Introduction to dose response assessment modeling"
"Use of PBPK modeling in risk assessment"
"Risk characterization"
The Regional Training Program on Risk Assessment, Bibliotheca Alexandrina, Alexandria, Egypt, April 24-27, 2017.

"Managing the non-cancer risks a hazardous waste sites: Trichloroethylene (TCE) as a case study"
Association for Environmental Health and Sciences (AEHS) Foundation. San Diego, California March 21, 2017.

"The concept of hormesis and application in risk assessment"
Society of Toxicology, Baltimore, Maryland, March 14, 2017.

"The concept of hormesis and application in risk assessment"
Society for Risk Analysis, San Diego, California, December 12, 2016

"Mechanics of Risk Assessment"
In workshop on Risk Analysis. **Institute for Humane Studies and the Mercatus Center at George Mason University**. Portland, Oregon, June 18th, 2016.

"Yes, 'Thresholdable' Carcinogens Are Still Delaney Carcinogens"

Roundtable Session: Is a "Thresholdable" Carcinogen Still a Delaney Carcinogen?
Society of Toxicology, New Orleans, Louisiana, March 14, 2016.

"Distinguishing between Mode and Mechanism of Action, and Some Key Events for MOA"
Colloquium: Role of Mode of Action in Dose-Response Assessment for Carcinogens.
Food and Drug Administration and the Society of Toxicology, College Park, Maryland, February 25, 2016.

"Harmonizing OELs: Commonalities and Differences"
Keynote talk at the annual meeting of the **Occupational Toxicology Roundtable**. New Brunswick, New Jersey, October 4, 2015

"Risk assessment and hazard identification for metals"
"Human health case study: mercury exposure and essential metals"
"Human health criteria and standards"
Asian Pacific Economic Conference Workshop on Metals Risk Assessment, Cebu, Philippines on 28-29th August 2015.

"Hepatotoxicity"
"Cardiac Toxicity"
"Hazard Identification/Dose Response"
"Exposure Assessment/Characterization"
International Workshop On Comprehensive Toxicology, Bengaluru, India, July 27-31, 2015.

"Defining the range of the reference dose: imprecision versus uncertainty"
The TCE Revolution and its Permanent Impact on Environmental Due Diligence, EDR Insight, National Teleconference/Webinar. June 24, 2015.

"Assessment and management of Elk River, West Virginia drinking water contamination incident, 2014"
British Toxicology Society Annual Congress, Birmingham, UK, April 20, 2015.

"Hazard & Dose Response Assessment: Roadmaps & Methods for Using 21st Century Data"
Ohio State University, Columbus, Ohio, February 23, 2015.

"Practical Guidance on the Development of a Non-cancer Hazard Range for Effective Risk Assessment and Risk Management of Contaminated Sites: A Case Study with Trichloroethylene and Other Chemicals"
Tri-Service Environmental Risk Assessment Work Group, Naval Medical Center, Portsmouth, VA. Jan. 21, 2015.

"Advances in Assessing Food Additive Safety"
SPI Food, Drug and Cosmetic Packaging Materials Committee. Food Packaging Summit. New Orleans, LA. Nov. 10-12, 2014.

"Mode of Action and Dose-Response Evaluation of the Effect of Partially Hydrogenated Oils on LDL-Cholesterol"
SOT-FDA Colloquia on Emerging Toxicological Science Challenges in Food and Ingredient Safety. Colloquium One. College Park, MD, Live Webcast. Nov. 7, 2014.

"Risk Assessment Roadmaps & Methods for Using 21st Century Data"
International Institute of Synthetic Rubber Producers, Inc. Houston, Texas. Nov. 6, 2014.

"Advances in Assessing Ingredient Safety"
Workshop on GRAS Determinations. International Society of Regulatory Toxicology and Pharmacology. Washington, DC. Oct. 14, 2014.

"Case study #3: Partially Hydrogenated Oils (PHOs)"
The Role and Use of Nutritional Studies I Evaluating the Safety of a Food or Ingredient. ILSI North American Special Workshop. Washington, DC. July 22, 2014.

"Dose Response Assessment Boot Camp---Lecture series"
Toxicology Excellence for Risk Assessment (TERA) at Gadjah Mada University, Yogyakarta, Indonesia. June 13-21, 2014.

"Opportunities and Challenges Posed By the Use of 'omics' data in Risk Assessment of Mixtures"
Toxicology Risk Assessment Conference (TRAC). Cincinnati, Ohio. April 8, 2014.

"Alliance for Risk Assessment (*ARA*), EDSP, TCE, Science and Decisions"
Monsanto. St. Louis, MO. April 10, 2013.

"Risk Assessment Roadmaps & Methods for Using 21st Century Data"
Weight of Evidence Workshop. **International Life Sciences Institute (ILSI)** North America Technical Committee on Food & Chemical Safety. Miami, Florida. January 23-24, 2013.

"Advancing human health risk assessment: Charting a Course through committee recommendations"
Society for Risk Analysis Annual Meeting. San Francisco, CA. Dec. 9-12, 2012.

"How Individual Variability is Currently Factored into Risk Assessment/Regulation/Decision Making"
Emerging Science for Environmental Health Decisions. **The National Academies of Science**, Board on Life Sciences, Board on Environmental Studies and Toxicology. Washington, D.C. April 18-19, 2012.

"A Hitchhikers Guide to the Galaxy of Practical Risk Assessment"
Resource sharing, partnering, and cooperative science policy resolution. US EPA and Region V States **Vapor Intrusion Video Conference Roundtable.** Columbus, OH. April 12, 2012.

"Problem formulation to dose response: Advance via the *ARA* Beyond Science and Decisions workshops"
New England Chapter of the Society for Risk Analysis. Boston, MA. January 24, 2012.

"Risk Analysis on the Coast"
Society for Risk Analysis Annual Meeting. Charleston, SC. Dec. 4-7, 2011.

"Current Environmental Risk Assessment: Getting ready for Century 21"
Association of Government Toxicologists. Washington, D.C. March 29, 2011.

"Risk Assessment"
Global Chemistry. Baltimore, MD. March 22, 2011.

"Peer Review and Consultation Program"
American Chemistry Council. Washington, D.C. Feb. 16, 2011.

"Fishbowl"
Risk 21: Realizing the Future of Risk Assessment Workshop. **International Life Sciences Institute**. Washington, DC. Jan. 11, 2011.

"Draft Toxicological Review of Hexavalent Chromium"
Environmental Protection Agency's IRIS listening session. Washington, D.C. November 18, 2010.

"Perspectives of Air Pollutants: Health Effects Research Update Session: Risk Assessment…*in the 21st Century*." **Clean Air Forum.** Houston, TX. Nov. 4, 2010.

"A Risk Assessment and Regulatory Agency Perspective on Mixtures Affecting Susceptible Populations"
Society of Toxicology Annual Meeting. Salt Lake City, Utah. March 6-12, 2010.

"Risk Analysis: The Evolution of a Science"
Society for Risk Analysis Annual Meeting. Baltimore, MD. Dec. 5-10, 2009.

"Environmental Risk in the 21st Century"
International Society of Regulatory Toxicology and Pharmacology. Washington, D.C. Dec. 9, 2009.

"Emerging issues and regulatory challenges and the science of risk assessment"
Keynote talk at the **Midwestern States Environmental Consultants Association** biannual meeting. Indianapolis, Indiana. November 3, 2009.

"Making a Successful Transition from Government to Non-Profit Sectors"
Society of Toxicology. Baltimore, MD. March 15-20, 2009.

"Exposure, and Risk Data: Ensuring the Best Science"
Society of Toxicology. Baltimore, MD. March 15-20, 2009.

"Scientific Peer Review: An Overview with Reference to the International Toxicity Estimates for Risk *(ITER)* Database"
Society of Toxicology. . Baltimore, MD. March 15-20, 2009.

"A Risk Assessment and Regulatory Agency Perspective on Mixtures Affecting Susceptible Populations"
Society of Toxicology. Baltimore, MD. March 15-20, 2009.

"Toxicology Excellence for Risk Assessment"
Environmental Council Of States and Department of Defense Sustainability Workgroup. Washington, D.C. June 20-21, 2007.

"Predicting risk above EPA's Reference Dose (RfD)"
Toxicology and risk assessment conference. **Multiple federal agency sponsors.** Cincinnati, Ohio. April 25, 2007.

"Using human data to protect public health"
Toxicology and risk assessment conference. **Multiple federal agency sponsors**. Cincinnati, Ohio. April 24, 2007.

"A Historical Perspective on Risk Assessment and Areas for Advancement"
Twenty-Eighth Annual Meeting of the **American College of Toxicology**. Nov. 11-14, 2007.

"Air toxics: Risk based analysis"
Symposium on air emission from large industrial sources. Endicott House, **Multiple sponsors**. August 16-17, 2006.

"What Should We Really Be Worried About?"
Seafood & Health '05: Issues, Questions and Answers. Session V. Assessing the Real Risks. **Department of Commerce**. Washington, D.C. December 2005.

"Future Use of Default Assumptions and Uncertainty Factors"
Michigan State University, Center for Integrative Toxicology. April 8, 2005.

"Mercury Regulation: Fishing For The Facts About Risk"
States and Nation Policy Summit. **American Legislative Exchange Council**. Washington D.C. December 3, 2004.

"Acceptable Daily Intakes (ADIs) and their Application in the Regulatory Process"
Meeting of the Technical Committee on Food Toxicology and Safety Assessment of the **International Life Sciences Institute**. North America. Washington, DC. Nov. 30, 2004.

"Human dose-response assessment of copper"
Science Symposium Update on Science Supporting the EU Voluntary Risk Assessment. **International Copper Association**. Rome. May 17, 2004.

"Integration of Toxicity and Molecular Mechanistic Data for Nonlinear Dose-Response Assessment. Application to Systems Biology and Risk Assessment"
2003 Annual Meeting. **Society for Risk Assessment**. Baltimore, Maryland. December 10, 2003.

"History of *TERA* Coordinated Public/Private Partnership on Perchlorate Research"
Perchlorate State-of-the-Science Symposium. **University of Nebraska, Center for Environmental Toxicology**. Omaha, Nebraska. September 29, 2003.

"Perchlorate Reference Dose (RfD)"
California Environmental Protection Agency. September 26, 2003.

"Small Non-Profits in a Big Risk World: Greasing the Wheels of Change"
Featured Meeting Speaker, The **Northern California Chapter of the Society for Risk Analysis**. September 25, 2003.

"Risk Assessment"
In: ATSDR and RIVM Expert Panel Meeting on Chemical Risk Assessment and Children's Health. **ATSDR** and **RIVM**, Brussels. June 26, 2003.

"Differential Sensitivity Of Children And Adults To Chemical Toxicity"
Midwestern States Risk Assessment Symposium. **Indiana Department of Environmental Management.** Indianapolis, IN. July 25, 2002.

"Modeling Of Population Variability"
Midwestern States Risk Assessment Symposium. **Indiana Department of Environmental Management.** Indianapolis, IN. July 25, 2002.

"Data Derived Replacement Of Default Uncertainty Factor"

Workshop on modeling of population variability. **Society of Toxicology.** Nashville, TN. March 19, 2002.

"Stone-Age Toxicity: From Factors of 10 to Compound-Specific Adjustments"
University of Cincinnati Medical Center, Dept. of Environmental Health Seminar. Nov, 2002.

"Does The Use Of Data-Derived Uncertainty Factors Allow Risk Assessors To Describe Uncertainty More Accurately?"
Fifth Annual Workshop on Evaluation of Default Uncertainty Factors in Health Risk Assessment. **New Jersey Medical School**. June 1, 2001.

"Risk Assessment"
HESI Agricultural Chemical Safety Assessment Subcommittee Steering Committee Meeting. **International Life Sciences Institute**. Washington, D.C. April 18, 2001.

"Risk Characterization Framework For Non-Lethal Weapons"
Symposium on comparative risk. **Society for Risk Analysis.** Seattle, WA. December 5, 2001.

"Noncancer Risk Assessment: A 20-Year Perspective"
Ohio Society for Risk Analysis. Noncancer Workshop. Cincinnati. June 13, 2000.

"Approaches to assessing dose response assessment relations"
Chulabhorn Research Institute. Training course on environmental and health risk assessment and risk management of toxic chemicals, Lak si, Bangkok, Thailand. November 21, 2000.

"Guidelines for Application of Data-Derived Uncertainty Factor in Risk Assessment"
Fourth Annual Workshop of Evaluation of Uncertainty Factors in Health Risk Assessment. **New Jersey Medical School.** May 3-4, 2000.

"Determining USEPA Reference Doses (RfDs) for Essential Minerals"
University of Ulster. Nutrition & Toxicology Excellence for Risk Assessment Workshop Series. Northern Ireland. June 18, 1999.

"The Challenges Of Using Common Mechanism Of Toxicity In Chemical Regulation"
Roundtable session. **Society of Toxicology**. New Orleans, LA. March 17, 1999.

"Extrapolating Data From Adults To Set ULs For Children"
Workshop on upper levels of nutrients. **National Academy of Sciences**. January 21, 1999.

Incidence and severity in relation to magnitude of intake: mixed effects, categorical regression"
International Life Sciences Institute. Workshop on the significance of excursions of intake above the ADI. Milan, Italy. April 23, 1998.

"Should there be an international accreditation of toxicologists? Accreditation in the USA"
International Congress of Toxicology. Paris, France. July 8, 1998.

"Quality Issues relating to scientific information"
US. EPA Data Quality and Gaps Workshop. **U.S. Environmental Protection Agency.** Washington, D.C. October 19, 1998.

"Noncancer Risk Assessment: Impact of Research on the Underlying Science"
International Society for the Study of Xenobiotics. Hilton Head, South Carolina. October 26-30, 1997.

"Alternatives to the NOAEL Approach (BMD, probabilistic approach)"

Federal Institute for Health Protection of Consumers and Veterinary Medicine. Workshop on Use of Uncertainty Factors in the Risk Assessment Process - New Directions. Berlin, Germany. May 5-7, 1997.

"Risk Assessment And The Role Of Risk Assessment Guidelines"
Workshop: EPA's neurotoxicity risk assessment guidelines. **Society of Toxicology**. Cincinnati, Ohio. March 11, 1997.

"Noncancer Risk Assessment: Impact Of Research On The Underlying Science"
Symposium V: Cancer and noncancer risk assessment. **International Society for the Study of Xenobiotics**. October 28, 1997.

"Overview: Classical Risk Assessment"
Risk Assessment in Establishing Upper Reference Levels of Nutrients Workshop. **Food & Nutrition Board, Inst. of Medicine,** Washington, DC. July 15-16, 1996.

"ADI, BMD, CEL...The Alphabet Soup of Methods for Dose Response Assessment"
In: Conference on Advances in Toxicology and Applications to Risk Assessment. **ATSDR, U.S. Army, Air Force, Navy and EPA.** Dayton, Ohio. April 25, 1996.

"Overview of EPA's Reference Dose Methodology"
In: Toxicology Peer Review Board Meeting of the **U.S. Army** Center for Health Promotion and Preventive Medicine. Aberdeen Proving Ground, Maryland. January 18,1996.

"Non-Cancer Risk Assessment: Three Practical Methods From A Decade Of Research"
In: New Techniques in Risk Assessment. **International Business Communication**. Orlando, Florida. February 15, 1996.

"Evolution of Science-based Uncertainty Factors in Noncancer Risk Assessment"
The 2nd Annual Workshop on the Evaluation of EPA 10X Safety Factors in Health Risk Assessment. **New Jersey Medical School**. Nutley, NJ. December 6, 1996.

"Noncancer Hazard Identification and Dose Response Assessment, Part 2"
In: Risk assessment. **University of Cincinnati, College of Medicine**. April 18, 1996.

"Dose Response Class Exercise: Aroclor"
In: Risk assessment. **University of Cincinnati, College of Medicine**. April 30, 1996.

"Introduction to Risk Assessment"
In: Risk assessment. **University of Cincinnati, College of Medicine**. March 26, 1996.

"Systemic Toxicants, Cross Route Extrapolation, Complex Mixtures"
In: Risk assessment. **University of Cincinnati, College of Medicine**. May 23, 1995.

"On Reference Dose and Its Underlying Toxicity Data Base"
Health Canada. Threshold of Regulation Workshop. Ottawa, Canada. March 28, 1995.

"Presentation of Ongoing Work on Characterization of Distributions of Data which Serve as the Basis for Uncertainty Factor" **Health Canada**. Planning Meeting on Uncertainty Factors. Ottawa, Canada. March 18, 1995.

"Advances in Research Used as an Adjunct to Toxicity Testing: EPA Perspective"
In: Regulatory Update: EPA Regulation and Test Requirements. **American College of Toxicology.** Annual Meeting. Vienna, Virginia. November 12, 1995.

"Alternatives To The RfD: What Are We Getting And How Much Effort Does It Cost?" Interagency Risk Assessment Committee. **State of New Jersey.** April 25, 1994.

"Panel Discussion"
In: Issues in reproductive and developmental risk assessment-boron toxicity as a test case. Annual Winter **Toxicology Forum**. February 22, 1994.

"Regulatory Considerations of the U.S. EPA"
In: Biological effects of low level exposures (BELLE) and potential implications for regulatory decision-making. **American College of Toxicology.** Annual Meeting. October 26, 1994.

"Noncancer Improvements Discussion Panel"
In: Health effects & risk assessment associated with noncarcinogenic, radioactive and mixed waste. **Air & Waste Management Association.** 87th Annual Meeting. June 23, 1994.

"Evaluating Subpopulations: Fish Consumption Advisory Methodology"
In: EPA Workshop on challenges in Risk Characterization. **U.S. Environmental Protection Agency,** Cincinnati. September 8, 1994.

"Inherent Imprecision of RfD"
In: EPA Regional Risk Assessors' Meeting. **U.S. Environmental Protection Agency**, Boston, MA. April 27th, 1994.

"New Methods: Benchmark Dose"
In: EPA Regional Risk Assessors' Meeting. **U.S. Environmental Protection Agency**, Boston, MA. April 26th, 1994.

"Components of Risk Assessment"
In: Risk assessment. **University of Cincinnati, College of Medicine**. March 29, 1994 (This same lecture was also given an additional two times at the Cincinnati State Technical and Community College on September 27th and November 15th).

"How Toxicity Data Are Used in the Process of Hazard Identification and Dose-Response Assessment"
In: Basic Risk Assessment: Current Developments. Continuing Education Course. **Society of Toxicology**. New Orleans, LA. March 14, 1993.

"Modifying Uncertainty Factors for Noncancer Endpoints"
In: Advanced Topics in Risk Assessment. Continuing Education Course. **Society of Toxicology**. New Orleans, LA. March 14, 1993.

"Noncancer Risk Assessment"
In: Course entitled "Introduction to Risk Assessment." **University of Kentucky.** Lexington, Kentucky. July 28, 1993.

"Noncancer Risk Assessment Science"
In: Risk Assessment and the Environment Series. Harvard Center for Risk Analysis. **Harvard School of Public Health.** Boston, MA. February 16, 1993.

"Statistical Research Planning of the Environmental Criteria and Assessment Office"
In: Workshop on Office of Research and Development Statistical Needs. **U.S. Environmental Protection Agency.** Research Triangle Park, North Carolina. May 12, 1993.

"EPA's Integrated Risk Information System"

International Programme on Chemical Safety, World Health Organization. Geneva, Switzerland. June 17, 1993.

"Noncancer Dose-response and Risk Characterization"
In: Course on Environmental Health Risk Assessment. **Nofer Institute of Occupational Health.** Lodz, Poland. March 31, 1993.

"Most Important Problems Encountered in Quantitative Risk Assessment at the National or International Level"
In: Meeting on Consultation on Guiding Principles and Methodology for Quantitative Risk Assessment in Setting Exposure Limits. **International Programme on Chemical Safety, World Health Organization**. Langen, Germany. January 19, 1993.

"Risk above the Reference Dose (RfD) Benchmark Dose (BMD)"
In: Conference on the Risk Assessment Paradigm after Ten Years. **U.S. Army, Air Force, Navy and EPA**. Dayton, Ohio. April 7, 1993.

"Benchmark Dose Approach to Risk Assessment"
In: **Federal-State Toxicology and Risk Analysis (FSTRAC)** Fall Meeting. Washington D.C. December 1-3, 1993.

"Overview of Alternatives to Benchmark Dose"
In: Workshop on Benchmark Dose Methodology. Public workshop sponsored by **U.S. Environmental Protection Agency, American Industrial Health Council, and International Life Sciences Institute**. Fairfax, Virginia. September 28-30, 1993.

"Development of RfDs and the IRIS Process"
In: Cincinnati Forum on Dose Response Issues of Risk Assessment for Trivalent and Hexavalent Chromium Salts. **Public workshop sponsored by U.S. Environmental Protection Agency**. Cincinnati, Ohio. August 19, 1993.

"The Use of Threshold Limit Values for Determining Community Standards: Current Issues"
In: Tutorial Session on Threshold Limit Values and Biological Exposure Indices. 11th International System Safety Conference. **Ohio Chapters of both the System Safety Society and the Society for Risk Analysis**. Cincinnati, Ohio. July 29, 1993.

"The IRIS Process"
In: Cincinnati Forum on Boron Containing Chemicals: Risk Factors and Characterizations. **Public workshop sponsored by U.S. Environmental Protection Agency**. Cincinnati, Ohio. February 11, 1993.

"Introduction to Risk Assessment"
In: Tutorial Session on Environmental and Occupational Risk Assessment and Risk Communication. 11th International System Safety Conference. **Ohio Chapter of the System Safety Society**. Cincinnati, Ohio. July 29, 1993.

"The U.S. EPA's Use of Uncertainty Factors"
In: Workshop on Safety Assessment for Non-Cancer Endpoints: The Benchmark Dose and Other Possible Approaches. **California EPA, U.S. EPA and U.S. Agency for Toxic Substances and Disease Registry**, Tiburon, California. May 12, 1992.

"Risk Assessment: Who needs it?"
All-Ohio Safety and Health Congress and Exhibit. Cincinnati, Ohio. April 1, 1992.

"Bridging the Chasm: Breakthroughs Needed in Noncancer Risk Assessment"

In: Kettering Seminar Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. January 22, 1992.

"Role of Risk Analysis and Risk Management in the U.S"
In: 3rd U.S.-Japan Governmental Conference on Drinking Water Quality Management. **Governments of the United States and of Japan**, Cincinnati, Ohio. September 22, 1992.

"The Reference Dose"
In: Conference on Trace Elements in Health and Disease. **International Society for Trace Element Research in Humans** and **Nordic Trace Element Society**, Stockholm, Sweden. May 27, 1992.

"Novel Approaches to the Estimation of Noncancer Health Risk"
International Programme on Chemical Safety, World Health Organization, Geneva, Switzerland. January 16, 1992.

"The Reference Doses for Chromium"
In: Workshop on Risk Assessment of Essential Elements. Public workshop sponsored by **U.S. Environmental Protection Agency, Agency for Toxic Substances and Disease Registry, and International Life Sciences Institute**, Herdon, Virginia. March 12, 1992.

"The Reference Dose"
In: Workshop on Risk Assessment of Essential Elements. Public workshop sponsored by **U.S. Environmental Protection Agency, Agency for Toxic Substances and Disease Registry, and International Life Sciences Institute**, Herdon, Virginia. March 10, 1992.

"Novel Approaches to the Estimation of Noncancer Health Risk: Probabilistic RfDs, Benchmark Dose, and Severity Modeling"
In: Workshop on Risk Assessment for Noncarcinogens. **Health and Welfare Canada**, Tunney's Pasture, Ottawa. April 29, 1991.

"Novel Approaches to Noncancer Health Risk Assessment"
In: EPA Regional Risk Assessors' Meeting. **U.S. Environmental Protection Agency**, Denver, Colorado. June 25, 1991.

"Risk Communication-A Challenge for the 1990's and Beyond"
System Safety Society, Cincinnati, Ohio. August 5, 1991.

"Quantitative Risk Assessment: The Reference Dose (RfD) and Research to Improve this Model Including the Use of Average Uncertainty Factors"
In: Symposium on Neurotoxicity Risk Assessment: State of the Art. **Society of Toxicology.** Dallas, Texas. March 1, 1991.

"Novel Approaches for Quantitative Assessment of Risks for Noncancer Effects"
Boston Risk Assessment Group and **New England Chapter of the Society for Risk Analysis.** Boston, Massachusetts. February 12, 1991.

"Impact of Risk Related Concerns on the EPA Programs"
In: Advanced Research Workshop on Nitrate Contamination: Exposure, Consequences and Control. **North Atlantic Treaty Organization (NATO)**, Lincoln, Nebraska. September 14, 1990.

"How Are Environmental Criteria Developed?"

In: A course entitled "Environmental and Occupational Health Risk Assessment and Risk Management." Developed for **City of Cincinnati Council** and other local decision-makers. Cincinnati, Ohio. May 3, 1990.

"Non-carcinogenic Risk Assessment"
In: Risk Assessment Workshop. **Federal-State Toxicology and Regulatory Alliance Committee**. Washington D.C. April 19, 1990.

"Risk above the RfD and Benchmark Dose Procedures"
In: Workshop to Discuss Noncancer Risk Assessment Methods/Data Needs to Support the New Clean Air Act Amendments. **U.S. Environmental Protection Agency**. Research Triangle Park, North Carolina. July 23, 1990.

"Reference Dose (RfD)"
In: Workshop to Discuss Noncancer Risk Assessment Methods/Data Needs to Support the New Clean Air Act Amendments. **U.S. Environmental Protection Agency**. Research Triangle Park, North Carolina. July 23, 1990.

"Guidelines Used to Assess Toxicological Hazards: Quantification Issues"
In: Symposium on Access and Use of Information Resources in Assessing Health Risks from Chemical Exposure. **Oak Ridge National Lab** and **U.S. Environmental Protection Agency**. Knoxville, Tennessee. June 28, 1990.

"How Statutes and Executive Orders Affect the Use of Scientific Information"
In: Regulation Development in EPA Course. **U.S. Environmental Protection Agency**. Washington, D.C. June 20, 1990.

"Risk Assessment and Its Uses: Directions of New Research"
National Institute of Occupational Safety and Health (NIOSH). Cincinnati, Ohio. June 20, 1989.

"Health Risk Assessment: Chronic Reference Dose"
In: Washington Conference on Risk Assessment. **Center for Energy and Environmental Management.** Washington, D.C. September 26, 1989.

"EPA's Approach to Developing Acceptable Air Quality Criteria"
In: 4th Annual Conference. **HAZTECH International.** Cincinnati, Ohio. September 13, 1989.

"The Underlying Basis of Risk Management Decisions"
In: 4th Annual Conference. **HAZTECH International.** Cincinnati, Ohio. September 12, 1989.

"Derivation of Risk Values by EPA"
Hazardous Materials Management Conference and Exhibition/Central. Rosemont, Illinois. March 15, 1989.

"The Reference Dose"
American Industrial Hygiene Association. Annual Toxicology Symposium. Williamsburg, Virginia. August 16, 1988.

"Reference Dose: Description and Use in Health Risk Assessments"
In: 54th Annual Meeting. **American Mosquito Control Association.** Denver, Colorado. February 2, 1988.

"Use of Uncertainty Factors for Reference Dose"

In: Workshop on the Use of the EPA Tools in State Risk Assessment. **National Governors' Association.** Copper Mountain, Colorado. May 4-6, 1988.

"Development of Oral Reference Doses"
In: Workshop on EPA's Integrated Risk Information System: Access, Use, and Interpretation. **U.S. Environmental Protection Agency.** Lexington, Massachusetts. July 22, 1987.

"The Systemic Toxicity of Air Pollutants: New Directions in Health Risk Assessment"
In: Session 100: Balanced Approach to Risk Assessment. Annual Meeting. **Air Pollution Control Association.** New York, New York. June 22, 1987.

"Safety Factors in Non-Carcinogenic Risk"
In: Workshop on Reducing Uncertainty in Risk Assessment. **Michigan State University.** East Lansing, Michigan. May 18, 1987.

"New Development in the Derivation and Application of Acceptable Daily Intake Values"
In: Workshop on Approaches to Ecological and Human Health Risk Analysis for Disposal of Contaminated Sediments and Human Consumption of Contaminated Seafood. **U.S. Environmental Protection Agency** and **U.S. Department of the Army**, Seattle, Washington. December 16, 1985.

"Human Health Assessment"
In: Workshop of Water Quality-Based Toxics Control. **U.S. Environmental Protection Agency**, Philadelphia, Pennsylvania. November 14, 1985.

"Systemic Health Hazard Assessment"
In: Workshop on Human Health Criteria. **U.S. Environmental Protection Agency**, Philadelphia, Pennsylvania. October 3, 1985.

"Novel Methods for the Estimation of Acceptable Daily Intake"
In: Course entitled "Risk Assessment 101." **U.S. Environmental Protection Agency**, Washington, D.C. February 19, 1985.

"Use of Risk Assessment to Set Safe Levels"
In: Conference on Emerging Issues in Environmental Analysis and Planning: Implication for Professional Education. **University of Cincinnati, U.S. Army Corps of Engineers** and the **U.S. Environmental Protection Agency.** Cincinnati, Ohio. April 12, 1985.

"Environmental Risk Assessment"
In: Course on Applied Toxicology. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. April 6, 1984.

"Toxicity Risk Assessment"
U.S. Environmental Protection Agency, Atlanta, Georgia. July 7, 1984.

"The Regulatory History and Experimental Support of Uncertainty (Safety) Factors"
In: Workshop on Toxic Air Pollution: A Regulatory Challenge. **State and Territorial Air Pollution Control Officials.** Washington, D.C. October 10-12, 1984.

"Traditional Means of Assessing the Safety of Non-carcinogens"
In: Symposium on Federal Regulation of Carcinogens. **American Chemical Society.** Washington, D.C. August 30, 1983.

"The U.S. Environmental Protection Agency Perspective of Qualitative Risk Assessment"

In: Course on Applied Toxicology. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. March 30, 1983.

"EPA Criteria Documents"
In: Fifth Annual Course in the Principles and Practices of Genetic Toxicology. Division of Environmental Toxicology. **University of Texas Medical Branch.** Galveston, Texas. 1980.

"Quantitative Considerations in Urethane Induced Neoplasia"
In: Toxicology Division Seminars Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. October 25, 1979.

"Some Quantitative Aspects of Chemical Carcinogenesis II"
In: Toxicology Division Seminar Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. February 2, 1979.

"Some Quantitative Aspects of Chemical Carcinogenesis I"
In: Toxicology Division Seminar Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. March 7, 1978.

"Computer Simulation Studies on Kehoe's Lead Data"
In: Toxicology Division Seminar Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. May 14, 1977.

"A New Approach to Minimum Toxic Dose"
In: Toxicology Division Seminar Series. **University of Cincinnati, College of Medicine.** Cincinnati, Ohio. February 25, 1976.

I also have given over 50 formal, but uninvited, presentations (e.g., abstracts at the scientific annual meetings).

RESEARCH: RISK ASSESSMENT PUBLICATIONS (Selected)

Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard. 2017. Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane. Regulatory Toxicology and Pharmacology 88:45-55.

Richard A. Becker, Vicki Dellarco, Jennifer Seed, Joel M. Kronenberg, Bette Meek, Jennifer Foreman, Christine Palermo, Chris Kirman, Igor Linkov, Rita Schoeny, *Michael Dourson*, Lynn H. Pottenger, and Mary K. Manibusan. 2017. Quantitative weight of evidence to assess confidence in potential modes of action. Regulatory Toxicology and Pharmacology, 86:205–220.

Michael Dourson and Raymond G York. 2016. Advances in Assessing Ingredient Safety. Regulatory Toxicology and Pharmacology. 79:S112-S118.

Michael Dourson, Bernard Gadagbui, Rod Thompson, Edward Pfau, and John Lowe. 2016. Managing Risks of Noncancer Health Effects at Hazardous Waste Sites: A Case Study Using the Reference Concentration (RfC) of Trichloroethylene (TCE). Regulatory Toxicology and Pharmacology 80:125-133.

Ted W. Simon, Yiliang Zhu, *Michael L. Dourson*, Nancy B. Beck. 2016. Bayesian methods for uncertainty factor application for derivation of reference values. Regulatory Toxicology and Pharmacology 80:9-24.

Dourson, Michael, Chinkin, Lyle, MacIntosh, D.L., Finn, Jennifer, Brown, Kathleen, Reid, Stephen, Martinez, Jeanelle. 2016. A Case Study of Potential Human Health Impacts from Petroleum Coke Transfer Facilities. Journal of the Air & Waste Management Association May. DOI: 10.1080/10962247.2016.1180328.

Nancy B. Beck, Richard A. Becker, Neeraja Erraguntla, William H. Farland, Roberta L. Grant, George Gray, Christopher Kirman, Judy S. LaKind, R. Jeffrey Lewis, Patricia Nance, Lynn H. Pottenger, Susan L. Santos, Stephanie Shirley, Ted Simon, *Michael L. Dourson*. 2016. Approaches for describing and communicating overall uncertainty in toxicity characterizations: U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS) as a case study. Environment International 89–90 (2016) 110–128. **(regulatory and safety evaluation paper of the year, Society of Toxicology, Regulatory and Safety Evaluation Specialty Section)**

Greenberg M, Goldstein BD, Anderson E, *Dourson M*, Landis W, North DW. 2015. Whither Risk Assessment: New Challenges and Opportunities a Third of a Century After the Red Book. Risk Analysis. 35(11): 1959-1968.

Nance, P., O. Kroner, L. Haber and *M. Dourson*. 2015. Assessing Risks to Human Health. In Reference Module in Biomedical Sciences (Online). In-Press.

Dankovic DA, Naumann BD, Maier A, *Dourson ML*, Levy LS. 2015. The Scientific Basis of Uncertainty Factors Used in Setting Occupational Exposure Limits. J Occup Environ Hyg. 2015 Nov 25:12 Suppl 1:55-68

Cope, Rhian B., Sam Kacew, *Michael Dourson*. 2015. A reproductive, developmental and neurobehavioral study following oral exposure of tetrabromobisphenol A on Sprague-Dawley rats. Toxicology 329 (2015) 49–59.

Dourson, M., Reichard, J., Nance, P., Burleigh-Flayer, H., Parker, A., Vincent, M., McConnell, E.E. 2014. Mode of action analysis for liver tumors from oral 1,4-dioxane exposures and evidence-based dose response assessment. Regul.Toxicol. Pharm. 68(3): 387-401.

Cope, R., Nance, P., *Dourson*, ML. 2014. "Chapter 4. Human Health Risk Assessment of Inhaled Materials." IN: Salem, H., Katz, S., eds. Inhalation Toxicology, 3rd Edition, CRC Press.

Juberg, D.R., Borghoff, S.J., Becker, R.A., Casey, W., Hartung, T., Holsapple, M.P., Marty, S.M., Mihaich, E.M., Van Der Kraak, G., Wade, M.G., Willett, C.E., Anderson, M.E., Borgert, C.J., Cody, K.K., *Dourson, M.L.*, Fowle, J.R., Gray, L.E. Lamb, J.C., Ortego, L.S., Schug, T.T., Toole, C.M., Zorrilla, L.M., Kroner, O.L., Patterson, J., Rinckel, L.A., Jones, B.R. 2014. Workshop Report, Lessons Learned, Challenges, and Opportunities: The US. Endocrine Disruptor Screening Program. ALTEX, ALTES. ALTES, 31:63-78, January. Workshop Report is now available via open access publication in ALTEX.

Rosen, JS; Whelton, AJ; McGuire, MJ; Clancy, JL; Bartrand, T; Eaton, A; Patterson, J; *Dourson, M*, Nance, P; Adams, C. 2014. The crude MCHM chemical spill in Charleston, W.Va. Journal AWWA. Vol. 106:65-74.

Patterson J., Maier A, Kohrman-Vincent M, and *ML Dourson*. 2013. Peer consultation on relationship between PAC profile and toxicity of petroleum substances. Reg. Tox and Pharm, Volume 67: S86–S93.

Dourson, M, Becker, R.A., Haber, L.T., Pottenger, L.H.,Bredfeldt, T., Fenner-Crisp, P. 2013. Advancing Human Health Risk Assessment: Integrating Recent Advisory Committee Recommendations. Crit. Rev. Toxicol. 43(6): 467-92 (doi: 10.3109/10408444.2013.807223).

Dourson, M., Gadagbui, B., Griffin, S., Garabrant, D.H., Haws, L.C., Kirman, C. and Tohyama, C. 2013. The importance of problem formulations in risk assessment: A case study involving dioxin-contaminated soil. Reg. Toxicol.Pharmcol. 66(2): 208-216.

Hasegawa R, Hirata-Koizumi M, *Dourson ML*, Parker A, Ono A, Hirose A. 2013. Safety assessment of boron by application of new uncertainty factors and their subdivision. Regul. Toxicol. Pharmacol. 65:1. 108-114.

Haber LT, JE Strawson, A Maier, IM Baskerville-Abraham, A Parker, *ML Dourson*. 2013. "Noncancer Risk Assessment: Principles and Practice in Environmental and Occupational Settings." In: Bingham, E., and B. Cohrssen, eds. *Patty's Toxicology, 6th Edition, Volume 5*. John Wiley and Sons Inc.

Meek, M.E., Bolger, M., Bus, J.S., Christopher, J., Conolly, R.B., Lewis, R.J., Paoli, G., Schoeny, R., Haber, L.T., Rosenstein A.B., *Dourson, M.L.* 2013. A Framework for Fit-for-Purpose Dose Response Assessment. Regul. Toxicol. Pharmacol. 66(2): 234-40 (doi: 10.1016/j.yrtph 2013.03.012.

Maier, A., Kohrman-Vincent, M., Hertzberg, R., *Dourson, M.*, Haber, L.T and Allen, B. 2012. Critical review of dose-response options for F344 rat mammary tumors for acrylamide – Additional insights based on mode of action. Food Chem. Toxicol. 50:5, 1763-1775.

Nance P, Patterson J, Willis A, Foronda N, *Dourson M*. 2012. Human Health Risks from Mercury Exposure from Broken Compact Fluorescent Lamps. Reg. Tox. Pharm: 62(3): 542–552.

Patterson J, Maier A, Kohrman-Vincent M, *Dourson ML*. 2012. Peer consultation on relationship between PAC profile and toxicity of petroleum substances. Regul. Toxicol. Pharmacol: pii: S0273-2300(12)00224-3.

Rider CV, *Dourson M*, Hertzberg RC, Mumtaz MM, Price PS, Simmons JE. 2012. Incorporating nonchemical stressors into cumulative risk assessments. Toxicol Sci: 127(1):10-7.

Rhomberg LR, JE Goodman, LT Haber, *M Dourson*, ME Andersen, JE Klaunig, B Meek, PS Price, RO McClellan, SM Cohen. 2011. Linear low-dose extrapolation for noncancer health effects is the exception, not the rule. Critical Reviews in Toxicology: 41(1): 1-19.

Dourson, M and Haber, L.. 2010. Linear Low-Dose Extrapolation. In: Cancer Risk Assessment. Ching-Hung Hsu and Todd Stedeford, ed. John Wiley &Sons.

Dourson, M.L., M.J. Kohrman-Vincent, B.C. Allen and W.S. Cain. 2010. Dose Response Assessment from Effects of Acute Exposure to Methyl Isothiocyanate (MITC). Reg. Toxicol. Pharmacol: 58(2): 181-188. Available on line.

Dourson, M. 2010. U-Shaped Dose-response Curves: Implications for Risk Characterization of Essential Elements and Other Chemicals. J. of Tox. and Env. Health, Part A, 73 (2), 181-186.

Cain, W., *M. L. Dourson*, M.J. Kohrman-Vincent and B.C. Allen. 2010. Human Chemosensory Perception of Methyl Isothiocyanage: Odor and Chemesthesi. Reg. Toxicol. And Pharmacol: 58(2): 173-180. Available online.

Chambers A, Krewski D, Birkett N, Plunkett L, Hertzberg R, Danzeisen R, Aggett PJ, Starr TB, Baker S, *Dourson M*, Jones P, Keen CL, Meek B, Schoeny R, Slob W. 2010. An exposure-response curve for copper excess and deficiency. J Toxicol Environ Health B Crit Rev. 2010 Oct;13(7-8): 546-78.

Gadagbui, B; Maier, *M; Dourson*, M; Parker, A; Willis, A; Christopher, JP; Hicks, L; Ramasany, S; Roberts, SM. 2010. Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation. Regulatory Toxicology and Pharmacology 57:220-234.

Hasegawa R, HK Mutsuko, *ML Dourson*, A Parker, LM Sweeney, A Nishikawa, M Yoshida, A Ono, A Hirose. 2010. Proposal of new uncertainty factor application to derive tolerable daily intake. Regul. Toxicol. Pharmacol. 58(2): 237-242.

Nance, P., Kroner, O., Haber, L. and *Dourson, M.* 2010. Assessing Risks to Human Health. In: The Occupational Environment: Its Evaluation, Control and Management. 3rd Ed., AIHA Press, D. Anna, ed.

Zhao, Q.J., Haber, L., Kohrman-Vincent, M., Nance, P., *Dourson, M.* 2010. Quantitative modeling in noncancer risk assessment. In: Quantitative Modeling in Toxicology, John Wiley, K. Krishnan and M.E. Anderson, ed.

Dourson, M., Hertzberg, R., Allen, B., Haber, L., Parker, A., Kroner, O., Maier, A. and Kohrman, M. 2008. Evidence-Based Dose Response Assessment for Thyroid Tumorigenesis from Acrylamide. Regulatory Toxicology and Pharmacology 52 (2008) 264–289.

Wullenweber, A; Kroner, O; Kohrman, M; Maier, A; *Dourson, M*; Rak, A; Wexler, P; Tomljanovic, C. 2008. Resources for global risk assessment: The International Toxicity Estimates for Risk (*ITER*) and Risk Information Exchange (RiskIE) databases. Toxicol. Appl. Pharmacol. 233: 45–53.

Hays, SM; Aylward, LL; LaKind, JS; Bartels, MJ; Barton, HA; Boogaard, PJ; Brunk, C; DiZio, S; *Dourson, M*; Goldstein, DA; Lipscomb, J; Kilpatrick, ME; Krewski, D; Krishnan, K; Nordberg, M; Okino, M; Tan, YM; Viau, C; Yager, JW. 2008. Guidelines for the derivation of Biomonitoring Equivalents: report from the Biomonitoring Equivalents Expert Workshop. Regul Toxicol Pharmacol. 51(3 Suppl):S4-15.

Dourson, M.L. and Parker, A. 2007. Past and Future Use of Default Assumptions and Uncertainty Factors: Default Assumptions, Misunderstandings, and New Concepts. Hum Ecol Risk Assess. 13(1):82-88.

Hasegawa R, Hirata-Koizumi M, *Dourson M*, Parker A, Hirose A, Nakai S, Kamata E, Ema M. 2007. Pediatric susceptibility to 18 industrial chemicals: A comparative analysis of newborn with

young animals. Regul Toxicol Pharmacol. 47(3):296-307. **(Risk assessment paper of the year, Society of Toxicology, Risk Assessment Specialty Section)**

Stedeford T, Zhor J, *Dourson ML*, Banasik M, Hsu CH. 2007. The Application of Non-Default Uncertainty Factors in the U.S. EPA's Integrated Risk Information System (IRIS). Part I: UF(L), UF(S), and "Other Uncertainty Factors". J Environ Sci Health C Environ Carcinog Ecotoxicol Rev. 25(3):245-79.

Stern, B.R., M. Solioz, D. Krewski, P. Aggett, T-C Aw, S. Baker, K. Crump, *M. Dourson*, L. Haber, R. Hertzberg, C.L. Keen, B. Meek, L. Rudenko, R. Schoeny, W. Slout, T. Starr. 2007. Copper and Human Health: Biochemistry, Genetics and Strategies for Modeling Dose-Response Relationships. J. Toxicol. and Environ. Health, Part B. 10(3):157-222.

Dourson, M and D. Drinan. 2006. Sensitive Populations and Risk Assessment. In: *Toxicokinetics in Risk Assessment*. Taylor and Francis Publishers. J.C. Lipscomb and E.V. Ohanian, Eds. Informa health care, New York. Pp. 251-210.

Gadagbui, B.K., L.T. Haber and *M.L. Dourson*. 2006. Chemical Risk Assessment as Used in Setting Regulatory Levels or Standards. Chap. 3.3.1 in Transforming Sustainability Strategy into Action: The Chemical Industry, edited by Beth Beloff, Marianne Lines, and Dicksen Tanzil. Hoboken , NJ : John Wiley & Sons, Inc.

Schoeny, R., L. Haber, and *M. Dourson*. 2006. Data considerations for regulation of water contaminants. Toxicology. 221 (2-3): 217-224.

Zhao, Qiyu , *M. Dourson* and B. Gadagbui. 2006. A Review of the Reference Dose (RfD) for Chlorpyrifos. Reg. Toxicol. Pharmacol. 44:111-124.

Dolan, D., B. Naumann, E. Sargent, A. Maier, *M. Dourson*. 2005. Application of the threshold of toxicological concern concept to pharmaceutical manufacturing operations. Reg. Toxicol. Pharmacol. 43:1-9.

Fields, C., *M.L. Dourson*, And J. Borak. 2005. Iodine-deficient vegetarians: A hypothetical perchlorate-susceptible population? Reg. Tox. Pharmacol. 42(1):37-46.

Lakind, Judy, Robert Brent, *Michael Dourson*, Sam Kacew, Gideon Koren, Babasaheb Sonawane, Anita Tarzian, Kathleen Uhl. 2005. Human Milk Biomonitoring Data: Interpretation and Risk Assessment Issues. Journal of Toxicology and Environmental Health, vol. 68, no. 20.

Zhao, Q., B. Gadagbui and *M. Dourson*. 2005. Lower birth weight as a critical effect of Chlorpyrifos: A comparison of human and animal data. Reg. Toxicol. Pharmacol. 42:55-63.

Dourson, M., G. Charnley, R. Scheuplein and M. Barkhurst. 2004. Chemicals and Drugs Risk Assessment: Differential Sensitivity of Children and Adults to Chemical Toxicity. Human and Ecol. Risk Assessment. 10:21-27.

Zhao, Q; Kan, H; Haber, L; Chen, B; *Dourson, M.* 2004. Advance in Dose-Response Analysis. Chinese J. Pharmacology and Toxicology. 18:152-160. Chinese edition.

Patterson, J., P.J. Hakkinen, P.M. Nance, *M.L. Dourson*, B.J. Klauenberg. 2004. Riot Control Agents: Issues in Toxicology, Safety, and Health by Eugene J. Olajos (Editor). W. Stopford (Editor). Chapter 13: An Approach for Assessing and Characterizing Risk from Use of Riot Control Agents. Pages 259-271.

Strawson, J., Q. Zhao and *M. Dourson*. 2004. Reference Dose for Perchlorate based on Thyroid Hormone Change in Pregnant Women as the Critical Effect. Reg. Tox. and Pharm. 39:44-65.

Zhao, Q., K. Hai-Dong, L. Haber, C. Bing-Heng and *M. Dourson*. 2004. Recent Development in Chemical Risk Assessment. Chin. J. Pharmacol. Toxicol. 18(2):152-160.

Dourson, M. and J. Patterson. 2003. A 20-Year Perspective on the Development of Non-Cancer Risk Assessment Methods. Special Issue of the Journal of Human and Ecological Risk Assessment Commemorating 20th Anniversary of the NRC's Red Book on Risk Assessment and Risk Management. Human and Ecological Risk Assessment. 9:1239-1252.

Dourson, M. and Maged Younes. 2002. Evolution In Noncancer Risk Assessment - Current Practice, Controversies, And Challenges. Comments On Toxicology. 7(5-6):399-414.

Dourson, M.L., G. Charnley and R. Scheuplein. 2002. Differential Sensitivity Of Children And Adults To Chemical Toxicity: II. Risk And Regulation. Regulatory Toxicology and Pharmacology. 35:448-467.

Elder, L., K. Poirier, *M. Dourson*, J. Kleiner, B. Mileson, H. Nordmann, A. Renwick, W. Slob, K. Walton and G. Wurtzen. 2002. Mathematical Modeling and Quantitative Methods. Food and Chemical Toxicology. 40:283-326.

Haber, L.T., A. Maier, P.R. Gentry, H.J. Clewell and *M.L. Dourson*. 2002. Genetic Polymorphisms In Assessing Interindividual Variability In Delivered Dose. Regulatory Toxicology and Pharmacology. 35:177-197.

Scheuplein, R., G. Charnley and *M.L. Dourson*. 2002. Differential Sensitivity Of Children and Adults To Chemical Toxicity: I. Biological Basis. Regulatory Toxicology and Pharmacology. 35: 429-447.

Anderson P.A., *M. Dourson*, J. Unrine, J. Sheeshka, E. Murkin, and J. Stober. 2002. Framework and case studies. In: Special issue. Comparative dietary risk: Balance the risk and benefits of fish consumption. Comments on Toxicology. 8(4-6):431-502. July-December.

Dourson M., P. Price, and J. Unrine. 2002. Health risks from eating contaminated fish. In: Special issue. Comparative dietary risk: Balance the risk and benefits of fish consumption. Comments on Toxicology. 8(4-6):399-420. July-December.

Dourson, M.L., A.E. Wullenweber, Kenneth A. Poirier. 2001. Uncertainties in the Reference Dose for Methylmercury. NeuroToxicology. 22 (5) pp. 677-689.

Dourson, M., M. Andersen, L. Erdreich and J. Macgregor. 2001. Using Human Data to Protect the Public's Health. Reg. Toxicol. Pharmacol. Vol. 33, No. 2, Apr 2001, pp. 234-256.

Haber, L.T., A. Maier, Q. Zhao, J.S. Dollarhide, R.E. Savage and *M.L. Dourson*. 2001. Applications of Mechanistic Data in Risk Assessment -- The Past, Present, and Future. Toxicological Sciences. 61:32-39.

Haber, L.T., Dollarhide, J.S., Maier, A., and *Dourson, M.L.* 2001. Noncancer Risk Assessment: Principles and Practice in Environmental and Occupational Settings. In: Patty's Toxicology, Fifth edition. Bingham, E., Cohrssen, and C.H. Powell, ed. Wiley and Sons, Inc.

Meek, B., A. Renwick, E. Ohanian, *M. Dourson*, B. Lake, B. Naumann and V. Vu. 2001. Guidelines For Application Of Compound Specific Adjustment Factors (CSAF) In Dose/Concentration Response Assessment. Comments On Toxicology. 7(5-6):575-590.

Haber, L.T., L. Erdreich, G.L. Diamond, A.M. Maier, R. Ratney, Q. Zhao and *M.L. Dourson*. 2000. Hazard Identification And Dose-Response Of Inhaled Nickel Soluble Salts. Reg. Tox. Pharmacol. 31:210-230.

Haber, L.T., G.L. Diamond, G.L. Q. Zhao, L. Erdreich and *M. L. Dourson*. 2000. Hazard Identification And Dose-Response Of Ingested Nickel Soluble Salts. Reg. Tox. Pharmacol. 31:231-241.

Lakind, J.S., M.E. Ginevan, D.Q. Naiman, A.C. James, R.A. Jenkins, *M.L. Dourson*, S.P. Felter, C.G. Graves and R.G. Tardiff. 1999. Distribution of Exposure Concentrations and Doses for Constituents of Environmental Tobacco Smoke. In: Risk Analysis. 19(3):375-390.

Teuschler, L.K., *M.L. Dourson*, W.M. Stiteler, P. Meclure and H. Tully. 1999. Health risk above the reference dose for multiple chemicals. Reg. Toxicol. And Pharmacol. 30:S19-S26.

Zhao, Q., J. Unrine and *M. Dourson*. 1999. Replacing the Default Values Of 10 With Data-Derived Values: A Comparison of Two Different Data Derived Uncertainty Factors for Boron. Human and Ecological Risk Assessment. 5(5):973-983.

Dourson, M.L., A. Maier, B. Meek, A Renwick, E. Ohanian and K. Poirier. 1998. Re-evaluation of toxicokinetics for data-derived uncertainty factors. Biological Trace Element research. 66(1-3): 453-463.

Felter, S.P. and *M. Dourson*. 1998. The Inexact Science of Risk Assessment (and Implications for Risk Management). Human and Ecol. Risk Assessment. 2:245-251.

Swartout, J., P. Price, *M. Dourson*, H. Carlson-Lynch and R. Keenan. 1998. A Probabilistic Framework for the Reference Dose. Risk Analysis. 18(3):271-282.

Dourson, M.L., L.K. Teuschler, P.R. Durkin, and W.M. Stiteler. 1997. Categorical Regression of Toxicity Data: A Case Study using Aldicarb. Reg. Toxicol. Pharmacol. 25:121-129.

Dourson, M.L. and S.P. Felter. 1997. Route-to-route extrapolation of the toxic potency of MTBE. Risk Anal. 25:43-57.

Boyes, W.K., *M.L. Dourson*, J. Patterson, H.A. Tilson, W.F. Sette, R.C. Macphail, A.A. Li and J.L. O'Donoghue. 1997. Fund and Applied Toxicology. EPA's Neurotoxicity Risk Assessment Guidelines. 40 (2): pp.175-184.

Felter, S.P., *M. Dourson* and J. Patterson. 1997. Chapter 2: Assessing Risks to Human Health from Chemicals in the Environment. In: Handbook of Environmental Risk Assessment & Management. P. Calow, Ed. Blackwell Science. Oxford. 9 - 23.

Felter, S.P. and *M.L. Dourson*. 1997. Hexavalent Chromium Contaminated Soils: Options for Risk Assessment and Risk Management. Reg. Tox. Pharmacol. 25:43-59.

Price, P., R. Keenan, J. Swartout, C. Gillis, H. Carlson-Lynch and *M. Dourson*. 1997. An Approach for Modeling Noncancer Dose Responses with an Emphasis on Uncertainty. Risk Anal. 17 (4):427-437. **(Risk assessment paper of the year, Society of Toxicology, Risk Assessment Specialty Section)**

Dourson, M.L., S.P. Felter, and D. Robinson. 1996. Evolution of science-based uncertainty factors in noncancer risk assessment. Regulatory Toxicol. Pharmacol. 24:108-120.

Ciemanec, J.L., *M.L. Dourson* and R.C. Hertzberg. 1996. Noncancer risk assessment: Present and emerging issues. In: Toxicology and risk assessment: Principles, methods, and applications. A.M. Fan and L.W. Chang (editors). Marcel Dekker. New York. New York. Pages 293-309.

Dourson, M.L. and F.C. Lu. 1995. Safety/Risk assessment of chemicals compared for different expert groups. Biomedical and Environmental Sciences. 8:1-13.

Dourson, M.L., 1994. Methodology for Establishing Oral Reference Doses (RfDs). In: Risk Assessment of Essential Elements. W. Mertz, C.O. Abernathy, and S.S. Olin (editors). ILSI Press Washington, D.C. Pages 51-61.

Abernathy, C.O. and *M.L. Dourson*. 1994. Derivation of the Inorganic Arsenic Reference Dose. In: Arsenic Exposure and Health. W.R. Chappell, C.O. Abernathy and C.R. Cothern (eds.). Science and Technology Letters, Northwood, England. Pages: 295-303.

Dourson, M.L., 1993. The Chromium Reference Doses (RfDs). In: Risk Assessment of Essential Elements. W. Mertz, C.O. Abernathy, and S.S. Olin (editors). ILSI Press. Washington, D.C. Pages 207-212.

Beck, B.D., R.B. Conolly, *M.L. Dourson*, D. Guth, D. Hattis, C. Kimmel, and S.C. Lewis. 1993. Improvements in quantitative noncancer risk assessment. Fundamental and Applied Tox. 20:1-14.

Hertzberg, R.C. and *M.L. Dourson*. 1993. Using categorical regression instead of a NOAEL to characterize a toxicologist's judgment in noncancer risk assessment. In: Toxicology of Chemical Mixtures: Case Studies, Mechanisms, and Novel Approaches. R.S.H. Yang (editor). Academic Press, San Diego.

Dourson, M.L., Knauf, L.A. and J.C. Swartout. 1992. On reference dose (RfD) and its Underlying Toxicity Database. Toxicology and Industrial Health. 8(3):171-189.

Farland, W. and *M.L. Dourson*. 1992. Noncancer health endpoints: Approaches to quantitative risk assessment. In: Comparative Environmental Risk Assessment. R. Cothern (Editor). Lewis Publishers, Boca Raton, Florida. Pages 87-106.

Lu, F.C. and *M. L. Dourson.* 1992. Safety/Risk assessment of chemicals "Principles, Procedures and Examples. J. Occupational Medicine and Toxicology. 1(4):321-335.

Dourson, M.L., Stern, B., Griffin, S., and K. Bailey. 1991. Impact of Risk-related Concerns on U.S. Environmental Protection Agency Programs. In: Proceedings from Advanced Research Workshop on nitrate contamination: exposure, consequences and control. I. Bogardi and R.D. Kuzelka (editors), North Atlantic Treaty Organization (NATO) ASI Series, Vol. G 30, Springer-Verlag, Berlin, Heidelberg. Pages: 477-487.

Dourson, M.L. and C.T. DeRosa. 1991. Uncertainty Factors in Establishing "Safe" Levels of Exposure. In: Statistics in Toxicology, Krewski and Franklin (editors), Gordon and Breach Science Publishers, New York.

Dourson M.L. 1991. Overview of EPA's Quantitative Noncancer Guidelines. In: Proceedings of the 84th Annual Meeting and Exhibition. Air and Waste Management Association, Vancouver, British Columbia. June 16-21.

Dourson, M.L. and J.M. Clark. 1990. Fish consumption advisories: Towards a Unified, Scientifically-credible Approach. Regulatory Toxicology and Pharmacology. 12:161-178.

Jarabek, A.M., Menache, M.G., Overton, J.H., *Dourson, M.L.*, and F.J. Miller. 1990. The U.S. Environmental Protection Agency's Inhalation RfD Methodology: Risk Assessment for Air Toxics. Toxicology and Industrial Health. 6(5):279-301.

DeRosa, C.T., *Dourson, M.L.*, and R. Osborne. 1989. Risk Assessment Initiatives for Noncancer Endpoints: Implications for Risk Characterization of Chemical Mixtures. Toxicology and Industrial Health. 5:805-824.

Jarabek, A.M., Menache, M.G., Overton, J.H., *Dourson, M.L.*, and F.J. Miller. 1989. Inhalation reference dose (RfDi): An application of interspecies dosimetry modeling for risk assessment of insoluble particles. Health Physics. 57:177-183.

Barnes, D.G., and *M.L. Dourson.* 1988. Reference Dose (RfD): Description and use in health risk assessments. Regulatory Toxicology and Pharmacology. 8:471-486.

Jarabek, A.M., *Dourson, M.L.*, and L.E. Erdreich. 1987. Inhalation reference dose (RfDi): Concept and issues related to risk assessment of toxic air pollutants. In: Proceedings of the APCA Specialty Conference on Regulatory Approaches for Control of Air Pollutants, February 17-20. Atlanta, Georgia. Pages 247-261.

Stara, J.F., R.J.F. Bruins, *M.L. Dourson*, L.S. Erdreich, R.C. Hertzberg, P.R. Durkin and W.E. Pepelko. 1987. Risk assessment is a developing science: Approaches to improve evaluation of single chemicals and chemical mixtures. In: Methods for Assessing the Effects of Mixtures of Chemicals. V.B. Vouk, G.C. Butler, A.C. Upton, D.V. Parke and S.C. Asher, Ed. 1987. SCOPE. pp 719-743.

Dourson, M. L., 1986. New approaches in the derivation of acceptable daily intake (ADI). Comments on Toxicology. 1(1):35-48.

Dourson, M. L., R. C. Hertzberg, R. Hartung, and K. Blackburn, 1985. Novel Methods for the Estimation of Acceptable Daily Intake. Toxicology and Industrial Health. 1(4):23-41.

Stara, J.F., Hertzberg, R.C., Bruins, R.J.F., *Dourson, M.L.*, Durkin, R.P., Erdreich, L.S. and W.E. Pepelko. 1985. Approaches to risk assessments of chemical mixtures. In: Karger Continuing Education Series Vol. 8: Safety Regulation of Chemicals in the U.S.A., S. Karger AG, Basel.

Dourson, M. L. and J. F. Stara. 1983. Regulatory History and Experimental Support of Uncertainty Safety) Factors. Regulatory Toxicology and Pharmacology, 3:224-238.

Lee, S. D., *M. L. Dourson*, D. Mukerjee, J. F. Stara and J. Kaweki. 1983. Assessment of Benzene Health Effects in Ambient Water. In: Carcinogenicity and Toxicity of Benzene, M.A. Mehlman (Editor), Princeton Scientific Publisher, Inc. Princeton, NJ. Pages 91-126.

Stara, J. F., D. Mukerjee, R. McGaughy, P. Durkin and *M. L. Dourson*, 1983. The Current Use of Studies on Promoters and Co-carcinogens in Quantitative Risk Assessment. Environmental Health Perspectives. 50:359-368.

Dourson, M. L. and E. J. O'Flaherty. 1982. Relationship of Lung Adenoma Prevalence and Growth Rate to Acute Urethane Dose and Target Cell Number. Journal of the National Cancer Institute. 69(4):851-857.

O'Flaherty, E. J. and *M. L. Dourson*. 1982. Relationship between Urethane Dose Rate and Adenoma Latency: Relevance of tumor growth rate and target cell number. Journal of the National Cancer Institute. 69(4):859-865.

Stara, J. F., *M. L. Dourson* and C. T. DeRosa. 1981. Water Quality Criteria: methodology and applications. In: Conference Proceedings in Environmental Risk Assessment: How New Regulations Will Affect the Utility Industry, Electric Power Research Institute, Palo Alto, California.

Dourson, M. L. and C. S. Baxter. 1981. Reduced incidence and growth rate of urethane induced lung adenomas in aging adult strain A mice. Toxicology, 20:165-172.

Manson, J. M., *M. L. Dourson* and C. C. Smith. 1977. Effects of Cytosine Arabinoside on *in vivo* and *in vitro* Mouse Limb Development. In Vitro. 13(7):434.

I have also co-authored well over 100 documents for the EPA, TERA and others that address either risk assessments for specific chemicals, or risk assessment methods, and have additional published manuscripts that are not listed here. I have also written three stories on integrating science and Biblical text: *Messiah's Star*, *The Beginning*, and *The Linen Cloths*.

RESEARCH: COMMENTARIES (Selected)

Thomas G. Osimitz, *Michael L. Dourson*, A. Wallace Hayes, and Sam Kacew. 2014. Crystallographic Analysis and Mimicking of Estradiol Binding: Interpretation and Speculation. Environmental Health Perspectives. Volume 122 (number 4), April 2014, page A 91.

Gail Charnley, Thomas Cluderay, *Michael Dourson*, George Gray, Tom Roberts. The Perchlorate Debate: Is the Chemical Worth Regulating. 2011. The Environmental Forum. Nov/Dec. Vol. 28(6), page 46-53.

Haber, L., Maier, A., and *Dourson, M.* 2006. Using Best Science in Cancer Risk Assessment, Editorial. Hum Ecol Risk Assess 12(1):1-8.

Strawson, J., *M. Dourson*, Q. Zhao. 2005. The NAS Perchlorate Review: Is the RfD Acceptable? 2005. Env. Health Perspect 113(11):A729-30; Nov. Author reply A730-2.

Naumann, B., B. Meek, *M.L. Dourson*, and E. Ohanian. 2005. The Future of Chemical Specific Adjustment Factors in Risk Assessment. Risk Policy Report. 12(31):14.

Strawson, J., Q. Zhao and *M. Dourson*. 2004. Response to Letter to the Editor. "Critical Effect of Perchlorate on Neonates is Iodide Uptake Inhibition". Reg. Tox Pharmacol. 40:378-379.

Dourson, M.L. 1996. Editorial: Uncertainty Factors in Noncancer Risk Assessment. Reg. Tox. and Pharmacol. 24, Article No. 0115, p. 107.

Dourson, M.L. 1995. How Regulatory Agencies View Biological Effects of Low Level Exposures. BELLE Newsletter. 4(1):7.

Dourson, M.L. and W. Jordan, 1989. How "Safe" Is the Groundwater that Americans Drink? Ground Water Monitoring Review, Fall Issue. 9:73-74.

Dourson, M. L., R. C. Hertzberg and J. F. Stara. 1986. Letters to the Editor. Fundamental and Applied Toxicology. 6:182-184.

O'Flaherty, E. J. and *M. L. Dourson*, 1983. A Reply to Letter to the Editor "Cells of Origin of Lung Tumors in Mice. Journal of the National Cancer Institute. 70(6):991-992.

SERVICE: SCIENTIFIC SESSIONS CHAIRED OR PLANNED (Selected)

Chair: Well Over 100 Risk Assessment Peer Review Meetings
Since 1986, and to the present, I have chaired well over 100 scientific peer review meetings for risk assessment documents. Documents have covered a number of topics including risk assessment methods and assessments including cancer and non-cancer toxicity. These meetings have been sponsored by a number of organizations through either Toxicology Excellence for Risk Assessment's (*TERA*) program of the International Toxicity Estimates for Risk (*ITER*) database (for examples, please see www.tera.org/peer), by EPA through its IRIS database (see www.epa.gov/iris), or by groups such as Versar. These reviews have discussed well over 400 chemicals or risk issues.

Chair: Tox21: Current Progress, Next Steps and Exploring the Concept of a New Center of Excellence
Society of Toxicology, Baltimore, Maryland. March 12, 2017.

Co-chair: Low-Dose Non-Monotonic Responses
Society of Toxicology, Baltimore, Maryland. March 14, 2017.

Chair: Endocrine Disruption: Research, Analysis, Regulation, & Communication
Society of Toxicology, New Orleans, Louisiana, March 14, 2016.

Chair: Derived No-Effect Levels+ Big Data Toxicology Meeting
Society of Toxicology, New Orleans, Louisiana, March 13, 2016.

Moderator: Can/Should peer-reviewed publications be used to formulate regulatory policy?
Society of Toxicology. San Diego, California. March 23, 2015.

Chair: Beyond Science and Decisions: From Problem Formulation to Dose Response
Alliance for Risk Assessment. Cincinnati, Ohio. May 9-11, 2015.

Facilitator: Integration of Scientific Evidence to Inform Ozone Effects on Human Health
Texas Commission on Environmental Quality. Austin, Texas. April 8, 2015.

Chair: TTC Threshold Levels & TTC Decision Tree
EFSA/WHO workshop on Threshold of Toxicological Concern (TTC). Brussels, Belgium. December 3-5, 2014.

Chair: Chemical Assessment Advisory Committee for Ammonia
U.S. Environmental Protection Agency (EPA). Washington, D.C. July 14-16, 2014.

Chair: Beyond Science and Decisions: From Problem Formulation to Dose Response
Alliance for Risk Assessment. Austin, Texas. May 20-22, 2014.

Chair: Expert Panel Review of Screening Levels for Exposure to Chemicals From the January 2014 Elk River Spill
West Virginia Testing Assessment Project. Charleston, West Virginia. March 31, 2014.

Chair: Workshop to Assess the Modes of Action of Lung Tumors in Mice From Exposures to Styrene Ethylbenzene, and Naphthalene
Styrene Information & Research Center. Cincinnati, Ohio. September 17, 2013.

Chair: Melding Exposure and Toxicology Science I the 21st Century: Moving from Hazard to a Risk Based Paradigm
The Toxicology Forum. Aspen, Colorado. July 7-11, 2013.

Co-chair: Advancing Risk Assessment Approaches...*in the 21st Century*
The Toxicology Forum. Washington, DC. January 30-Feb. 2, 2012.

Rapporteur: Weight of Evidence Workshop, Session #1: From Review to Inference
Center for Advancing Risk Assessment Science and Policy (ARASP). Washington, DC. December 4, 2012.

Chair: Soil Exposure: What Have We Learned and How Do We Improve Problem Formulations for Risk Assessment
The Toxicology Forum. Aspen, Colorado. July 10-14, 2011.

Co-Chair: Determination of the Contribution of Individual Stressors in Cumulative Risk Assessments
Society of Toxicology Annual Meeting. Salt Lake City, Utah. March 6-12, 2010.

Chair: Fetal and Early-Life Perchlorate Exposures and Outcomes
Symposium. Perchlorate Exposures, Iodine Modulation of Effect, and Epidemiologic Associations: Implications for Risk Assessment. An Ancillary Program of the Annual Meeting of the Society of Toxicology. Seattle, Washington. March 2008.

Chair: Perchloroethylene (PERC): Approaches To Evaluating Uncertainty In Health Risk Assessment
Toxicology Forum. Washington D.C. January 30-February 1, 2007.

Chair: Mechanism/Mode Of Action Analyses
Risk Assessment Methodology Technical Committee. Weight of Evidence Workshop. Health and Environmental Sciences Institute. Baltimore, Maryland. December 7-8, 2006.

Session Planner and Chair: Issues In Trichloroethylene Risk Assessment
Midwest States Risk Assessment Symposium. Indianapolis, Indiana. August 23, 2006.

Session Planner and Chair: Panel Discussion On Trichloroethylene Toxicity
Midwest States Risk Assessment Symposium. Indianapolis, Indiana. August 25, 2004.

Chair: Screening Level Assessment Of Exposure And Characterization Of Risk For Humans
Risk Methodologies External Peer Review Panel Meeting. The Soap and Detergent Association. Washington, D.C., January 14, 2004.

Chair: A Review of the Reference Dose (RfD) and Reference Concentration (RfC) Processes
External Peer Review for U.S. EPA via Versar. Washington, D.C., June 19, 2002.

Session Planner and Co-Chair: Modeling of Population Variability
Society of Toxicology. Nashville, TN., Tuesday, March 19, 2002.

Co-Chaired Methyl Mercury: Risk Assessment, Policy and Research Needs
Children's Health and the Environment 2000. 19th International Neurotoxicology Conference. Colorado Springs, Colorado, September 26, 2000.

Session Planner and Co-Chair: Effective Risk Communication: Avoiding the Pitfalls
Continuing Education Course at the Society of Toxicology Annual Meeting. Seattle, Washington. March 1, 1998.

Lead: Panel Discussion on Information Resources for Toxicology and Environmental Health
Society of Toxicology, NCAC. George Washington University. Washington, DC, June 18, 1996.

Moderator: Workshop on Toxicity Assessment
At Harmonization of State/Federal Approaches at the Environmental Risk Symposium. Michigan State University. May 20-21, 1996.

Chair: Session on Risk Assessment
Chromium Symposium. Multiple Sponsors. Arlington, Virginia. April 23-24, 1996.

Session Planner and Co-Chair: Risk Assessment of Essential Trace Elements (ETES)
Society of Toxicology Annual Meeting. Anaheim, California. March 13, 1996.

Session Planner and Chair: Risk Characterization
In: New Techniques in Risk Assessment. International Business Communication. Orlando, Florida, February 16, 1996.

Session Planner and Chair: EPA's Integrated Risk Information System: Future Directions
In: New Techniques in Risk Assessment. International Business Communication. Orlando, Florida, February 14, 1996.

Session Planner and Co-Chair: Role of Toxicology in Tomorrow's Risk Assessment Practices
Sponsored by the Society for Risk Analysis and the International Congress of Toxicology. Seattle, July 2-6, 1995.

Session Planner and Chair: Techniques for Quantifying Uncertainty in Risk Assessment
Society of Toxicology Annual Meeting, March 19, 1995.

Session Planner and Co-Chair: Statistical and Dose Response Models in Risk Assessment
Society of Toxicology Annual Meeting, March 18, 1995.

Member of the Planning Committee: Workshop on Benchmark Dose Methodology
Sponsored by the EPA, the American Industrial Health Council and the International Life Sciences Institute, Fairfax, Virginia, September 28-30, 1993.

Session Planner and Co-Chair: Basics of Risk Assessment
In: Conference on the Risk Assessment Paradigm after Ten Years: Policy and Practice Then, Now, and in the Future. Sponsored by the U.S. Army, Air Force, Navy and EPA, Dayton, Ohio, April 5, 1993.

Session Planner and Co-Chair: Basic Risk Assessment: Current Developments
Continuing Education Course at the Society of Toxicology Annual Meeting, New Orleans, Louisiana, March 14, 1993.

Member of the Planning Committee: Risk Assessment of Essential Elements
Sponsored by U.S. ATSDR, EPA and the International Life Sciences Institute. Herndon, Virginia, March 10-12, 1992.

Session Planner and Co-Chair: Improvements in Quantitative Noncancer Risk Assessment
Society of Toxicology, Seattle, Washington. February 27, 1992.

Session Planner and Co-Chair: Neurotoxicity Risk Assessment: State of the Art
Society of Toxicology, Dallas, Texas. March 1, 1991.

Session Planner and Co-Chair: Improvements in Quantitative Noncancer Risk Assessment
Society of Toxicology. San Francisco, California, February 27, 1985.

SERVICE: APPOINTMENTS OR ELECTIONS (Selected)

2017 to… **Associate Editor**
Toxicological Sciences

2011-17 **Member**
Science Advisory Board of the U.S. Environmental Protection Agency (EPA)

2009 to… **Fellow**
Society for Risk Analysis

2007 to… **Advisor**
African Society of Toxicological Sciences

2007 to… **Fellow**

Academy of Toxicological Sciences

1999 to… **Member and Vice Chair (2003)**
Health Advisory Board. NSF International

1995 to… **Member**
Editorial Board of the Journal "Regulatory Toxicology and Pharmacology"

1994 to… **Member**
Editorial Board of the Journal "Human and Experimental Toxicology"

2016 to 2017 **Secretary**
Board of Directors, Toxicology Forum

2014 to 2017 **Vice President Elect, Vice President, President**
Society of Toxicology's Specialty Section for Regulatory and Safety Evaluation

2012 to 2017 **President and Member**
Board of Directors, Toxicology Education Foundation

2012 to 2017 **Member**
Science Advisory Council. North American Flame Retardant Association

2016 **Member**
Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR)

2015 **Discussant**
Increasing the manganese reference value despite the growing environmental and health concerns, International Manganese Institute, University of Ottawa, October 14, 2015

2015 **Member**
Joint Meeting of the Food and Agriculture Organization of the United Nations (FAO) Panel of Experts on Pesticide Residues in Food and the Environment and the World Health Organization (WHO) Core Assessment Group on Pesticide Residues (JMPR)

2014 **Member**
World Health Organization & European Food Safety Commission Expert Panel. Workshop on Review of the Threshold of Toxicological Concern (TTC) Approach. Brussels, Belgium. December 2-4, 2014.

2011-2014 **Member, Co-Chair, Chair**
Membership Committee of the Society of Toxicology

2010-2015 **Chair**
Audit Committee of the Society for Risk Analysis

2010 **Faculty**

Resource person to the Risk Assessment Summer School (RASS) in Calabar, Nigeria, sponsored by the International Union of Toxicology, May 26 to 30

2009-2011 **Vice President Elect, Vice President, President**
Society of Toxicology's Specialty Section on Mixtures

2008-2014 **Member and President**
Council of Mt. Zion Lutheran Church

2008 **Participant, Essential Metals Workshop**
Institute of Population Health, University of Ottawa

2008 **Member**
Green Chemistry Initiative Science Advisory Panel, California Environmental Protection Agency, Department of Toxic Substances Control. San Francisco, CA

2007 **Lecturer**
Shanghai Municipal Center for Disease Control and Prevention (Shanghai CDC). National Continuing Education Training Workshop on Chemical Risk Assessment and Its Development. Shanghai, P.R. China

2006 to 2007 **Member**
The ECOS and DoD Sustainability Workgroup. Department of Defense, Washington, D.C.

2006 **Panelist**
Joint meeting of the dental products panel of the medical devices advisory committee of the CDRH and the peripheral and central nervous system drugs advisory committee of the CDER, Food and Drug Administration. September 6-7

2005 **Rapporteur**
Workshop on Poisons Centres and the Use of Human Data in Consumer Product Risk Assessment. Work Health Organization (WHO). Berlin, Germany. May 9-10, 2005

2004 **Panelist**
Technical workshop on human milk surveillance and biomonitoring for environmental chemicals in the United States. Milton Hershey Medical Center, Penn State, Pennsylvania, September 24 to 26

2003 to 2006 **Member and Chair**
World Wide Web Advisory Committee. Society of Toxicology

2003 **Panel Member**
Mid-Cycle Peer Review for NHEERL's Neurotoxicology Division, U.S. EPA, RTP, NC

2001 to 2005 **Secretary**
Society for Risk Analysis.

2001 **Panel Member**
Peer Review for NHEERL's Neurotoxicology Division, U.S. EPA, RTP, NC

2000 to 2001 **Temporary Advisor**

World Health Organization for Consultation on Uncertainty and Variability: BGVV, Berlin Germany, 9-11 May

2000 to 2001 **Advisor and Rapporteur**
Food Safety in Europe: Risk assessment of chemicals in food and diet. ILSI: Barcelona, Spain

1999 **Member**
Panel for the harmonization of cancer and non-cancer risk assessment. Society of Toxicology. November 1-3

1999 to 2002 **Member**
Oversight Group for the EPA Cooperative Agreement. George Washington University

1999 to 2002 **Vice President Elect, Vice President, President and Councilor**
Society of Toxicology's Specialty Section on Risk Assessment

1998 to 2004 **Executive Director and Treasurer**
Concordia Lutheran Church, Cincinnati, Ohio

1996 to 1998 **Member**
FDA Science Board Subcommittee on Toxicology

1995 **Co-Guest Editor**
EPA Uncertainty Factor Workshop. Human and Ecological Risk Assessment. 1(5):512-662

1995 to 1999 **Member, Treasurer, Vice President, and President (1998)**
Board of Directors of the American Board of Toxicology

1995 to 1996 **President (first elected)**
Dose-Response Specialty Group, Society for Risk Analysis

1995 to 2006 **Scoutmaster, Assistant Scoutmaster**
Troop 133 of Concordia Lutheran Church, Cincinnati, Ohio

1994 to 2007 **Member**
Editorial Board of the Journal Human and Ecological Risk Assessment

1994 to 1995 **Director, Property Board**
Concordia Lutheran Church, Cincinnati, Ohio

1994 to 1995 **Cubmaster**
Pack 133 of Concordia Lutheran Church, Cincinnati, Ohio

1991 to 1994 **President-Elect, President and Councilor**
The Ohio Valley Chapter of the Society of Risk Analysis

1993 **Member**
Committee on Lutheran Mission Ministry Strategy for Greater Cincinnati

1993 **Expert Witness**
OSHA for Informal Public Hearing on the Proposed Rule on Occupational Exposure to Glycol Ethers, Washington, D.C., July 21

1993 **Temporary Advisor and Joint Rapporteur**
World Health Organization for Consultation on Guiding Principles and Methodology for Quantitative Risk Assessment in Setting Exposures Limits: III. Geneva, Switzerland, June 14-18

1993 **Faculty**
As part of an EPA-sponsored delegation to teach a course on Environmental Management-Risk Assessment Training, Lodz, Poland, March 29-April 2

1993 **Temporary Advisor**
World Health Organization for Consultation on Guiding Principles and Methodology for Quantitative Risk Assessment in Setting Exposures Limits: II. Langen, Germany, January 19-22

1992 **Temporary Advisor and Co-Vice Chair**
World Health Organization for Consultation on Guiding Principles and Methodology for Quantitative Risk Assessment in Setting Exposures Limits: I. Geneva, Switzerland, January 14-17

1990 to 1993 **Vice President and President**
Academy of Kettering Fellows, University of Cincinnati, College of Medicine

1988 to 1992 **Councilor**
The Ohio Valley Chapter of the Society of Toxicology

1988 to 1990 **Vice President (interim), President (first elected) and Councilor**
Society of Toxicology's Specialty Section on Risk Assessment

1987 to 1992 **Chair**
EPA Risk Assessment Forum's technical panel to develop Risk Assessment Guidelines for Non-Cancer Health Effects

1986 to 1993 **Treasurer, Vice President and President**
Lutheran Church of the Cross, Cincinnati, Ohio

1986 to 1994 **Chair and Co-Chair**
Reference Dose (RfD) Work Group of the EPA (with a 1 year break in service)

1986 to 1995 **Charter Member**
Risk Assessment Forum of the EPA

AWARDS (Selected)

2017 **Outstanding Regulatory and Safety Evaluation Paper**. Given for the outstanding published paper in regulatory and safety evaluation during 2016. Regulatory and Safety Evaluation Specialty Section (RSESS). Society of Toxicology. Award was based on a group effort.

2013 **Risk Communication Award.** KidsChemicalSafety.org was honored with the Alliance for Chemical Safety. The risk communication award recognizes a

company, organization or individual who has shown outstanding leadership in communicating about chemical risks. Award was based on a group effort.

2013 **Best Charity Award.** Toxic Chemical Safety awarded for recognition as one of the 'BEST' charities in America. Presented upon rigorous independent review for being able to certify, document and demonstrate on an annual basis that met the highest standards of public accountability, program effectiveness, and cost effectiveness.

2009 **International Achievement Award.** In recognition of his outstanding contributions nationally and internationally to the advancement of regulatory science, policy, and methodologies in risk assessment and risk management and for his distinguished and creative participation in regulatory organizations and in decisions of ultimate public health significance worldwide. International Society of Regulatory Toxicology and Pharmacology.

2008 **Outstanding Risk Assessment Paper**. Given for the outstanding published paper in 2007 demonstrating an application of risk assessment. Risk Assessment Specialty Section, Society of Toxicology. Award was based on a group effort.

2008 **The Independent Charities Seal of Excellence.** Given to the members of Independent Charities of America and Local Independent Charities of America that have, upon rigorous independent review, been able to certify, document, and demonstrate on an annual basis that they meet the highest standards of public accountability, program effectiveness, and cost effectiveness. These standards include those required by the US Government for inclusion in the Combined Federal Campaign, probably the most exclusive fund drive in the world. Of the 1,000,000 charities operating in the United States today, it is estimated that fewer than 50,000, or 5 percent, meet or exceed these standards, and, of those, fewer than 2,000 have been awarded this Seal. Award was based on a group effort.

2007 **Service to the Voluntary Children's Chemical Evaluation Program (VCCEP)**. Given for service as chair and participant on external review panels. Toxicology Excellence for Risk Assessment, Cincinnati, Ohio.

2003 **Arnold J. Lehman Award.** An award in recognition of major contributions to risk assessment and the regulation of chemical agents, including pharmaceuticals. Society of Toxicology.

2002 **Environmental Stewardship Award.** An award issued in gratitude for serving on the C8 Assessment of Toxicity Team as a toxicologist in the development of toxicity factors and screening levels. West Virginia, Department of Environmental Protection. Award was based on a group effort.

2000 **Key Risk Award.** Environmental Studies Topic, Links2Go. *TERA*'s International Toxicity Estimates for Risk (*ITER*) database won this award by being 7th most accessed environmental web site in the world. Award was based on a group effort.

1998 **Outstanding Risk Assessment Paper.** Given for the outstanding published paper in risk assessment during 1997. Risk Assessment Specialty Section. Society of Toxicology. Award was based on a group effort.

1995 **In Appreciation.** An award for outstanding service and scientific contribution to the Environmental Protection Agency and to United States Government.

1994 **Special Achievement.** An award for noteworthy contribution as a member of the Risk Characterization Team towards an EPA-wide workshop on risk characterization.

1992 **Bronze Medal.** An award for outstanding service in the review of EPA's 503 Sludge Regulations. Award was based on a group effort.

1992 **OHEA Peer Award for Scientific Achievement.** An annual peer award for scientific achievement in EPA's Office of Health and Environmental Assessment

1992 **RfD/RfC Work Group Appreciation Award.** For sustained superior leadership of and scientific contributions to EPA's Reference Dose/Reference Concentration Work Group.

1991 **Bronze Medal.** An award for outstanding service in the development of EPA's Integrated Risk Information System (IRIS). Award was based on a group effort.

1990 **Special Achievement.** An EPA award for ensuring ORD's successful involvement in regulatory support issues with EPA's Office of Pesticides and Toxic Substances.

1988 **Special Achievement.** An EPA award for resolution of generic issues associated with the minimum data base needed to estimate Reference Doses (RfDs).

1987 **Special Achievement.** An award for further development of the EPA's -- Integrated Risk Information System (IRIS).

1986 **Bronze Medal.** An EPA award "for outstanding service in the organization and review of Risk Reference Doses (Acceptable Daily Intakes) and the science from which they are derived." Award was based on a group effort.

1984 **Tribute of Appreciation.** An EPA award for the "Development of Risk Assessment Guidelines."

1982 **Coach of the Year (soccer).** Greater Cincinnati League (Catholic Boys High School)

1980 **Bronze Medal.** An EPA award recognizing "Outstanding dedication, completion of tasks and contributions to environmental protection in the development of Water Quality Criteria." Award was based on a group effort.

AFFILIATIONS

I am a member of the American Association for the Advancement of Science **(AAAS)**, the Society for Risk Analysis **(SRA)**, and the Society of Toxicology **(SOT)**. I am a Diplomate of the American Board of Toxicology (October 1985) and was recertified in 1990, 1995, 2000, 2005, 2010, and 2015. I am an elected Fellow of the Academy of Toxicological Sciences and the Society for Risk Analysis.

REFERENCES

References will be readily supplied upon request.

Summary of billed hours of Toxicology Excellence for Risk Assessment (TERA) for the years 1995 to 2015, and donated time.*

Year	Non Profit	% of Billed	Profit	% of Billed	Donated Time	% of Billed
1995	917	67%	457	33%	166	12%
1996	1,248	38%	2,073	62%	701	21%
1997	2,173	53%	1,949	47%	769	19%
1998	4,841	61%	3,106	39%	1,133	14%
1999	5,631	66%	2,925	34%	879	10%
2000	4,949	58%	3,583	42%	1,501	18%
2001	5,197	47%	5,964	53%	1,391	12%
2002	11,407	72%	4,527	28%	2,104	13%
2003	10,534	79%	2,870	21%	2,335	17%
2004	12,238	82%	2,629	18%	2,109	14%
2005	11,477	82%	2,538	18%	1,962	14%
2006	9,932	73%	3,741	27%	1,807	13%
2007	10,727	72%	4,225	28%	2,112	14%
2008	9,588	67%	4,812	33%	1,578	11%
2009	10,806	69%	4,966	31%	1,767	11%
2010	10,548	66%	5,434	34%	1,849	12%
2011	9,569	67%	4,713	33%	1,650	12%
2012	9,250	60%	6,166	40%	1,126	9%
2013	11,183	63%	6,585	37%	1,577	9%
2014	8,071	57%	6,006	43%	1,541	11%
2015	9,669	68%	4,550	32%	1,403	10%

* These hours do not include marketing, general science or administrative times.

Sponsor	Project Description	Project Type
Acrylonitrile Group	Proposal to review acrylonitrile IRIS external draft and prepare public comments for	Private Sector
AECOM	TERA organized an independent expert panel to review a draft work plan for a	Private Sector
Albermarle	Review EPA design for environment text on flame retardants.	Private Sector
American Chemistry Council	This project is an enhancement of the ARA Dose Response Framework that was	Collaboration
American Chemistry Council	For Beyond Science & Decisions, continuation of case study 17. Low dose linear	Collaboration
American Chemistry Council	Develop a kids risk webpage, in part.	Collaboration
American Chemistry Council	Build on previous work to develop RfD, including critical evaluation of issues,	Private Sector
American Chemistry Council	TERA will review DINP toxicity data and provide expert opinion on relevance of chronic	Private Sector
American Chemistry Council	Conduct mode of action assessment for liver tumors in mice exposed to diethanolamine.	Private Sector
American Chemistry Council	Assessment Science and Policy's (ARASP) Weight of Evidence Workshop.	Private Sector
American Chemistry Council	Reviewed studies to determine critical effect(s); prepared manuscript; submitted.	Private Sector
American Chemistry Council	Analyze the current display of the uncertainty and variability in the IRIS summaries.	Private Sector
American Chemistry Council	Co-writing a paper on Bayesian approach to developing RfDs	Private Sector
American Chemistry Council	ITER (International Toxicity Estimates for Risk) Peer Review Program for TCDD.	Private Sector
American Chemistry Council	Presentation of recent ecological TBBPA data at SETAC in 2014.	Private Sector
American Chemistry Council	Provide assistance in developing and presenting a continuing education course at AIHce	Private Sector
American Chemistry Council	Gift letter funding the mutagenic mode of action adverse outcome case study.	Private Sector
American Chemistry Council	Conduct BMD analysis of key studies and review data for other studies worthy of	Private Sector
American Chemistry Council	Revise rat PBPK model of propyl series compounds, prepare report and poster, present	Private Sector
American Cleaning Institute	Develop proposal for conducting safety assessment case studies for selected cleaning	Private Sector
American Cleaning Institute	Organize workshop on scientific issues regarding asthma and cleaning products.	Private Sector
American Petroleum Institute	Prepare a manuscript for submission to a peer-reviewed journal that describes the	Private Sector
American Petroleum Institute	The proposed work includes (1) further developing the draft framework, (2) expanding	Private Sector
Amgen Reagents	Developing risk values (permissible daily exposures, PDEs) to calculate toxicology-based limits for drug substances and/or reagents designated by the sponsor. A PDE is the dose that would not result in an appreciable effect to human health from relevant drug substance routes of administration. The PDE is derived by analyzing all potential toxic effects such as acute, chronic, reproductive, and carcinogenicity and choosing the most	Private Sector
Aquilent	Organize and conduct subject matter expert workshop on term and definitions of toxic	Government
Aquilent	Develop content for additional chemicals in CHEMM.	Government
AWWA - American Water Works Association	Brief assessment of the validity of conclusions some commenters have attributed to the	Private Sector
Battelle Memorial Institute	ORNL Health Advisory Guidance. Respond to EPA comments on revisions to draft	Government
Battelle Memorial Institute	Scoping assessment of vinyl acetate PBPK models for possible use in US EPA IRIS	Government
Battelle Memorial Institute	Scoping assessment of PBPK models for possible use in US EPA IRIS assessment of	Government

Battelle Memorial Institute	Develop brodifacoum model based on warfarin model; develop bromadiolone model if	Government
Battelle Memorial Institute	PBPK modeling support for US EPA IRIS assesesment of PCBs	Government
Battelle Memorial Institute	"Quick Response Statistical Report" EPA Contract No. EP-C-09-006. QA of Hissink et	Government
Bowles and Verna LLP	Contaminated site necessitates review and possible court testimony on the plaintiffs' side regarding comparison of levels of contaminant exposure and health benchmarks. TCE	Non-Profit
British Society of Toxicology	Attend the BSOT annual meeting and make a presentation.	Non-Profit
California Chamber of Commerce	Review the CalEPA Env Health Screening Tool and provide comments at a "meeting of	Non-Profit
Cardno Chemrisk	Provide a peer review on evaluation of the weight of evidence for endocrine disruption	Private Sector
CEFIC	Investigate mode of action for ethylene oxide-induced lung tumors in male mice. Project	Collaboration
Charles A. Pittinger, LLC	Draft ecological manuscripts for TBBPA.	Private Sector
Chevron	An emergency response course for the EHS team, and perhaps individuals from other	Private Sector
Chevron Phillips Chemical LP	Preparation of a Test Plan document, with robust summaries, for chemicals as identified	Private Sector
Chevron Phillips Chemical LP	2-day Emergency Medical Response training course offered to Chevron.	Private Sector
City of Cincinnati	Evaluate the health risks associated with outdoor wood fired boilers.	Government
Combined Federal Campaign	Develop a kids risk webpage, in part.	Collaboration
Coca Cola	Develop a benchmark dose (BMD) for 5-HMF	Private Sector
Concurrent Technologies Corporation	Provide senior-level peer review and comment on several individual susbtance report	Government
Corona Environmental Consulting, LLC	One day meeting in West Virginia to review available tox data and scientific support for	Government
Dow AgroSciences	Develop a manuscript based on the previously developed issue paper with a critical	Private Sector
Dow Chemical	Prepare and assist in preparation of manuscripts from the nuclear receptor workshop.	Collaboration
Dow Chemical	Chair session on soil exposure at the July 2011 Tox Forum meeting.	Private Sector
Dow Chemical	BMD course (related to Boot Camp) and DR 1 and 2.	Private Sector
Dow Corning	Review and revise industrial hygiene guides and occupational exposure limits (OELS).	Private Sector
Dow Corning	Application of uncertainty factor for the development of the IHG. Submission of literature	Private Sector
Drinker, Biddle & Reath LLP	Identify, gather, review and assemble available data on chemicals as defined in the ELSIE document Safety Database Search and Compilation Protocol.	Non-Profit
Eastern Research Group	Review EPA's text entitled: Application of Quantitative Data to Develop Data-Derived	Government
Electric Power Research Institute	Case study review for Workshop 9: Adverse outcome pathway (AOP) for arsenic	Collaboration
Eli Lilly	Development of OEL documents for pharmaceutical compounds	Private Sector
EnRisks	Develop course training package, descriptions and outlines of all courses and review	Government
EnSIGHT	Determine cancer slope factors for DINP using California proposition 65 logic and EPA	Private Sector
ERM Alaska, Inc.	Alaska DEC has tasked TERA with conducting an independent, expert peer review of the	Government
Ethyleneamines Product Stewardship Discussion Group	BMD modeling support for aminoethylethanolamine, evaluate relevance of endpoints and	Private Sector
ExxonMobil Biomedical Sciences, Inc	Critical review of available information on decalin (decahydronaphthalene) to confirm if	Private Sector
Genentech	Assist in developing risk assessment procedures	Private Sector
Georgia Pacific	Met with sponsor to discuss options for IRIS reinvention.	Private Sector

GMA	Development of a periodic newsletter	Private Sector
Gradient	ITERate (International Toxicity Estimates for Risk) Peer Review Program: Manganese	Private Sector
Gradient	Comment on and contribute to manuscript on issues and assumptions behind arguments	Private Sector
Halogenated Solvents Industry Alliance	Provide comments on EPA IRIS assessment for TCE to EPA's Scientific Advisory Board.	Private Sector
Hamp, Mathews & Associates, Inc.	Procure and translate Japanese studies on 1,4-dioxane; develop analysis and publish a	Collaboration
HAP Task Force	Route-to-route extrapolation of NOAELs and LOAELs from existing and new studies	Private Sector
Health Canada	Letter review of phthlataes.	Government
Health Canada	Peer review of risk assessment documents on PFOS and PFOA with emphasis on dose	Government
Health Canada	Letter peer consultation on flame retardant dechlorane plus.	Government
Health Canada	Review a 4-5 page special issue paper on boron dealing with PBPK, BE and uncertainty.	Government
Health Canada	Letter Consultation on 3 flame retardants.	Government
Health Canada	Assessment AEEA and Ethyl.	Government
Health Canada	CoCAM 5. Three assessment peer reviews	Government
Health Canada	Review of petroleum substances.	Government
Health Canada	TERA organized and conducted an independent peer consultation of the draft screening	Government
Health Canada	Review documents provided by HC: draft Screening Assessment reports and outlines	Government
Health Canada	Coordinate and manage an independent peer consultation of the draft screening level	Government
Health Canada	Develop a guidance document for using biomonitoring studies to estimate exposures for	Government
Health Canada	Position paper and internal Health Canada peer consultations on risk assessment for	Government
Health Canada	Custom 3-day Boot Camp course	Government
Health Canada	Peer review of Batch 12 substances N,N-diphenyl -guanidine; carbon black, cristobalite;	Government
Health Canada	Letter peer consultation on flame retardants tricresyl phosphate (TCP).	Government
Health Canada	Letter peer consultation on 2 flame retardants, bis(2-ethylhexyl)	Government
Health Canada	TERA will select a minimum of 5 Canadian Public Health Summaries, based on	Government
Health Canada	TERA organized and conducted a letter peer consultation on two draft guidance	Government
Health Canada	Assessment of Non-Cancer Effects due to Short-Term Exposure and Short-Duration	Government
Health Canada	Update and complete the human health screening risk assessment report for acetone	Government
Health Canada	(1) prepare "toolbox" of risk assessment methods, (2) framework and discussion of	Government
Health Canada	Organize and conduct independent scientific peer consultation on two draft Health	Government
Health Canada	Organize and conduct an independent scientific peer consultation on the draft Health	Government
Health Canada	Coordinate and manage an independent external scientific and technical peer review of	Government
Health Canada	Review of screening assessment for triclosan	Government
Health Canada	Review exposure scenarios for azo dyes.	Government
Health Canada	Conduct peer consultation of the revised hydrogen sulfide assessment document. TERA	Government
Health Canada	Peer consultation of the revised State of the Science report on 1,1-biphenyl.	Government

Health Canada	Organize and conduct letter peer consultations on petroleum stream products.	Government
Health Canada	Letter peer consultation on 4 azobenzidine assessments.	Government
Health Canada	Organize and conduct independent scientific opinion on the Health Canada documents	Government
Health Canada	Organize and conduct letter reviews on Petroleum Stream Products.	Government
Health Canada	Organize and conduct a second letter peer consultation on petroleum stream products.	Government
Health Canada	Organize and conduct independent scientific peer consultation on the Health Canada	Government
Health Canada	Organize and conduct independent scientific peer consultation on the Health Canada	Government
Health Canada	TERA will review rat-human dosimetric models and evaluate for diesel exhaust exposure	Government
Health Canada	Participate in 2-day workshop on current state-of-knowledge in the health risk	Government
Health Canada	Quantitative Uncertainty and Variability Analysis of Perfluorinated Chemicals (PFCs)	Government
ICF Incorporated, LLC	The goal of this project is to finalize the content for about 50 potential mass casualty	Government
ICL-IP America Inc.	Case study review for Workshop 9 – flame retardant framework - for addressing risk and	Collaboration
ILSI North America	Dose-response evaluation of relationship between Trans-fat intake and LDL-cholesterol	Non-Profit
Institute of Environmental Science & Research Limited	Review of NZ risk methods document	Government
Institute of Environmental Science & Research Limited	Carry out a review of the Hobsonville Health Risk Assessment undertaken by Golders	Government
Institute of Environmental Science & Research Limited	Written peer review for health assessment titled Health risk assessment of diluted	Government
Institute of Environmental Science & Research Limited	Task 1: Technical Information Resources. TERA would provide ESR with a list of	Government
Institute of Environmental Science & Research Limited	Technical review and detailed comments relating to the review of the report entitled "A	Government
Institute of Environmental Science & Research Limited	Technical review and detailed comments relating to the review of the report entitled "A	Government
JT International S.A.	Provide two presentations (40-60 mins) on "Principles for the risk assessment of	Private Sector
LifeLine Group	For Health Canada, TERA organized and managed an expert scientific letter review of a	Government
LifeLine Group	For Health Canada, Development of assessment materials to be used for evaluating	Government
LifeLine Group	For Health Canada, development of a proposed approach for identifying polymers that	Government
Lockheed Martin	Review and comment on new CatReg software interface.	Government
Longenecker & Associates	Providing services for Dept. of Energy (DOE), Office of River Protection (ORP) Tank	Government
McKenna Long and Aldridge	Prepare comments on the trichloroethylene IRIS document on issues related to cancer	Government
Merck & Co.	Develop and deliver an OEL presentation.	Private Sector
Merck & Co.	Provide support for development of dose-response analyses for tumorigenic effects	Private Sector
Methanol Institute	Conduct a letter peer review of a methanol cancer bioassay published as Soffritti et al.	Private Sector
Morrison & Foerster	Rview of information regarding acrylamide in coffee	Private Sector
Multiple sponsors	TERA hosted and organized a workshop on the Endocrine Disruptor Screening Program	Collaboration
Multiple sponsors	Workshop III of Beyond Science and Decisions- to continue the discussion toward a	Collaboration
Nease Corporation	Prepare response to proposed HPV program test rule	Private Sector
Neptune	Develop white paper on aggregate and cummulative risk for OPPT.	Government
New Zealand Ministry of Health	Provide review of document regarding recommended cleanup of broken mercury	Government

New Zealand Ministry of Health	Develop publication based on the screening level health assessment on exposure to	Government
Nickel producers research association	Review and comment on draft manuscript on reference value for nickel in ambient air:	Private Sector
Nickel producers research association	Conduct a meta-analysis and meta-regression of respiratory cancer risk following	Private Sector
Nickel producers research association	Monitor progress of research related to evaluation of nickel MOA, provide advice to	Private Sector
Nickel producers research association	Review and rate proposals related to nickel MOA; monitor progress of funded work;	Private Sector
Noblis Inc.	Facilitate the development of a WEEL.	Government
Noblis Inc.	(1) Evaluate of toxicity of emerging contaminants to provide Sponsor with a scientific	Government
NSF International	Run CatReg model for one set of data with chronic progressive nephropathy (CPN) as	Non-Profit
NSF International	Add new data to ITER from NSF International.	Non-Profit
NSF International	Evaulate the MOA and safety studies on DMAA; contribute to the writing of a paper on	Non-Profit
NSF International	Review of polymer toxicity information.	Non-Profit
Ohio State University	Present lecture on environmental risk assessment at Ohio State University.	Government
Ontario Ministry of the Environment	Review Ontario MOE approaches to setting air standards. Conduct research into how	Government
Pfizer Global Research and Development	Provide support for development of dose-response analyses for tumorigenic effects	Private Sector
PPG Industries	Changed dioxane publication to open access.	Private Sector
PPG Industries	Conduct Japanese study translation and anaylsis in part.	Private Sector
Proctor & Gamble	Determination of whether the current TTC limits are protective for	Private Sector
PSA Inc.	Manage registration and workshops for 2011 TRAC conference	Government
PSA Inc.	Provide assistance with online and onsite registration, catering details and workshop	Government
Quinn Emanuel Urquhart & Sullivan, LLP	Review information on petroleum coke and related materials to assist in understanding	Private Sector
Sapphire Group	Respond to reviewer comments, edit acrylamide manuscript, review proofs.	Private Sector
Shell Inc.	Communicate toxicology related to siting a plant in Pittsburgh.	Private Sector
Silicones Environmental Health and Safety Council	Gather and consolidate SEHSC data in order to develop a summary of all relevant data	Non-Profit
Society for Risk Analysis	Compile information on local contacts at universities for student award for DRSG.	Non-Profit
Society of Toxicology	Host SOT 2013 Global Senior Scholar Exchange program. The program aims to	Non-Profit
State of Maine	Examine whether current pesticide residues have the potential to affect the lobster	Government
State of New Mexico	Provide a comprehensive technical and regulatory support to New Mexico Environment	Government
State of Oregon	Review of in vitro study conducted by private party to determine likely bioavailability of	Government
State of Texas	Organize and hold a workshop on technical and scientific issues related to ozone	Government
State of Texas	Organize and conduct scientific peer review of chemicle-specific development support	Government
State of Texas	Add new data from TCEQ to ITER in the ITER column.	Government
State of Texas	Enter Hexavalent Chromium toxicity factors from the chromium development support	Government
State of Texas	Organize an external technical letter review of the TCEQ draft Development Support	Government
State of Texas	Enter Nickel Toxicity Factors from Nickel Development Support Document on the ITER	Government
State of Texas	Conduct a letter peer review of TCEQ's revised ESL (effects screening level) guidelines,	Government

State of Texas	Letter peer review with follow up teleconference of section 4.2 Carcinogenic Potential of	Government
State of Texas	Letter peer review of section 4.3 Carcinogenic Potential od the DSD for isoprene.	Government
Steptoe	Review CalEPA chloropicrin cancer risk assessment.	Private Sector
Strategic Regulatory Consulting	Review draft MSDS forms provided by SRC for format and content. Editing of forms as	Private Sector
Styrene Information and Research Center	Technical support for public workshop on mouse lung tumor mode of action issues (for	Private Sector
Sudbury Integrated Nickel Operations, a Glencore company	Review and comment on Quebec 24-hour nickel standard.	Private Sector
Summit Toxicology	Work with Sean Hays of Summit Toxicology to add biomonitoring equivalents data to	Government
ToxServices	Conduct literature search, retrieve papers, and write toxicokinetics chapters for the	Government
ToxStrategies	Organize and conduct a letter peer review of a rat 90-day study, conducted as part of a	Private Sector
ToxStrategies	Organize and conduct a letter peer review of a mouse genomics study, conducted as	Private Sector
ToxStrategies	ITERate review of chromium VI	Private Sector
U.S. Air Force	Conduct focused science reviews of up to 6 chemical risk assessments that assess	Government
U.S. Air Force	Conduct a 4-day boot camp course on-site at WPAFB.	Government
U.S. Army	Form an expert panel and conduct a technical review of two occupational exposure levels	Government
U.S. Army Corps of Engineers	2a. Prepare slides in support of Task 1 (problem formulation) -- draft and final --	Government
U.S. Borax	Develop manuscript on the previous work we did in developing an independent OEL for	Private Sector
U.S. Consumer Product Safety Commission	Develop and deliver a course on mixtures risk assessment issues.	Government
U.S. Consumer Product Safety Commission	Review and compile data relating to human exposure to selected flame retardants.	Government
U.S. Consumer Product Safety Commission	Cconduct literature searches regarding the concentrations of specified elements	Government
U.S. Consumer Product Safety Commission	Conduct research regarding the production and use of specified phthalates. Results of	Government
U.S. Consumer Product Safety Commission	Conduct research regarding the production and use of specified plastics with regards to	Government
U.S. Consumer Product Safety Commission	Review epidemiology and toxicology literature on common molds.	Government
U.S. Consumer Product Safety Commission	Review literature and prepare hazard characterization (tk and toxicity sections) and	Government
U.S. Consumer Product Safety Commission	Conduct a broad, high-level , letter peer review of the CPSC Chronic Hazard Advisory	Government
U.S. Consumer Product Safety Commission	Organize exposure data on flame retardants into database for use in exposure	Government
U.S. Consumer Product Safety Commission	Conduct research regarding the production of engineered wood products and research	Government
U.S. Consumer Product Safety Commission	Conduct a letter peer review of a CPSC draft report on Nanomaterial Toxicity and	Government
U.S. Environmental Protection Agency	Review Technical Qualifications Document provided by NHEERL. Review evaluation	Government
U.S. Environmental Protection Agency	TRAC Conference - TERA to manage social, registration, oversee catering at hotel and	Government
U.S. Food and Drug Administraton	Organize and conduct a 3 day boot camp course.	Government
U.S. National Institute of Occupational Safety and Health	Create and publish TRAC2016 website, work with TRAC committee and provide onsite	Government
U.S. National Institute of Occupational Safety and Health	Create and publish TRAC2014 website, work with TRAC committee and provide onsite	Government
U.S. National Institute of Occupational Safety and Health	Give presentation to NIOSH staff on the use of basic research in developing risk	Government
U.S. National Library of Medicine	Peer consultation workshop for NLM CHEMM to agree on terminology and definitions.	Government
U.S. National Library of Medicine	Continued lease, maintenance and update of ITER database for use on TOXNET.	Government

Underwriters Lab- Environment	QA of ingredient reviews and guide to preparing a toxicological assessment	Non-Profit
Vanadium Producers & Reclaimers Association	Evaluation of K-Ras and cII mutations in the lungs of Big Blue mice exposed to	Private Sector
Versar	Review of Consumer Products Safety Commission on metal levels in toys.	Government
Versar	IRIS external peer review of hexachloroethane	Government
Versar	Review CPSC assessment on cadmium in children's metal jewelry	Government
Vinyl acetate council	Phase I in potential evaluation of vinyl acetate MOA. Conduct validation, cytotoxicity	Collaboration
Waste Management	Support the development of a collaborative effort on 1,4-dioxane risk assessment.	Collaboration
Water Environment Research Foundation	Identify and assemble data on health and ecological endpoints to support an EPA risk	Non-Profit



TERA
Toxicology Excellence
for Risk Assessment
a nonprofit corporation
dedicated to the best use
of toxicity data for risk values

Understanding the Science of Mercury's "Safe" Dose

Michael Dourson
and
Patricia Nance
Toxicology Excellence for Risk Assessment (*TERA*)

June 2004



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The "Safe" Dose Method As Defined by EPA:

An Reference Dose (RfD) is…

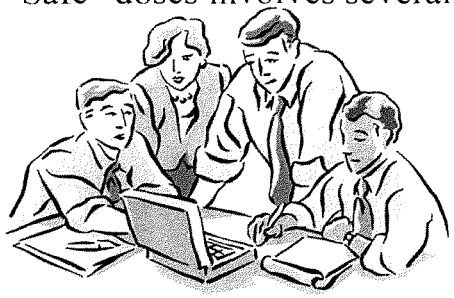
...an estimate (with uncertainty spanning perhaps an **order of magnitude**) of

a **daily** (for RfD) **or continuous** (for RfC) exposure to the human population (including **sensitive** subgroups)

that is **likely to be without** an appreciable risk of deleterious effects during a lifetime.

TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The estimation of these "Safe" doses involves several judgments



such as...

- the choice of the most appropriate No Observed Adverse Effect Level (NOAEL) or Benchmark Dose (BMD) of the critical effect, usually from experimental animal data, and

- the choice of the appropriate Uncertainty Factors based on a review of the entire database.

"Safe" Doses for Mercury Compared

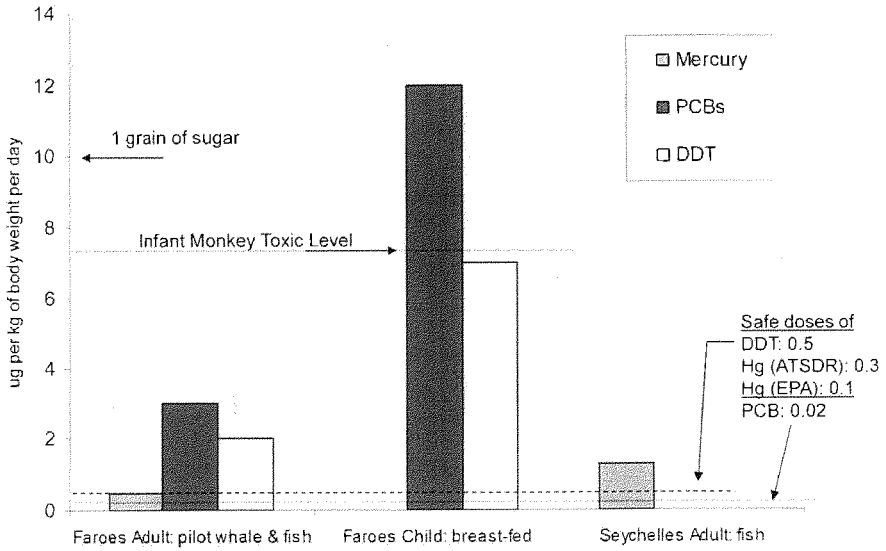
see www.tera.org/iter

Organization Name	ICF	ATSDR	RIVM	EPA	WHO
"Safe" Dose (µg/kg-day)	0.3 to 1	0.3	0.1	0.1	0.23
Year	**1998**	**1999**	**2000**	**2001**	**2003**
Study	Seychelles	Seychelles	Seychelles	Seychelles, Faroes, New Zealand	Seychelles, Faroes
NOAEL/BMD (µg/kg-day)	0.9 to 3	1.3	1.3	0.9 to 1.5	1.5
Uncertainty Factors	3	4.5	10	10	6.4

TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Contaminant Intakes in Faroe & Seychelle Islands

(adapted from Dourson et. al., 2001)

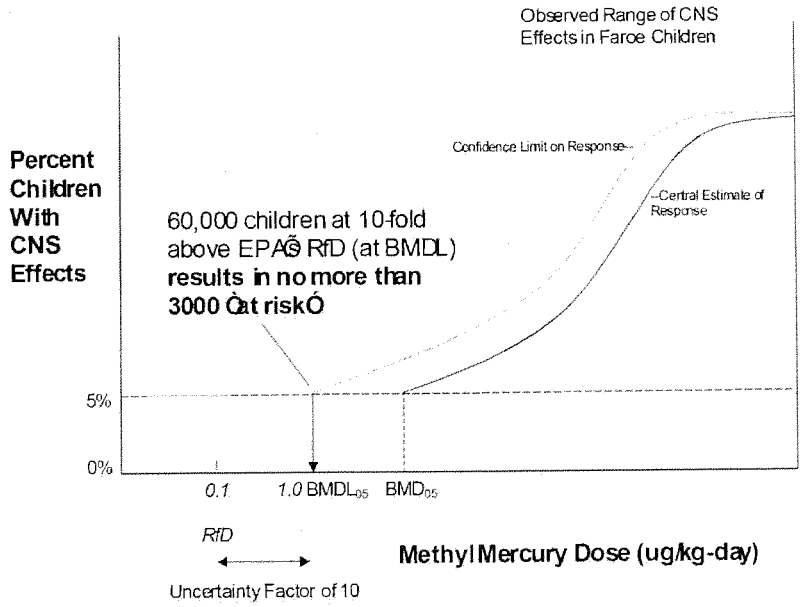


The Faroe islands studies are very good at understanding a mixed exposure. The Seychelle islands studies are very good at understanding exposures to primarily methyl mercury.

TERA

Toxicology Excellence for Risk Assessment

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





TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What Might a Fish Advisory Look Like for Mercury?

- First, calculate the Safe Fish Intake based on the safe Hg dose multiplied by a given body weight and divided by the measured Hg level in fish, for example, 0.1 ppm (EPA, 1997).

- Safe Fish Intake

  = Safe Hg Dose x Body Weight ÷ Fish Level

  = 0.1 ug/kg-day (EPA, 2001) x 60 kg ÷ 0.1 ug Hg/gram of fish

  = 60 grams of fish/day



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What Might a Fish Advisory Look Like for Mercury?

- Second, translate this Safe Fish Intake into meals per month or week
- 60 kg of fish/day falls into the range of 30 to 100 grams of fish per day and is consistent with eating three meals per week (Dourson and Clark, 1990).
- This level would be expected to be "safe" for sensitive individuals. Higher fish consumption would be appropriate for others.



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The Fish Advisories Compared

Organization Name	ATSDR	EPA	ICF
"Safe" Dose (µg/kg-day)	0.3	0.1	0.3 to 1
Advisory at 0.1 ppm (meals per week)	7	3	7 to unlimited
Advisory at 1 ppm (meals per month)	4	1	4 to 12

Advisories that are inappropriately low compromise health by removing a medically recommended protein source from the food supply (e.g., Dourson et al., 2002).



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Extra slides



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

References

- Dourson, M.L. and J.M. Clark. 1990. Fish consumption advisories: Toward a unified, scientifically credible approach. Regul Toxicol Pharmacol. 12: 165-172. (EPA staff publication)
- Dourson, M.L, A.E. Wullenweber and K.A. Poirier. 2001. Uncertainties in the Reference Dose for Methylmercury, NeuroToxicology 22 (5) (2001) pp. 677-689. (*TERA* staff publication)
- Dourson, M.L., et al. 2002. Comparative Dietary Risk: Balance the Risk and Benefits of Fish Consumption. Comments on Toxicology 8:335-536. (EPA cooperative agreement publication)
- U.S. EPA. 1997. Guidance for assessing chemical contaminant data for use in fish advisories. Vol. 2: Risk assessment and fish consumption limits, 2nd ed. Office of Science and Technology, Office of Water. EPA 823-B-97-009.



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What is Toxicology Excellence for Risk Assessment (TERA) ?

- *TERA* is a 501(c)(3) non-profit research and education organization dedicated to the best use of toxicity data for risk values.
- *TERA's* mission: protect public health
  - educating folks on risk issues
  - developing & communicating risk values
  - conducting independent peer reviews
  - improving methods through research
- *TERA* founded in 1995 by former EPA staff with >45 years experience working in risk assessment and IRIS.

Partial History of Mercury's "Safe" Dose

Date	Action Taken on Mercury	Michael Dourson's Involvement
1980	EPA Develops RfD of 3 E-4 mg/kg-day	Internal EPA reviewer
1986	EPA Places RfD of 3 E-4 mg/kg-day on IRIS	EPA workgroup chair
1995	EPA Places new RfD of 1 E-4 mg/kg-day on IRIS	Co-author, EPA chair
1998	*ITER* Peer Review for ICF Kaiser RfD of 3 to 10 E-4 mg/kg-day	Chair of independent peer review meeting
2000	*TERA* reviews RfD for the State of Maine & notes heavy PCB contamination of milk	Pro bono reviewer
2000	*TERA* reviews EPA's Draft RfD for the National Food Producers Association	Paid Reviewer
2001	*TERA* publishes on research needs for the mercury RfD, sponsored in part by the EPRI	Co-author
2001	EPA Places New RfD of 1 E-4 mg/kg-day on IRIS	None



TERA
Toxicology Excellence
for Risk Assessment
a nonprofit corporation
dedicated to the best use
of toxicity data for risk values

Understanding the Science of Mercury's "Safe" Dose

Michael Dourson
and
Patricia Nance
Toxicology Excellence for Risk Assessment (*TERA*)

June 2004



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The "Safe" Dose Method As Defined by EPA:

An Reference Dose (RfD) is...

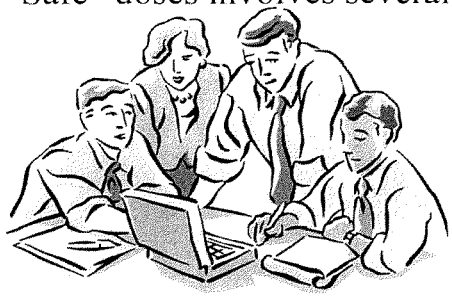
...an estimate (with uncertainty spanning perhaps an **order of magnitude**) of

a **daily** (for RfD) **or continuous** (for RfC) exposure to the human population (including **sensitive** subgroups)

that is **likely to be without** an appreciable risk of deleterious effects during a lifetime.

TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The estimation of these "Safe" doses involves several judgments



such as...

- the choice of the most appropriate No Observed Adverse Effect Level (NOAEL) or Benchmark Dose (BMD) of the critical effect, usually from experimental animal data, and

- the choice of the appropriate Uncertainty Factors based on a review of the entire database.

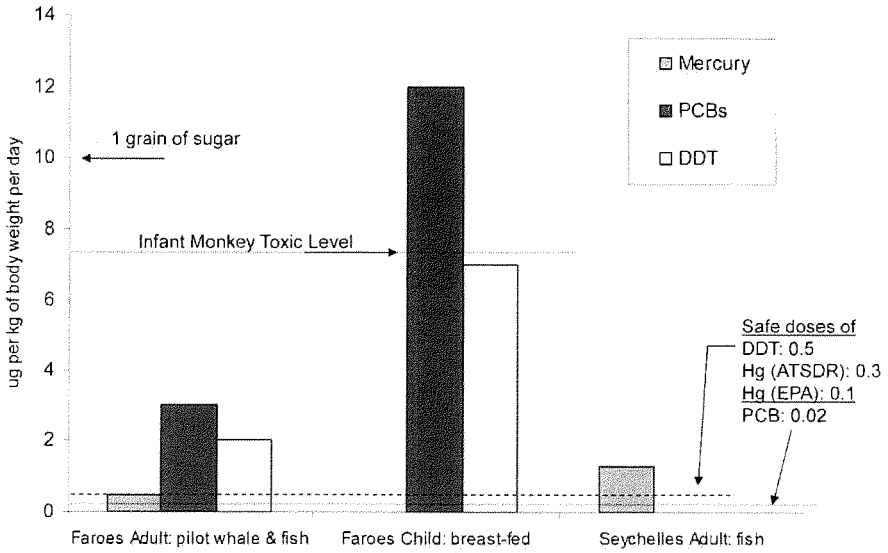
"Safe" Doses for Mercury Compared

see www.tera.org/iter

Organization Name	ICF	ATSDR	RIVM	EPA	WHO
"Safe" Dose (µg/kg-day)	0.3 to 1	0.3	0.1	0.1	0.23
Year	**1998**	**1999**	**2000**	**2001**	**2003**
Study	Seychelles	Seychelles	Seychelles	Seychelles, Faroes, New Zealand	Seychelles, Faroes
NOAEL/BMD (µg/kg-day)	0.9 to 3	1.3	1.3	0.9 to 1.5	1.5
Uncertainty Factors	3	4.5	10	10	6.4

TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Contaminant Intakes in Faroe & Seychelle Islands
(adapted from Dourson et. al., 2001)



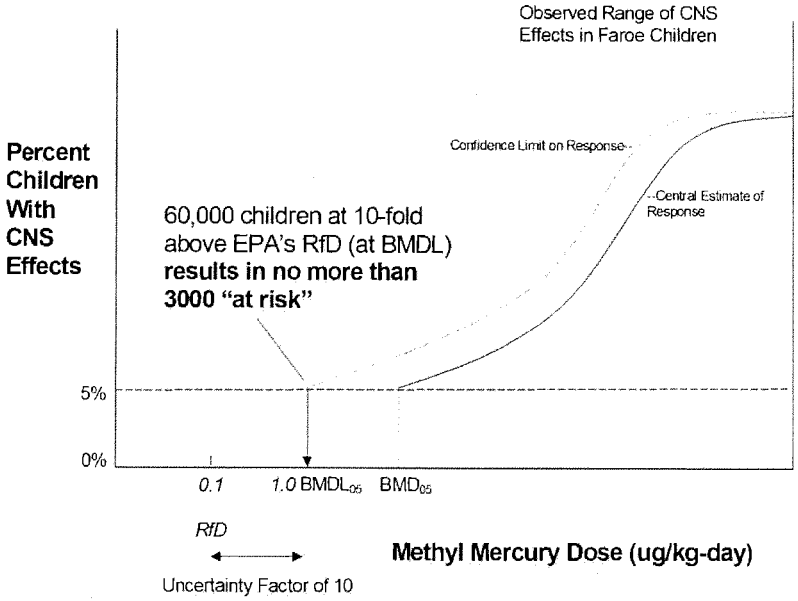
The Faroe islands studies are very good at understanding a mixed exposure. The Seychelle islands studies are very good at understanding exposures to primarily methyl mercury.

December 3rd, 2004, American Legislative Exchange Council

TERA

Toxicology Excellence for Risk Assessment

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





TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What Might a Fish Advisory Look Like for Mercury?

- First, calculate the Safe Fish Intake based on the safe Hg dose multiplied by a given body weight and divided by the measured Hg level in fish, for example, 0.1 ppm (EPA, 1997).

- Safe Fish Intake

  = Safe Hg Dose x Body Weight ÷ Fish Level

  = 0.1 ug/kg-day (EPA, 2001) x 60 kg ÷ 0.1 ug Hg/gram of fish

  = 60 grams of fish/day



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What Might a Fish Advisory Look Like for Mercury?

- Second, translate this Safe Fish Intake into meals per month or week
- 60 kg of fish/day falls into the range of 30 to 100 grams of fish per day and is consistent with eating three meals per week (Dourson and Clark, 1990).
- This level would be expected to be "safe" for sensitive individuals. Higher fish consumption would be appropriate for others.



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

The Fish Advisories Compared

Organization Name	ATSDR	EPA	ICF
"Safe" Dose (µg/kg-day)	0.3	0.1	0.3 to 1
Advisory at 0.1 ppm (meals per week)	7	3	7 to unlimited
Advisory at 1 ppm (meals per month)	4	1	4 to 12

Advisories that are inappropriately low compromise health by removing a medically recommended protein source from the food supply (e.g., Dourson et al., 2002).



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Extra slides



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

References

- Dourson, M.L. and J.M. Clark. 1990. Fish consumption advisories: Toward a unified, scientifically credible approach. Regul Toxicol Pharmacol. 12: 165-172. (EPA staff publication)

- Dourson, M.L, A.E. Wullenweber and K.A. Poirier. 2001. Uncertainties in the Reference Dose for Methylmercury, NeuroToxicology 22 (5) (2001) pp. 677-689. (*TERA* staff publication)

- Dourson, M.L., et al. 2002. Comparative Dietary Risk: Balance the Risk and Benefits of Fish Consumption. Comments on Toxicology 8:335-536. (EPA cooperative agreement publication)

- U.S. EPA. 1997. Guidance for assessing chemical contaminant data for use in fish advisories. Vol. 2: Risk assessment and fish consumption limits, 2nd ed. Office of Science and Technology, Office of Water. EPA 823-B-97-009.



TERA
Toxicology Excellence
for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

What is Toxicology Excellence for Risk Assessment (TERA) ?

- *TERA* is a 501(c)(3) non-profit research and education organization dedicated to the best use of toxicity data for risk values.
- *TERA's* mission: protect public health
  - educating folks on risk issues
  - developing & communicating risk values
  - conducting independent peer reviews
  - improving methods through research
- *TERA* founded in 1995 by former EPA staff with >45 years experience working in risk assessment and IRIS.

Partial History of Mercury's "Safe" Dose

Date	Action Taken on Mercury	Michael Dourson's Involvement
1980	EPA Develops RfD of 3 E-4 mg/kg-day	Internal EPA reviewer
1986	EPA Places RfD of 3 E-4 mg/kg-day on IRIS	EPA workgroup chair
1995	EPA Places new RfD of 1 E-4 mg/kg-day on IRIS	Co-author, EPA chair
1998	*ITER* Peer Review for ICF Kaiser RfD of 3 to 10 E-4 mg/kg-day	Chair of independent peer review meeting
2000	*TERA* reviews RfD for the State of Maine & notes heavy PCB contamination of milk	Pro bono reviewer
2000	*TERA* reviews EPA's Draft RfD for the National Food Producers Association	Paid Reviewer
2001	*TERA* publishes on research needs for the mercury RfD, sponsored in part by the EPRI	Co-author
2001	EPA Places New RfD of 1 E-4 mg/kg-day on IRIS	None

Toxicology Excellence for Risk Assessment
Independent Peer Consultation
Hexavalent Chromium
Mode of Action Research Plan
Mitchell Dourson
Toxicology Excellence for Risk Assessment (TERA)
Presentation to U.S. EPA's Public Listening
Session on Hexavalent Chromium
November 18, 2010
Independent • Non-profit • Science
for the public interest

Summary

- An independent science panel conducted a consultation of a proposed chromium VI Mode of Action (MOA) plan.
- Panel gave suggested improvements, but commented that research like this is the future of risk assessment.
- Suggested studies are being completed.
- Panel will peer review study results.

...Peer consultation is credible based on adherence to COI procedures & use of known experts.

...Targeted research is public health protective and consistent with EPA (2005) Guidelines.

Independence
is essential for a credible review

Administrative ground rules to protect independence of the process

- Measures to avoid influence of interested or involved parties on the outcome of the expert consultation/review.
- TERA **independently** selects panel, runs meeting, and prepares report
- Sponsors, authors, and other interested parties do not have direct communication with the panel.

Cr(VI) Review: The Research Plan

Research plan that describes a 6-phase research program to delineate the MOA for Cr VI following oral exposure including

- 90-day drinking water study
- Genomics evaluation via microarray analysis
- PBPK modeling
- In vivo mutation analysis
- In vitro high content imaging analysis
- Integrating MOA analysis into risk assessment

The Charge to Reviewers

- The charge is a critical element of each peer review that serves as an outline for the meeting discussion.
- Purpose of the charge is to identify the **key** scientific issues and guide the panel to thoroughly consider each one; leading to independent panel conclusions.
- Developed by *TERA* with input from the authors and sponsors.

Cr VI Review: The Charge

The 3-page panel charge addressed the research plan:

–Mode of Action (MOA) Hypothesis

–General Review of the Study Design

–Questions on Specific Studies

The full charge is available in the final peer review report, which is available at http://www.tera.org/Peer/Chromium/Chromium.htm

Meeting report is also available at the website above and will be submitted to the public comment docket .

Cr VI Review: Required Expertise

Based on its review of the research plan, TERA determined that the following types of expertise were required for the panel:

- Risk assessment, particularly use of MOA data in risk assessment,
- PBPK modeling,
- Chromium MOA research design and conduct
- Expertise in specialized analysis such as HCA, MRI, genomics etc
- Statistics

- All panelists were screened against COI concerns with sponsors, authors and principal investigators

Cr VI Review: The Panel

- Michael Dourson, Toxicology Excell. for Risk Assess.
- Jeffery Fisher, University of Georgia
- David Gaylor, Gaylor and Associates
- Kirk Kitchin, Environmental Protection Agency
- Bette Meek, Health Canada/University of Ottawa
- Xianglin Shi, University of Kentucky
- Patrick Winter, Washington University

Cr VI Review: The Results – Mode of Action

The panel agreed that dose response and temporal relationships should be examined simultaneously for the following key events:

–cellular uptake of chromium,
–oxidative stress,
–DNA adducts,
–DNA inter- and intra-strand crosslinks,
–mutation,
–cytotoxicity, and
–cell proliferation.

Furthermore, since oxidative stress might be a primary key event, the panel recommended that the research must include more measurements of this endpoint.

Cr VI Review: The Results – Mode of Action (2)

The panel recommended measurement of DNA interaction, such as DNA chromium adducts and DNA inter- or intra-strand crosslinks.

Some panel members also recommended measuring circulating inflammatory markers...

...although it was noted that the microarray study would identify inflammatory changes in the target tissue if those changes were regulated transcriptionally.

Cr VI Review: The Results- Study Design

The panel recommended adding 5 animals/dose, for a total of n=10, for at least the histopathology study to improve the study sensitivity to identify an effect...

> *...The panel noted that the proposed number of animals was probably adequate for defining the shape of the dose-response curve for continuous data, but was marginal for pairwise comparisons of quantal data.*

The increased number of experimental animals may also allow some of the suggested testing for oxidative stress endpoints.

Cr VI Review: The Results- Study Design (2)

The panel agreed with the authors to run the 90-day study using 6 dose groups (including the control)...

... but recommended two unspecified low doses plus the top three doses in the NTP bioassay.

The panel agreed with the authors that the MOA would not likely be different between males and females and, as such, concurred that using only females in the research was sufficient.

Cr VI Review: Next Steps

TERA will organize and conduct peer reviews of 12 MOA studies in a transparent and independent fashion.

Study/Paper	Ready for Review
Mouse 90 day	November, 2010
Mouse genomics, Mouse DNA Adducts	January, 2011
Rat DNA Cr Adducts, Mouse & Rat PK PK Data, Human PK	March, 2011
Rat 90 day, Rat Genomics In vivo Mutation, Mode of Action High Content Imaging	April, 2011

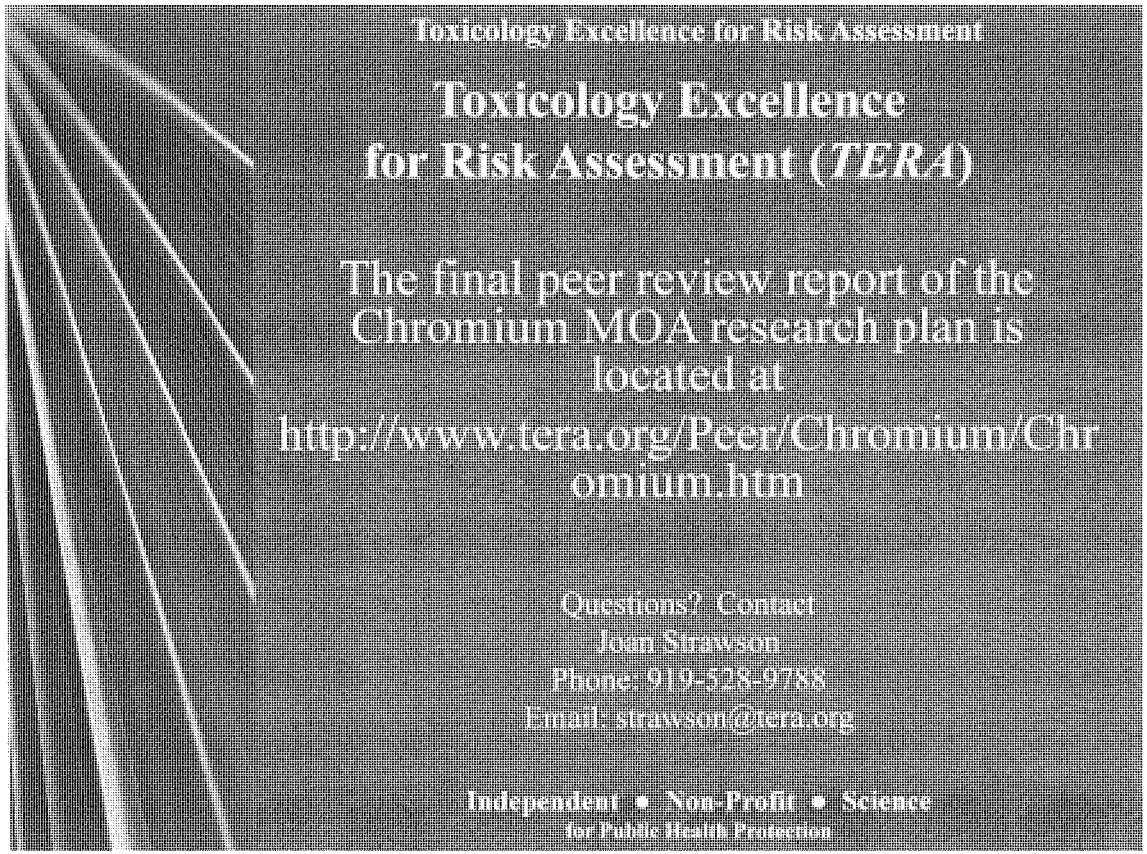
Cr VI Review: Next Steps

- The panel for each review will be composed of 3 to 5 appropriate experts and screened for COI issues...

  ...We anticipate having to add reviewers in areas of toxicokinetics, modeling, genomics, genotoxicity, and high content imaging.

- TERA will create a single core set of charge questions. Separate reports will be prepared for each review, and will include the combined reviewer written comments for each question.

- EPA's and others' thoughts on areas to be covered in these charge questions would be welcome.


Toxicology Excellence for Risk Assessment
Toxicology Excellence
for Risk Assessment (TERA)
The final peer review report of the Chromium MOA research plan is located at
http://www.tera.org/Peer/Chromium/Chromium.htm
Questions? Contact
Joan Strawson
Phone: 919-528-9788
Email: strawson@tera.org
Independent • Non-Profit • Science
for Public Health Protection

Extra Slides



Toxicology Excellence for Risk Assessment (TERA)

Statement of Purpose & Mission
Founded in 1995

Toxicology Excellence for Risk Assessment (*TERA*) is a non-profit, 501(c)(3) corporation organized for scientific and educational purposes.

The mission of *TERA* is to support the protection of public health by developing, reviewing and communicating risk assessment values and analyses, improving risk methods through research, and educating risk assessors and managers and the public on risk assessment issues.

www.tera.org

TERA

Staff of board certified toxicologists with extensive experience in risk assessment, toxicology, and peer review.

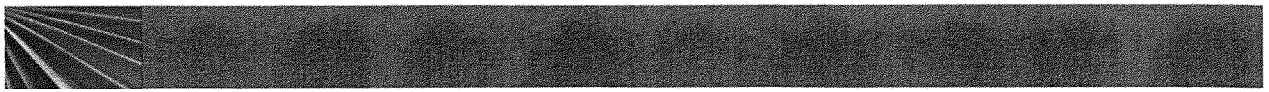
- Prepare high quality risk assessments and organize expert peer reviews
- Improve the underlying methods for risk assessment through research and publication
- Distribute peer reviewed risk values through the International Toxicity Estimates for Risk (*ITER*) database - www.tera.org/iter
- Train others on state-of-the-science risk methods.

Mix of work is 65% government & NGO, and 35% industry & Industry related



What is Peer Review?

- For risk assessment products, it involves an in-depth assessment of the assumptions, calculations, alternate interpretations, methodology, and conclusions.
- Peer review panels seek to reach consensus or common agreement regarding the adequacy of the product reviewed.



TERA's Independent Peer Review Process

1. Scientific screen of the documents to insure they are ready for review, and to identify critical scientific issues and questions for development of the charge and needed expertise for panel.
2. Develop the scientific charge to the panel.
3. Identify appropriate expert candidates and select panel members. Identify conflicts of interest and biases.
4. Schedule meeting and logistical arrangements.
5. Prepare meeting report of discussions, conclusions, and recommendations.
6. Distribute the results to the public.

Panel Selection Procedures

- Identification of scientific expertise necessary to address key issues in charge.
- Search for appropriate candidates, evaluate credentials
- Contact most promising for interest and availability. Query them on conflicts of interest and biases.
- Select a panel that is balanced with regard to necessary disciplines and has a diversity of perspectives.

Conflict of Interest (COI)

An independent panel is essential for a credible scientific review

TERA follows National Academy of Sciences (NAS) procedures for panel selection and conflict of interest.

- NAS defines a conflict of interest as *"any financial or other interest which conflicts with the service of the individual because it (1) could significantly impair the individual's objectivity or (2) could create an unfair competitive advantage for any person or organization. ...The term 'conflict of interest' means something more than individual bias. There must be an interest, ordinarily financial, that could be directly affected by the work of the committee."*

Bias

- *"Questions of lack of objectivity and bias ordinarily relate to views stated or positions taken that are largely intellectually motivated or that arise from the close identification or association of an individual with a particular point of view or the positions or perspectives of a particular group."* [NAS]
- Biases are not necessarily disqualifying, but a balance of potentially biasing backgrounds or professional or organization perspectives is needed.
- Some potential sources of bias may be so substantial that they would prevent an individual from considering others perspectives or relevant evidence contrary to their strongly held position.

Meeting Structure

1. Introductory Remarks, Ground Rules and Conflict of Interest discussion

2. Short presentation by authors

3. Panel asks clarifying questions of authors

4. Chair facilitates in-depth discussion of each charge question by panel. Authors available to answer panel questions.

Michael L. Dourson, PhD, DABT, FATS
Toxicology Excellence for Risk Assessment (TERA)

Dr. Dourson was selected for this panel for his expertise in dose-response assessment & mode of action analysis, and familiarity with U.S. EPA's carcinogen risk assessment guidelines. In addition, Dr. Dourson has extensive experience effectively chairing panels.

Disclosure: Dr. Dourson is the President of *TERA*, which is under contract with ToxStrategies to independently organize and conduct this peer review. See further discussion on website. In 1995, Dr. Dourson testified in a legal case about the risk assessment approach used by U.S. EPA to develop the maximum contaminant level (MCL) for chromium. *TERA* has concluded that this is not a conflict of interest or a bias because Dr. Dourson's testimony was limited to explaining how existing U.S. EPA standards were derived, and he did not provide his professional opinion on the toxicity of chromium at concentrations under discussion.

Jeffery Fisher, PhD, FATS, University of Georgia

Dr Fisher was selected for this panel for his expertise in the development of physiologically based pharmacokinetic models and his experience in serving on panels of expert scientists in review of risk assessments. *Disclosure*: None.

David Gaylor, PhD, FATS, Gaylor and Associates

Dr Gaylor was selected for this panel for his expertise in biostatistics, dose-response assessment, and for his experience in serving on panels of expert scientists in review of risk assessments.

Disclosure: Dr. Gaylor indicated that he is a past employee of General Electric, Co. and General Dynamics, Co. In addition, he has consulted in the past with 3M Corporation (2002-May 2009). All three companies are currently members of Aerospace Industry Association, which is the Sponsor of the review. *TERA* concluded that there is no conflict of interest or bias because none of the past work involved chromium and Dr. Gaylor has no current, ongoing financial relationship with these companies.

Kirk Kitchin, PhD, DABT, U.S. EPA

Dr. Kitchin was selected for this panel for his expertise in metals carcinogenicity, cancer mode of action research, and use of genomics in risk assessment.

Disclosure: None.

Bette Meek, M.Sc., University of Ottawa

Ms. Meek was selected for this panel for her expertise in genotoxicity, dose-response assessment, and mode of action analysis in a regulatory context. In addition, Ms. Meek has experience in serving on panels of expert scientists in review of toxicity assessments.

Disclosure: None.

Xianglin Shi, PhD, University of Kentucky

Dr. Shi was selected for this panel due to his expertise in chromium mode of action research, particularly for his understanding of the role of oxidative stress and DNA damage in chromium toxicity. Dr. Shi also has expertise in genomics, proteomics, transcriptional analysis, and imaging.

Disclosure: None.

Patrick Winter, PhD, Washington University

Dr Winter was selected for this panel for his expertise in molecular imaging.

Disclosure: None.



WV TAP

WEST VIRGINIA TESTING ASSESSMENT PROJECT

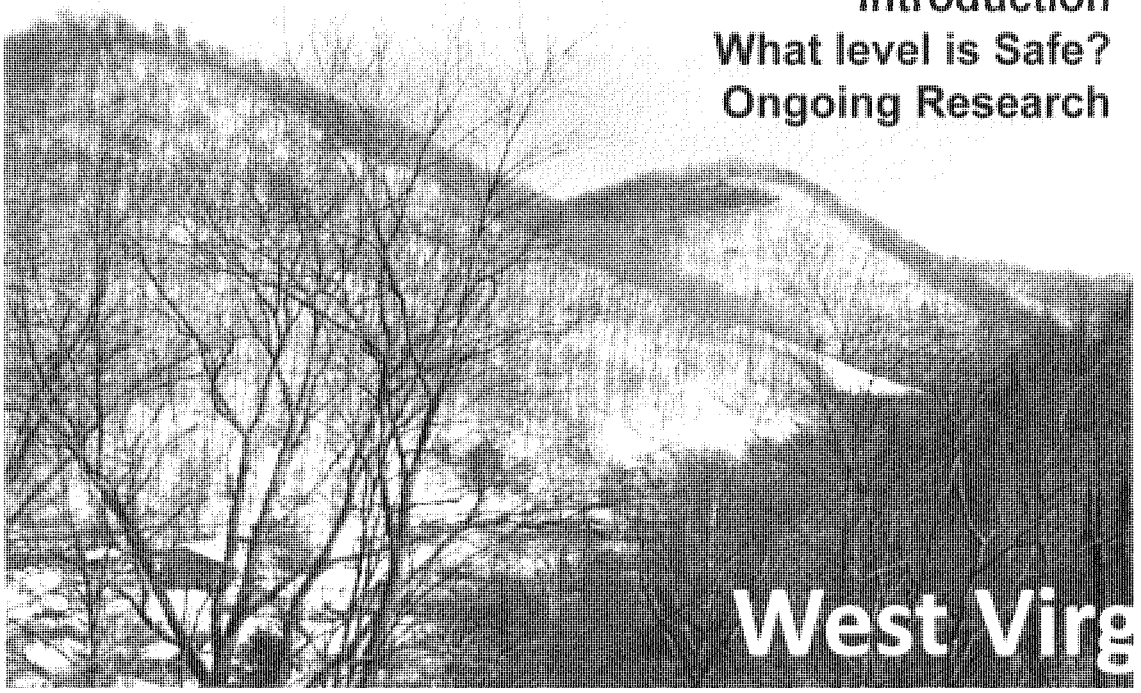
Short Term Health Advisories for Elk River Crude MCHM Spill

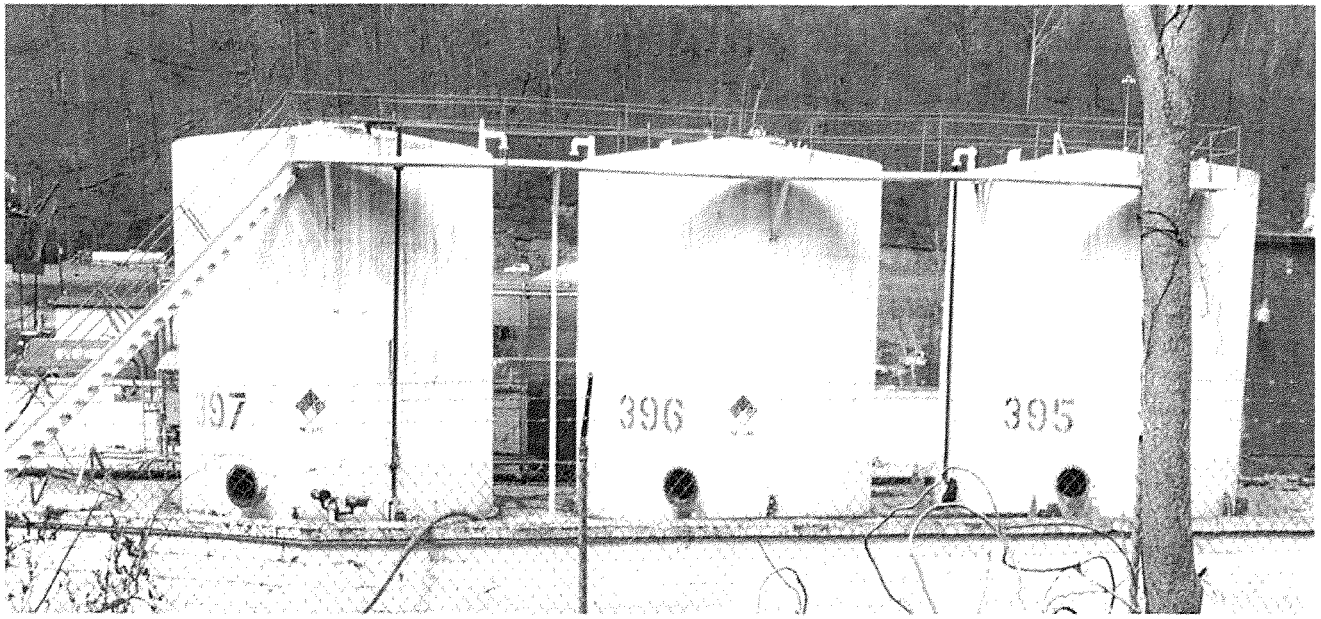
Michael Dourson
Toxicology Excellence for Risk Assessment

British Society of Toxicology
April 20, 2015
St. Johns Hotel, Solihull, England

Talk Outline:

Introduction
What level is Safe?
Ongoing Research

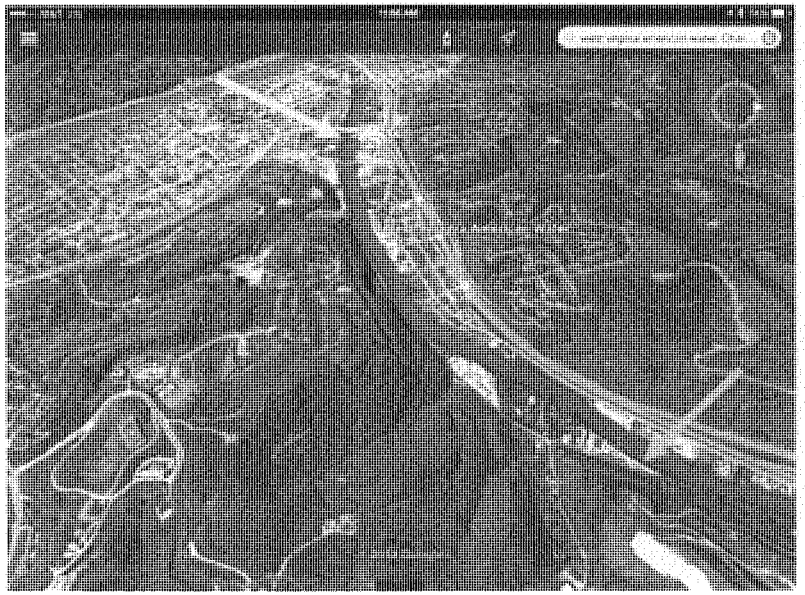




Freedom Industries, Inc.

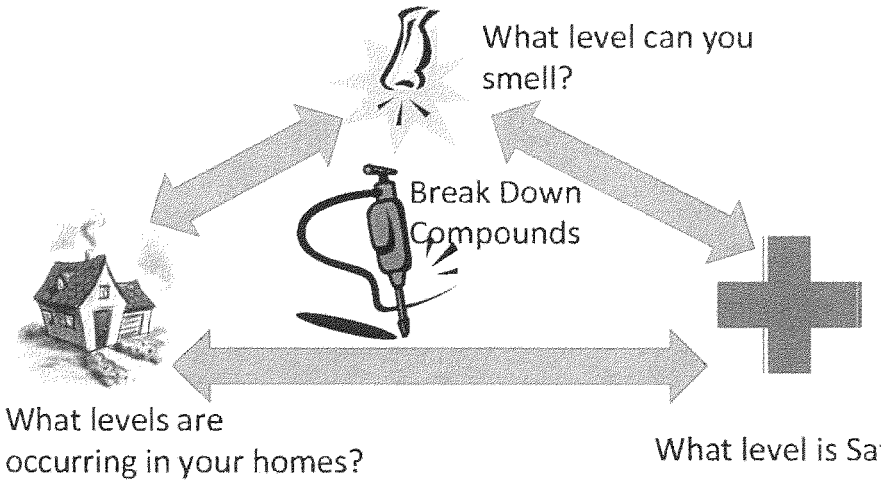
Spill occurred from tank 396 and later discovered also from 397

Window of Detection and Action



- About 1 mile from intake.
- Travel time estimated to be 1.1 – 1.8 hours
- Spill may have started a few days before it was detected.
- First detection, human olfactory sensors.
- Freedom Inc. knew about the spill and was trying to clean it up when it was discovered by state DEP

The Structure and Rationale of WVTAP



What Level is Safe?

TASK: Independently evaluate the safe levels of MCHM and PPH for all members of the population for all intended uses

- Comprehensive literature review of relevant toxicological literature (Adams, 2014)
- Health Effects Expert Panel on March 31, 2014 in Charleston, West Virginia: evaluate available toxicity data and health advisories

What Was Spilled?

- **Crude MCHM (Eastman) 88.5%**
  - Used in coal processing
  - The Crude MCHM is a mixture containing:
    - **4-Methyl-1-cyclohexanemethanol (MCHM) @ 68-89% (w/w);**
    - 4-(Methoxymethyl) cyclohexane methanol (**MMCHM**) @ 4-22% (w/w) ;
    - Methyl 4-methylcyclohexane-1-carboxylate (**MMCHC**) @ 5% (w/w);
    - 1,4-Dimethyl cyclohexanedicarbonate (**DMCHDC**) @ 1-2% (w/w);
    - 1,4-Cyclohexanedimethanol (**CHDM**); and
    - Methanol (**MeOH**) @ 1-2% (w/w).

Specific Charge Questions to Panel

1. Given data now available, what would be appropriate screening levels for MCHM and PPH in drinking water?
2. What additional data, analyses, or studies might reduce uncertainty and provide greater confidence?
3. How should the presence of multiple chemicals in the release to the Elk River be considered?
4. Are the screening values protective for all potential routes of exposures (i.e., ingestion, dermal and inhalation)?
5. Other issues?

WV TAP Expert Panel

(affiliations listed for identification purposes only)

Expertise in toxicology, risk assessment, deriving risk values for water contaminants, and water quality and distribution systems.

- **Dr. Michael Dourson, chair,** Toxicology Excellence for Risk Assessment, Cincinnati, OH, USA
- **Dr. Shai Ezra,** Mekorot, Israel National Water Company Ltd, Tel Aviv, Israel
- **Dr. James Jacobus**, Minnesota Department of Health, Saint Paul, MN,USA
- **Dr. Stephen Roberts**, University of Florida, Gainesville, FL. USA
- **Dr. Paul Rumsby**, National Centre for Environmental Toxicology at WRc plc, Swindon, UK

Available Data on MCHM – very limited

- Crude MCHM, acute gavage in rats, 250 - 1000 mg/kg-day; Possible hematuria (Eastman 1998, 1999)
- Pure MCHM, gavage in rats Eastman (1990)
  - 0, 25, 100, and 400 mg/kg/day, 5 days a week, for 4 weeks
  - 400 mg/kg/day – anemia (F), kidney and liver effects
  - NOEL 100 mg/kg/day
  - Proprietary, OECD and GLP
  - **Study used by CDC**

Critical Effect of MCHM?

Absolute kidney weights for male rats heavier at 25 mg/kg.
Relative kidney weights statistically heavier for all treated males.

No differences were seen in female rats.

Relative and absolute changes might be adverse. However:

- Higher doses did not show statistically significant increase in absolute kidney weights;
- Kidney weights, both relative and absolute, did not show a dose-related trend; and
- Low dose effects did not have matching clinical changes or histopathology, which when compared with organ weight changes, are more definitive.

CDC Advisory MCHM

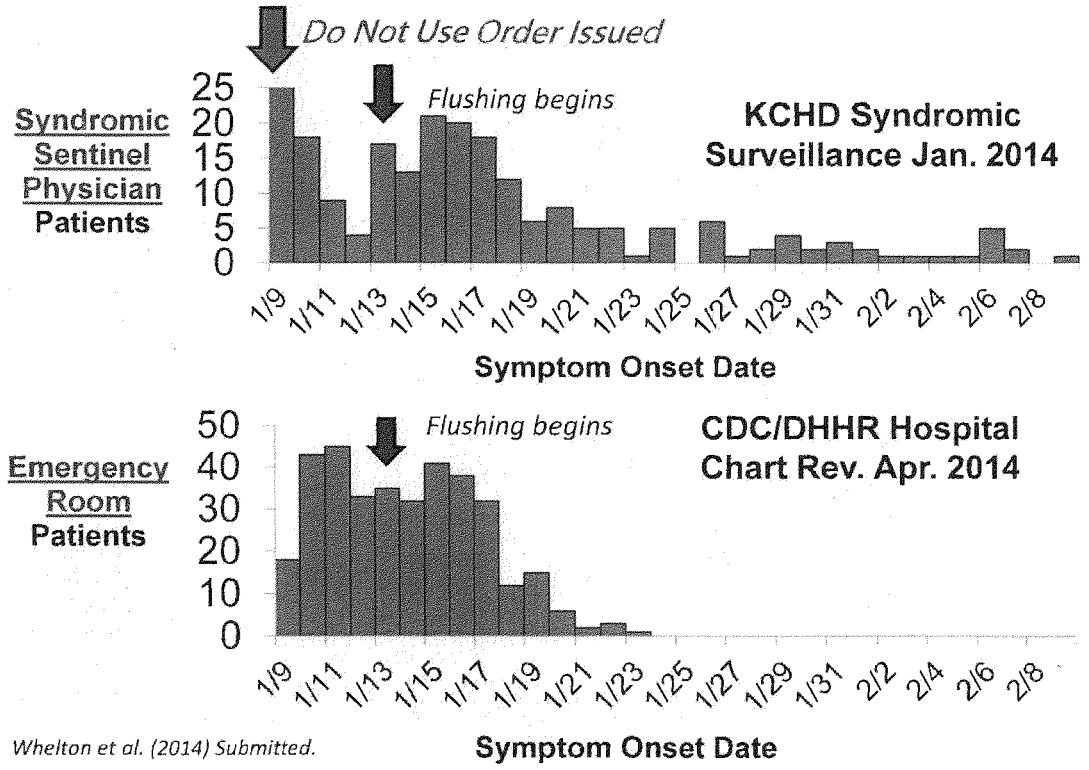
- January 9, 2014, January 20, 2014
- Methodology: EPA DW advisory methods (Donohue and Lipscomb, 2002)

DW Advisory Level ≤ (NOEL × BW) / (UF × Intake)

- NOEL: 100 mg/kg-day (Eastman, 1990)
- Consumption:
  - BW of a child: 10 kg
  - Intake: 1 liter/day, water intake for child.
- Uncertainty Factors (UF): 1000 (UFA, UFH, UFDB)
- **1 ppm or 1000 ppb screening level**

CDC (2014) "Information about MCHM - 2014 West Virginia Chemical Release" http://www.bt.cdc.gov/chemical/MCHM/westvirginia2014/mchm.asp . January 20

Plumbing System Flushing: REAL-TIME Syndromic Surveillance Would Have Revealed Illnesses were being Caused



Whelton et al. (2014) Submitted.

WV TAP Expert Panel

- CDC used traditional methods and reasonable assumptions to develop their screening levels

- The Panel considered additional exposure routes:
  - Direct ingestion of water, including formula-fed infants
  - Inhalation from showering and cooking
  - Skin exposure to water uses in the house
  - Incidental exposures, including brushing teeth, watering plants.

- The Panel determined formula-fed infants to be the most highly exposed population/life stage

Panel Advisory for MCHM

- Methodology – not constrained, used full experience
- NOEL: 100 mg/kg-day (Eastman, 1990)
  - Adjusted to 71 mkd for 5 day/week dosing
- Consumption: 0.285 liters/kg bw (95th percentile)
  - Formula fed infant - most exposed life stage
- Allow for other possible sources and routes of exposure (i.e., dermal, inhalation): factor of 0.5
- Uncertainty Factors (UF): 1000 (UFA, UFH, UFDB)

Panel Calculated Level for MCHM

DW Advisory Level = (NOEL × BW) / (UF × Intake)

→ DW Advisory Level ≤ [(NOEL) / (UF × Intake/BW)] · Exposure factor

where:

DW Advisory Level is the drinking water advisory level (µg/L or ppb)

NOEL = No Observed Effect Level in the experiment = 71 mg/kg/day

UF = uncertainty factors (unitless)

- for differences between humans and animals (10x)
- to account for more sensitive humans (10x)
- to account for in the toxicity database data (10x)

Intake / BW = water consumed daily by a bottle-infant (0.285 L/kg·d)

Exposure factor = to account for other sources of exposure (0.5)

4-week DW Advisory Level = (NOEL) / (UF × Intake/BW) · Exposure factor

= [(72 mg/kg/d)] / [(10×10×10) = 0.0072 (rounded to 0.07)

0.07 mg/kg-day / (0.285 L/kg·day)] · 0.5 = 0.123 mg/L (rounded to 120 µg/L)

PPH and DiPPH

- CDC
  - PPH: 1200 ppb
  - DiPPH: Limited data suggest similar or lower toxicity, the PPH screening value would also be protective for DiPPH.
- Expert Panel
  - PPH: 880 ppb
  - DiPPH:260 ppb

  See expert panel report for details - http://www.tera.org/Peer/WV/WV%20Expert%20Report%2012%20May%202014.pdf

What about the Mixture?

- Toxicity data on specific chemical mixtures are rarely available.
- Toxicity of mixtures in spill could be approximated by a simple additive approach (MCHM, PPH, DiPPH, etc) following US EPA's mixtures guidelines (US EPA 1986 and 2000)
- For example, it is reasonable to assume that the toxicity of the mixture (Crude MCHM) would be similar to the pure MCHM.

Research Needs

1. Determine MCHM potential to cause skin irritation.
2. Conduct toxicology studies for MCHM in pregnant animals.
3. Organize all available data on exposures and health effects (from immediately following the spill) to facilitate the estimation of initial conditions.
4. Pending results of #2 and #3, consider the need for long term health effects study.
5. Determine chemical fate and transport within the treatment plant and water distribution system.

US National Toxicology Program
Research Progress

February 2015 Update for 5-Day *In Vivo* Micronucleus Assay

- The results for all three chemicals were negative; none increased the frequency of micronucleated red blood cells in male rats after oral administration for five days.

December 2014 Update for **Prenatal Developmental Toxicity**

- 150 to 900 mg/kg-day of MCHM was gavaged to pregnant Harlan Sprague Dawley rats from gestational day 6 to 20.
- The results indicate increased post-implantation pregnancy loss occurred at doses that induced maternal toxicity.

Summary

- The WV TAP Expert Panel reviewed the CDC and WV screening values and reached conclusions that are not incompatible with the CDC values.

- Panel used more refined methods, including an adjustment to account for dermal and inhalation exposure.

- MCHM concentrations below 120 ppb are safe for ALL members of the community for ALL intended uses for up to 1 month of exposure.

Acknowledgements

- WV TAP Technical Team
  - Jeffrey Rosen, Program Manager
  - Andrew Whelton, University of South Alabama
  - Craig Adams, Utah State University

- Funding and support from:
  - West Virginia Bureau for Public Health (WVBPH)
  - West Virginia Department of Health and Human Resources (WVDHHR).

More Information and References

Expert Panel Report

- http://www.tera.org/Peer/WV/WV%20Expert%20Report%2012%20May%202014.pdf

WVTAP Web Site

- http://www.dhsem.wv.gov/wvtap/test-results/Pages/default.aspx

Questions?

WVTAP Literature Review

Adams, C., Whelton, A., Rosen, J. (2014) "Health Effects for Chemicals in 2014 West Virginia Chemical Release: Crude MCHM Compounds, PPH and DiPPH,"

Public report by West Virginia Testing Assessment Project (WV TAP) to the State of West Virginia.

Very limited data for MCHM

TOXICOLOGY EXCELLENCE FOR RISK ASSESSMENT
INDEPENDENT • NON-PROFIT • SCIENCE
FOR PUBLIC HEALTH PROTECTION

WV TAP
WEST VIRGINIA TESTING ASSESSMENT PROJECT

Additional Question by WV for the Expert Panel

- **Was the additional safety factor applied by the State of West Virginia protective of public health, based on available data?**

  - CDC initial screening value of 1 ppm (1,000 ppb) 4-MCHM
  - WV screening level later set at 10 ppb

Was the additional safety factor applied by the State of West Virginia was protective of public health, based on available data?

--CDC initial screening value of 1 ppm (1,000 ppb)

--WV screening level later set at 10 ppb

- Panel derived short-term advisory of 120 ppb
- Protect all portions of the population (inc. infants, children, pregnant women)
- Protect for exposures from direct ingestion, inhalation from showering and household water use, dermal exposure.
- Appropriate for apply to exposure situations of 1 day up to 3 months.

What Was Spilled?

- **DOW PPH Basic 7.3%**
  - It is reported that the source of the Freedom Industries' PPH was DOW PPH Basic
  - DOW Basic contains:
    - Dipropylene glycol phenyl ether (**DiPPH**) concentration at between 40% and 85%;
    - Propylene glycol phenyl ether (**PPH**); and
    - Other compounds.

Key Studies for PPH

- Oral toxicological data on PPH include:
  - A 90-day drinking water study (and 28-day range finding study) in rats (OECD 408 – BASF AG 1997a) study used by PANEL
  - A two-generation study drinking water study in rats (OECD 416 – BASF 2000)
  - A prenatal developmental toxicity studies using gavage with rats (OECD 414 – BASF AG 2000) and rabbits (OECD 414 – BASF AG 1995 and OECD 2006c) study used by CDC
  - In vitro and in vivo genetic toxicity tests

WV TAP Panel Screening Level for PPH

DW Advisory Level ≤ (NOEL × BW) / (UF × Intake)

→ DW Advisory Level ≤ [(NOEL) / (UF × Intake/BW)] · Exposure factor

where:

DW Advisory Level is the drinking water advisory level (µg/L or ppb)

NOEL = No Observed Effect Level in the experimental species = 146 mg/kg/day (from 90-day DW study)

UF = uncertainty factors (unitless)

for differences between humans and animals (10x)

to account for more sensitive humans (10x)

to account for in the toxicity database data (3x)

Intake / BW = water consumed daily by a bottle-infant (0.285 L/kg·d)

Exposure factor = factor to account for other sources of exposure other than ingestion (i.e., inhalation, dermal) (0.5)

90-day DW Advisory Level = (NOEL) / (UF × Intake/BW) · Exposure factor

= [(146 mg/kg/d)] / [(10×10×3) = 0.49 (rounded to 0.5 for a short term RfD)

0.5 mg/kg-day / (0.285 L/kg·day)] · 0.5 = 877 (rounded to 880 µg/L or ppb)

CDC	PANEL
No Observed Adverse Effect Level (NOAEL) = 40 mg/kg-day teratology study in rats, maternal toxicity	NOAEL = 146 mg/kg-day ((ECHA, 2014), 90-day DW study in rats
Uncertainty Factor = 10H, 10A, 10D	Uncertainty Factor = 10H, 10A, 3D (missing second repeat dose tox study)
Intake = 1 liter water/day (child) Body Weight = 10 kg (child)	0.285 liters/kg bw (95th percentile) Formula fed infant most exposed life stage
Ingestion of water only	RSC = 0.5 to allow for other possible sources and routes of exposure (i.e., dermal, inhalation)
PPH Screening Level = 1200 ppb	PPH Short-Term Health Advisory = 880 ppb

10H = 10x human variability; 10A = 10x animal to human extrapolation; 10D = 10x data base sufficiency

WV TAP Panel Screening Level for DiPPH

DW Advisory Level ≤ (NOEL × BW) / (UF × Intake)

→ DW Advisory Level ≤ [(NOEL) / (UF × Intake/BW)] · Exposure factor

where:

DW Advisory Level is the drinking water advisory level (µg/L or ppb)

NOEL = No Observed Effect Level in the experimental species = 146 mg/kg/day (from 90-day DW study)

UF = uncertainty factors (unitless)

for differences between humans and animals (10x)

to account for more sensitive humans (10x)

to account for in the toxicity database data (10x)

Intake / BW = water consumed daily by a bottle-infant (0.285 L/kg·d)

Exposure factor = factor to account for other sources of exposure other than ingestion (i.e., inhalation, dermal) (0.5)

90-day DW Advisory Level = (NOEL) / (UF × Intake/BW) · Exposure factor

= [(146 mg/kg/d)] / [(10×10×10) × (0.285 L/kg·d)] · 0.5 ≤ 256 or 260 µg/L (ppb)

Note short term Reference Dose not calculated since toxicity is based on PPH.



TERA

Toxicology Excellence for Risk Assessment

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

Environmental Risk Assessment…
…in the 21st Century

Michael L. Dourson, Ph.D., DABT, ATS



TERA

Toxicology Excellence for Risk Assessment

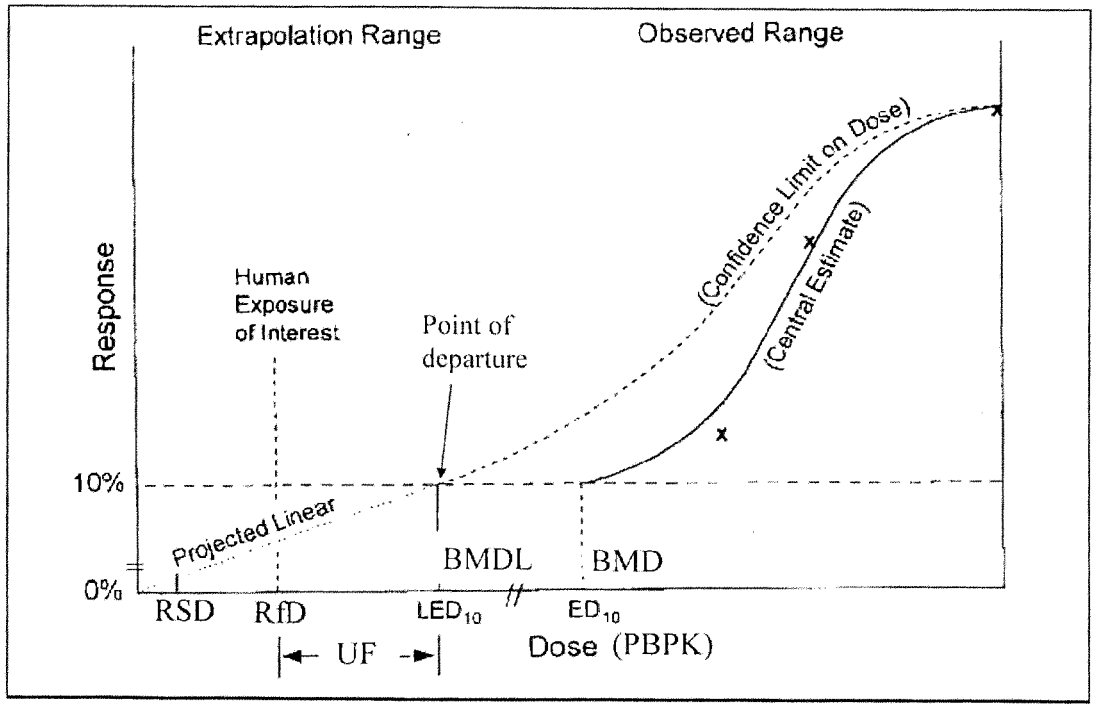
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Seminar Overview

- Know traditional risk methods…cold
  - Think like a clinician
  - Challenge non-experts
- Use contemporary methods often
  - BMD, categorical regression, CSAF, PBPK
- Create future by collaboration and research
  - Hang together, or hang separately (paraphrased B. Franklin)
  - Focus on collaboration among agencies

Do You Know the Traditional Methods?

Adapted from EPA, 1999





TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Do You Know the Traditional Methods?

- If we had a array of effects that were all linked into one syndrome of toxicity, what would be the point of departure for a dose response assessment?
- If we had only 8 fingers, what would be the uncertainty factor covering experimental animal to human and within-human variation?



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Traditional: Critical Effect

- Risk assessment is… preventive medicine. Thus, involve clinicians in judgment of critical effect, or at least think like one…
  - …but do not let them do the dose response assessment!
  - 25 years in the clinic does not prepare one to estimate an RfD, even if the critical effect appears to lie within your area of expertise.
- Critical effect is…

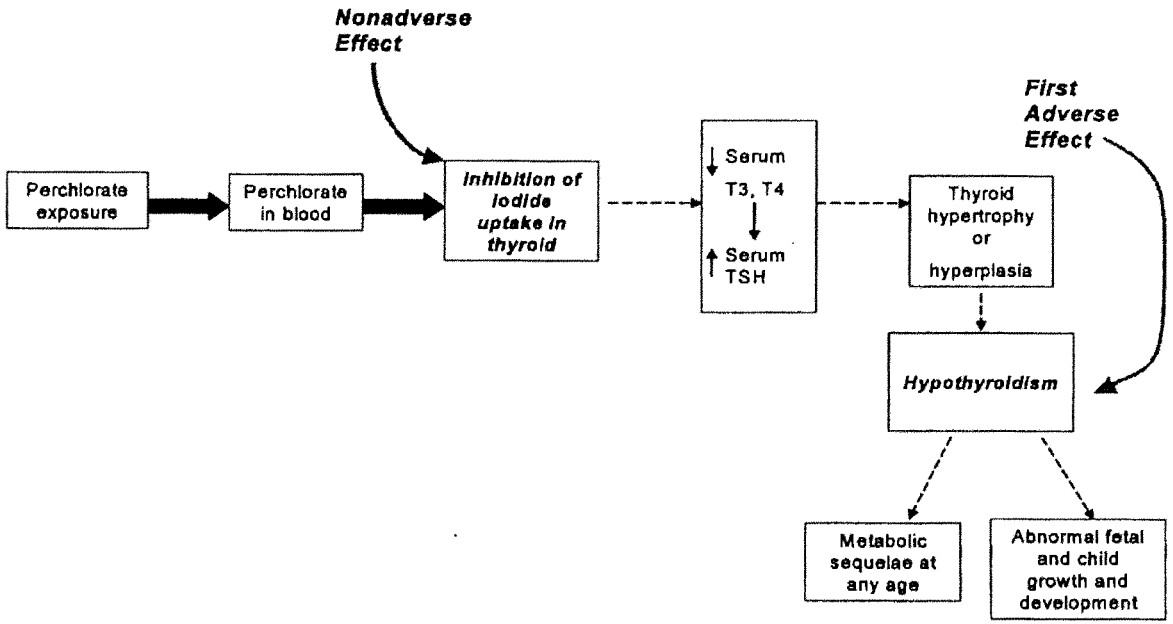


FIGURE 5-2 Committee's suggested mode-of-action model for perchlorate toxicity in humans indicating first adverse effect in the continuum.



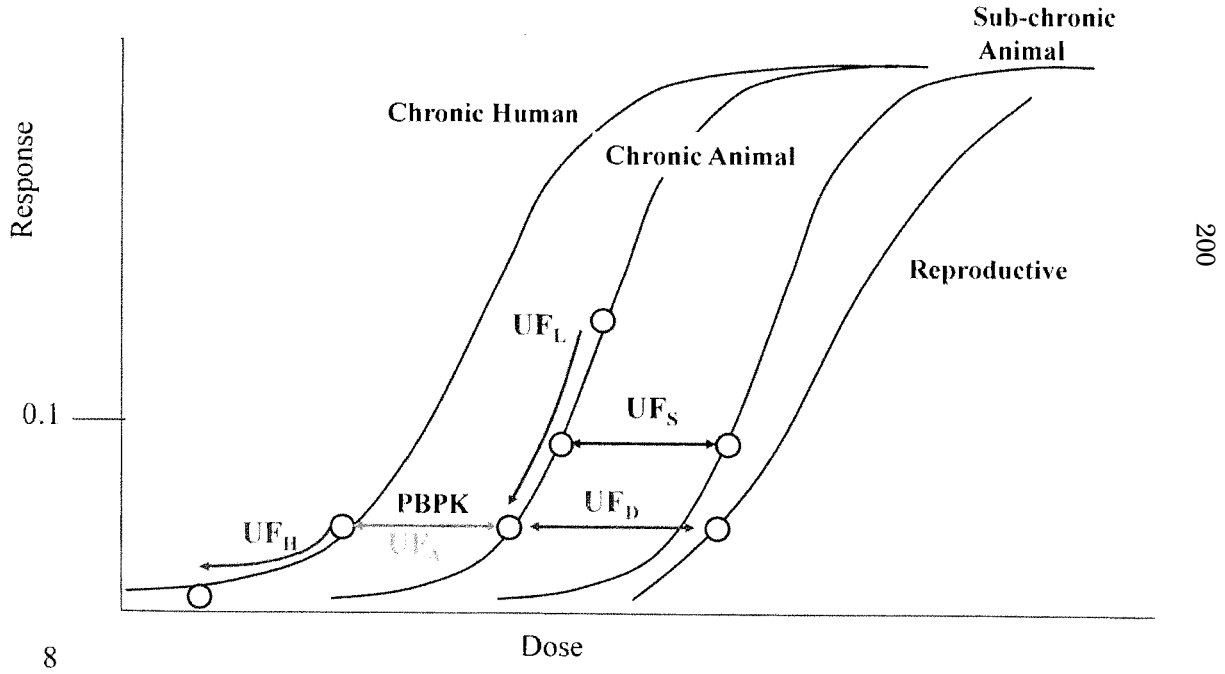
TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Traditional: Uncertainty Factors

- Uncertainty factors for within human, experimental animal to human, LOAEL to NOAEL, subchronic to chronic and lack certain data.

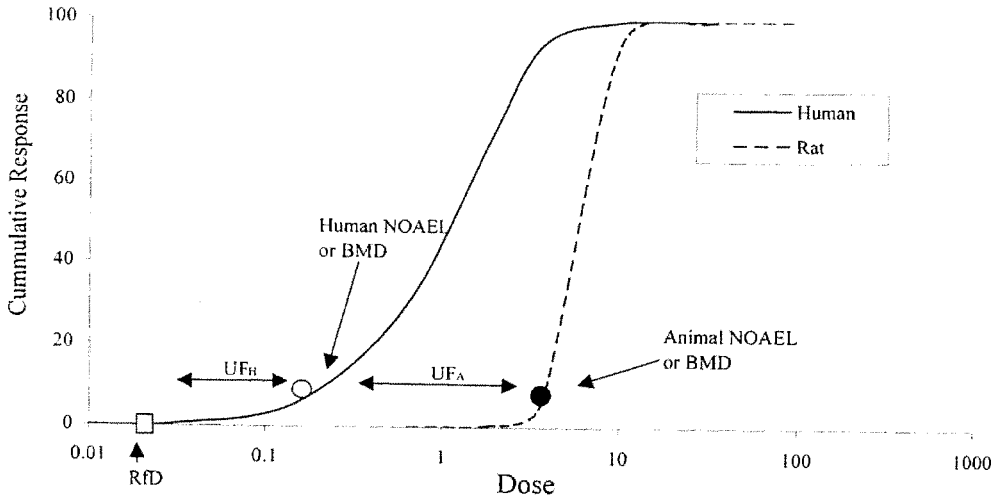
- Misconceptions:
  - Studies with small "n" are not useful.
  - An uncertainty factor of 10-fold with human data is often not enough.

Areas of Uncertainty to Consider in Noncancer Dose Response Assessment



Factor of 10 Enough?

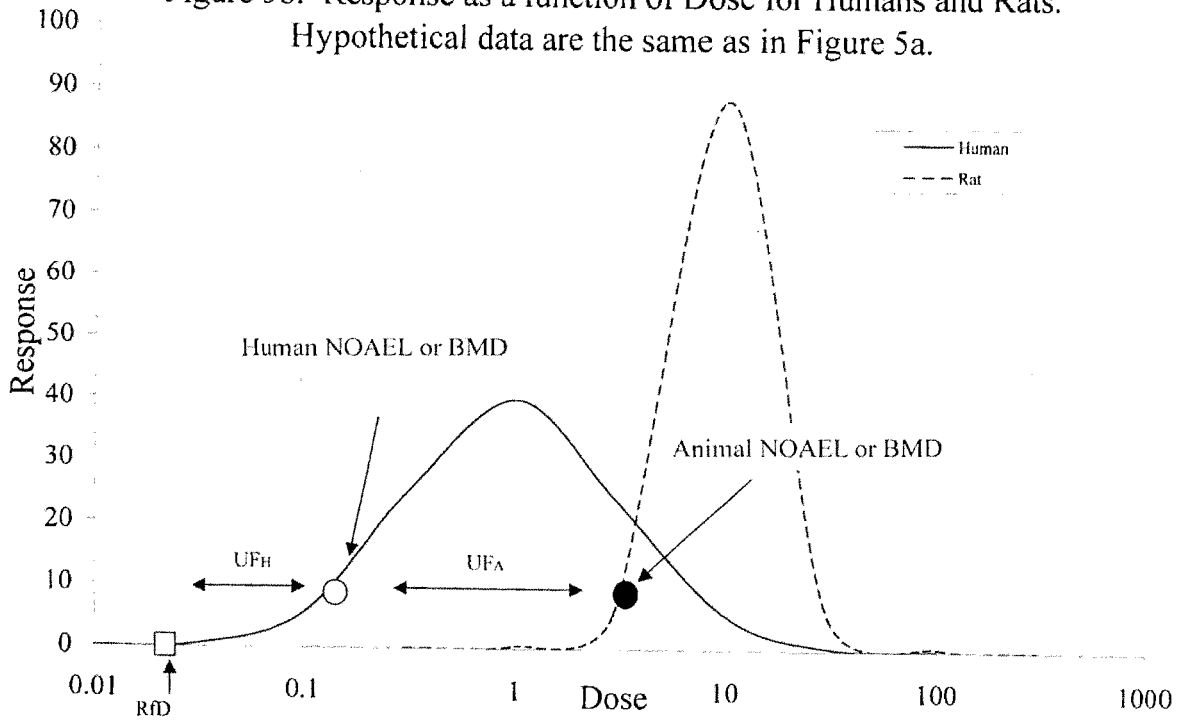
Figure 5a. Cumulative Response as a function of Dose for Humans and Rats. Data are hypothetical, but approximate real situations.



Dourson, M.L., G. Charnley and R. Scheuplein, 2002

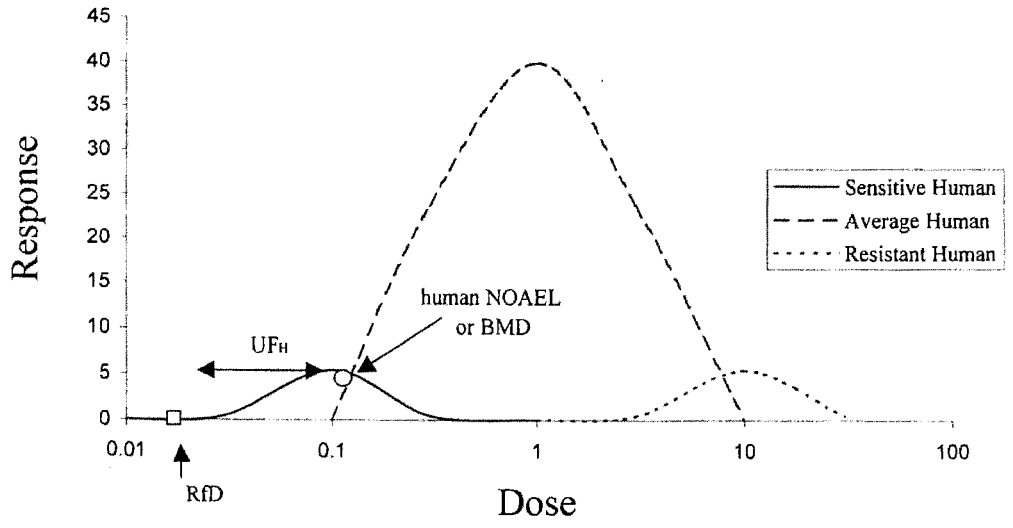
Factor of 10 Enough?

Figure 5b. Response as a function of Dose for Humans and Rats.
Hypothetical data are the same as in Figure 5a.



Factor of 10 Enough?

Figure 6a. Response as a function of dose for humans of different sensitivities. Hypothetical data for humans are the same as in Figure 5b.





TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

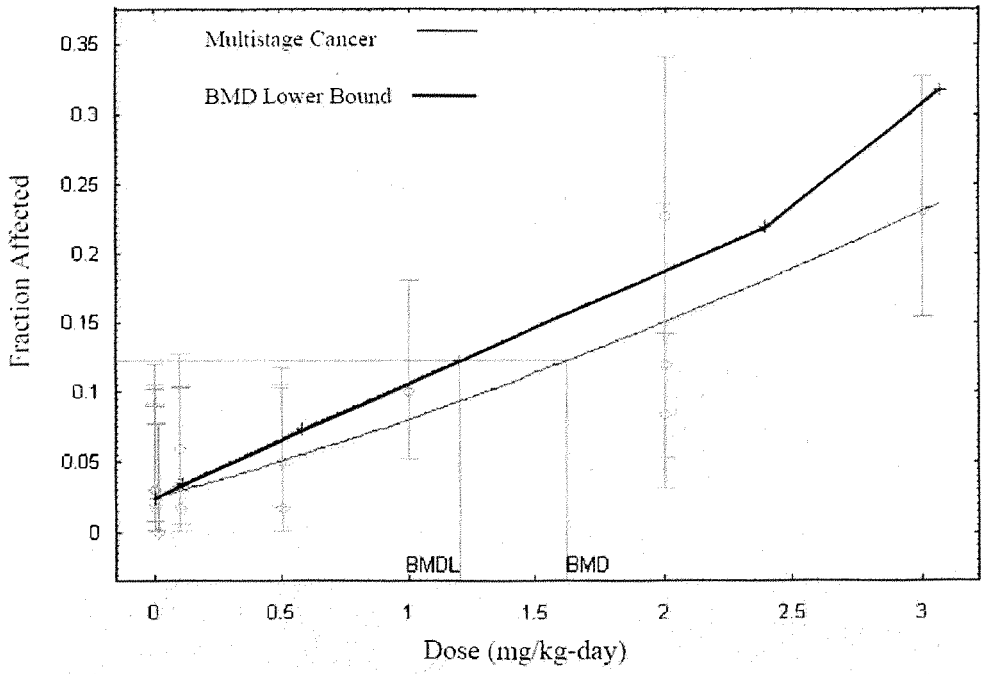
Contemporary: BMD

Clear advantages and disadvantages exist in the use of a benchmark dose (BMD)

- Uses responses near the range of observation.
- Includes a measure of variability in the response.
- Determines a consistent measure of response.
- Applies to fewer, more robust, toxicity data sets.
- Accounts for more dose response of critical effect.

Casarett and Doull (Sixth Edition) page 94

Figure 2a. Multistage Model Fitted To Pooled Thyroid Tumors, Showing Small Change In Slope Between Low & High Doses



Dourson M.L., R. Hertzberg, B. Allen, L. Haber, A. Parker, O. Kroner, A. Maier, and M. Kohrman, 2008

Figure 2b. Probit Model Fitted To Pooled-all Thyroid Tumor Data, Showing Differing Slopes Between The Low & High Doses

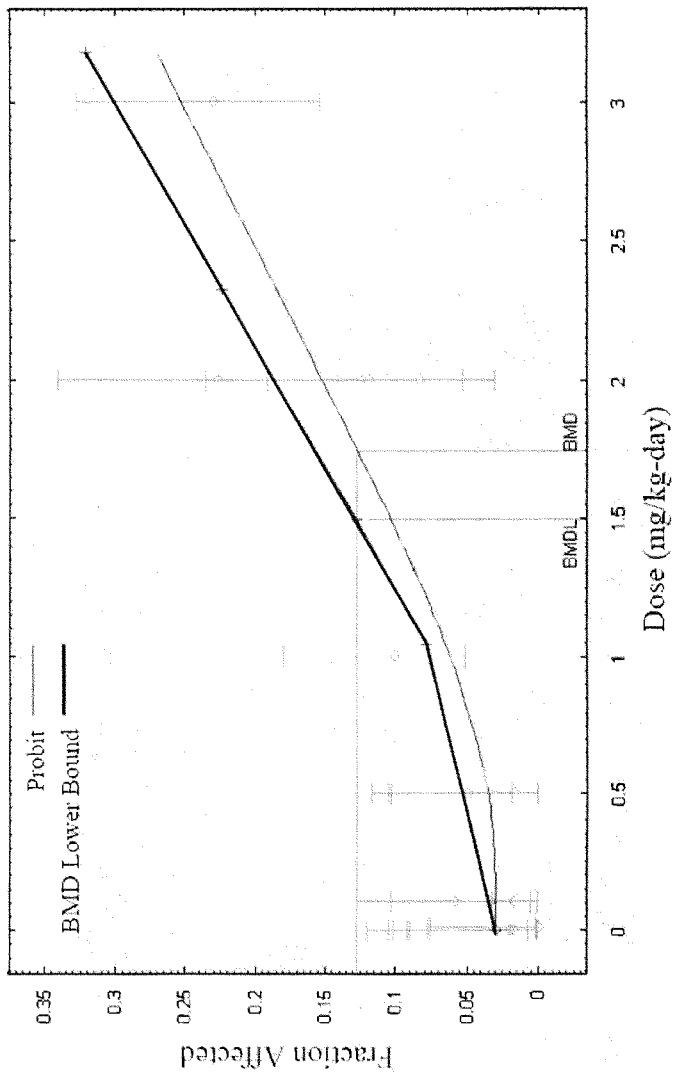


Table 5. Comparison Of 2% BMD, BMDL & Slope Factors (SF) For Acrylamide's Thyroid Tumors In Rats

Data Set	Model	BMD_{02}	SF BMD_{02}	$BMDL_{02}$	SF $BMDL_{02}$	BMD/BMDL
All pooled tumors	Multistage	0.39	0.052	0.23	0.087	1.7
Low-dose pooled tumors	Multistage	0.80	0.025	0.23	0.088	3.5
All pooled tumors	**Probit**	**0.81**	**0.025**	**0.69**	**0.029**	**1.2**
All pooled tumors	Weibull	0.82	0.024	0.72	0.028	1.1
Low-dose pooled tumors	Weighted linear regression	0.92	0.022	0.33	0.061	2.8

P-values for all regressions exceed 0.1 and thus are acceptable; AICs and residuals for the multistage and probit models with all pooled tumors were comparable, however, BMD/BMDL ratios (above) and visual fit differ (see Figure 2a,b). Bold printed row indicates model chosen for extrapolation to humans.

Contemporary: Categorical Regression

RfD Definition	Regression model
"without appreciable risk"	$r < 10^{-2}$
"is likely to be"	$P(*) > 0.95$
"deleterious effect"	severity = moderate or frank

New RfD Definition

$P (r < 10^{-2}$ at dose<RfD $) > 0.95$

where $r = P$ (severity >1)

Hertzberg R.C. and M.L. Dourson, 1993

Aldicarb Clinical Studies

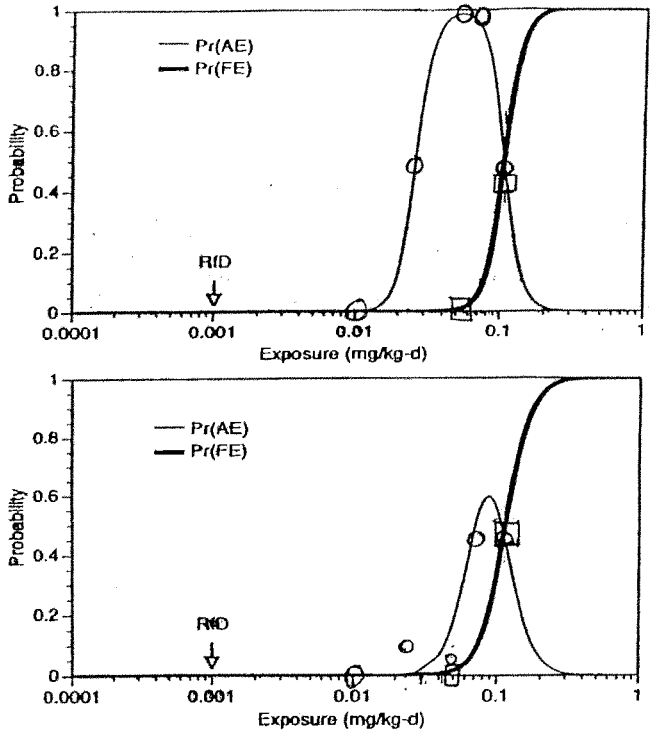
Frequency of Clinical Signs or Blood Cholinesterase				
Study	**Dose (mg/kg-day)**	**Group Size**	**Clinical Signs**	**Blood Cholinesterase Inhibition[a]**
Haines, 1971	0.025	4	1 Apprehension	4 Whole blood
	0.05	4	1 Runny nose[c]	4 Whole blood
	0.10	4	4 Weakness and sweating, Nausea in 2 individuals	4 Whole blood
Wyld et al., 1992[b]	0	22	0	0 Plasma & 0 RBC
	0.010	8	2 Headaches[c]	0 Plasma & 0 RBC
	0.025	12	1 Sweating	12 Plasma & 11 RBC
	0.050	12	1 Sweating	1 Plasma & 1 RBC
	0.06	1	1 Sweating	1 Plasma & 1 RBC
	0.075	3	1 Lightheadedness	3 Plasma & 3 RBC

Dourson, M.L., L.K. Teuschler, P.R. Durkin and W.M. Stiteler, 1997

Effect Categories of Aldicarb Exposure in Humans

Frequency of Categories of Effect Associated with Aldicarb Exposure in Humans						
Study	Dose (mg/kg/day)	Group Size	Frequency of Responders within Categories of:			
			NO Effects	Non-adverse Effects	Adverse Effects	Frank Effects
Wyld	0.0	22	**22 (22)**	0 (0)	0 (0)	0 (0)
Wyld	0.010	8	**8 (0)**	0 (0)	0 (0)	0 (0)
Wyld	0.025	12	0 (0)	**8 (11)**	**4 (1)**	0 (0)
Wyld	0.025	4	0 (0)	**0 (3)**	**4 (1)**	0 (0)
Wyld	0.50	12	0 (0)	**1 (11)**	**11 (1)**	0 (0)
Wyld	0.50	4	0 (0)	**0 (4)**	**4 (0)**	0 (0)
Wyld	0.075	4	0 (0)	**0 (2)**	**4 (2)**	0 (0)
Haines	0.10	4	0 (0)	0 (0)	**2 (2)**	**2 (2)**

Probability of Category with Aldicarb

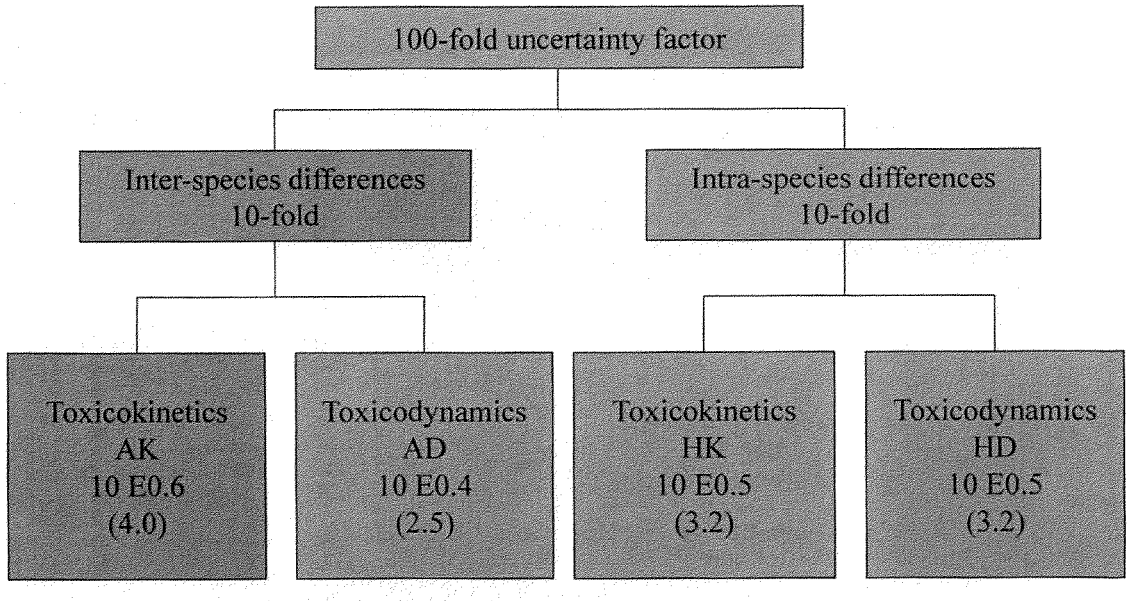


Contemporary: Categorical Regression

- Advantages:
  - provides a consistent basis for calculating risk above the RfD
  - all useful data can be categorized
  - accounts for severity of toxic effect
- Limitations:
  - animal to human extrapolation is still needed
  - data are transformed into categories which loses information

Patty's Toxicology, Volume 1 (Fifth Edition) pages 209-213

Contemporary: Chemical Specific Adjustment Factor (CSAF)



International Programme on Chemical Safety (IPCS). 2005.

Boron...	CSAF	Justification
Absorption	1	Absorption is complete.
Distribution	1	Distribution occurs by passive diffusion.
Metabolism	1	No metabolism.
Elimination	4	Clearance is 3 to 4 times faster in rats than humans.
Total kinetics (default is 4)	4	Interspecies differences in kinetics were dominated by elimination.
Dynamics (default is 2.5)	2.5	Default of 2.5 was retained.
Interspecies	10	Factor to be applied.

Dourson, M.L., A. Maier, B. Meek, A. Renwick, E. Ohanian and K. Poirier. 1998.

Boron Area	CSAF	Justification
Absorption	1	As above
Distribution	1	As above
Metabolism	1	As above
Elimination	1.8	Elimination dominated by the glomerular filtration rate, a 1.8 fold variation between the average pregnant woman and two standard deviations below that.
Total kinetics (default is 3.2)	1.8	See note under elimination above.
Dynamics (default is 3.2)	3.2	Default of 3.2 was retained.
Intraspecies	5.7	Factor to be applied.



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of science data for risk values

Final CSAF for Boron

$$CSAF = AK_{AF} \times AD_{AF} \times HK_{AF} \times HD_{AF}$$

$$= 4 \times 2.5 \times 1.8 \times 3.2$$

$$= 57 \text{ (rounded to 60)}$$

EPA IRIS (2009) uncertainty factor is

$$= 3.3 \times 3.16 \times 2 \times 3.16$$

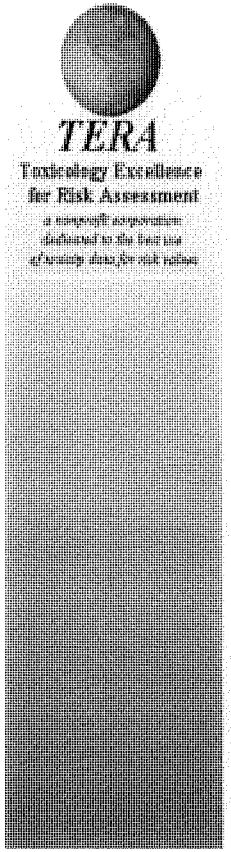
$$= 66$$



TERA
Toxicology Excellence for Risk Assessment
a nonprofit corporation dedicated to the best use of toxicity data for risk values

Contemporary: PBPK

- It is now routine to ask folks whether or not a PBPK model is available for the chemical of interest.
- Numerous PBPK papers; some have been given top awards (RASS of SOT papers of the year):
  - Sweeney, L. et al. (2001). Proposed occupational exposure limits for select glycol ethers using PBPK models and Monte Carlo simulation. Toxicol. Sci. 62(1):124-139.
  - Kirman, C.R., et al. (2004). Addressing nonlinearity in the exposure-response relationship for a genotoxic carcinogen: cancer potency estimates for ethylene oxide. Risk Anal. 24:1165-1183.



Create the Future: Collaborate/Research

- Risk Information Exchange (RiskIE)
- International Toxicity Estimates for Risk (*ITER*)
- Alliance for Risk Assessment (*ARA*)
- CRADAs, testing of mutational MOA with NCTR
- Genomics
- NAS (2008)
- Peer review

RiskIE

Risk Information Exchange

www.allianceforrisk.org/RiskIE.htm



- An interactive Database to Communicate In-Progress Risk & Toxicity Assessments
- Includes over 7000 projects being conducted by more than 27 organizations representing 13 countries
- Available at the Alliance for Risk Assessment (*ARA*) website

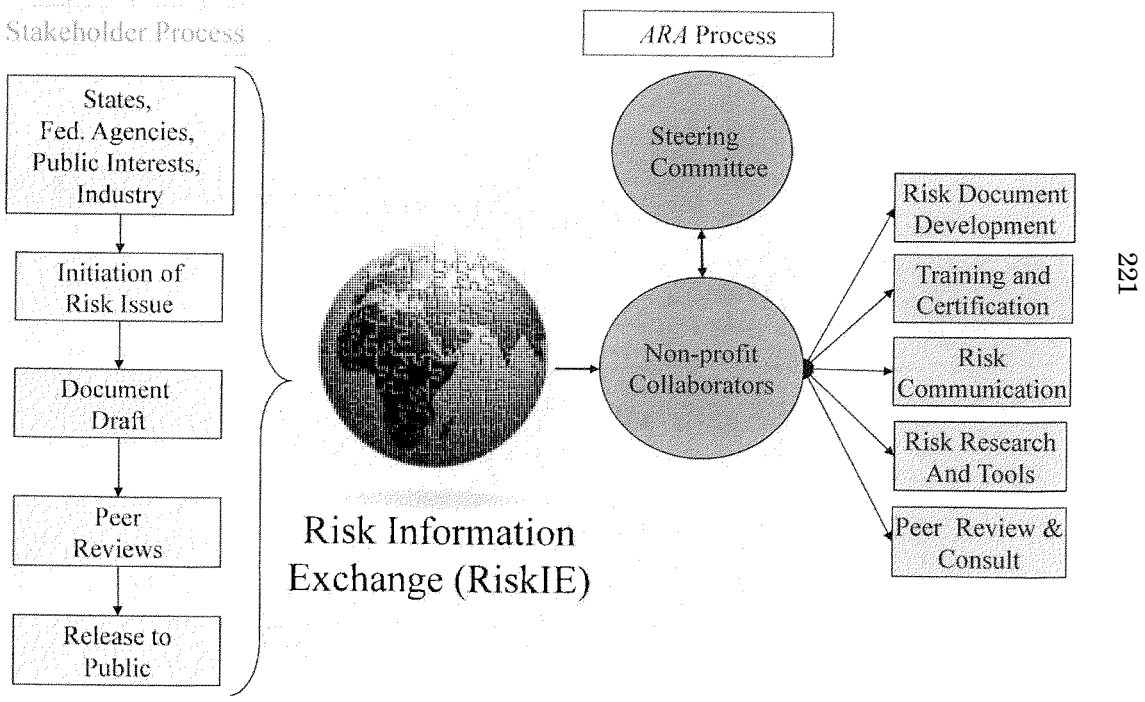
ITER

International Toxicity Estimates for Risk

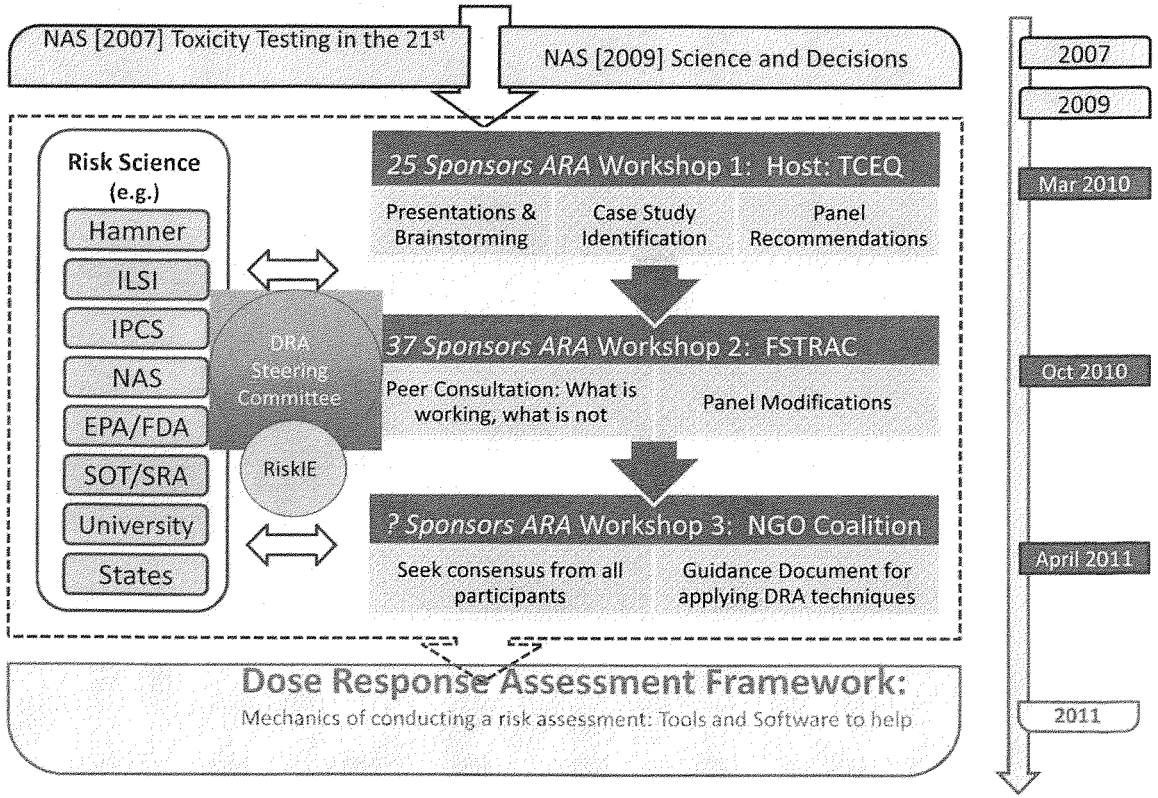
www.tera.org/ITER
http://toxnet.nlm.nih.gov

- Provides chronic human health risk values and cancer classifications from organizations around the world for over 650 chemicals
- Includes a synopsis that explains the underlying basis and rationale for each risk value and differences in risk values
- A link to each organization's website or source document
- A forum through which independent parties can share their peer reviewed risk values

Alliance for Risk Assessment (*ARA*)
(www.allianceforrisk.org)

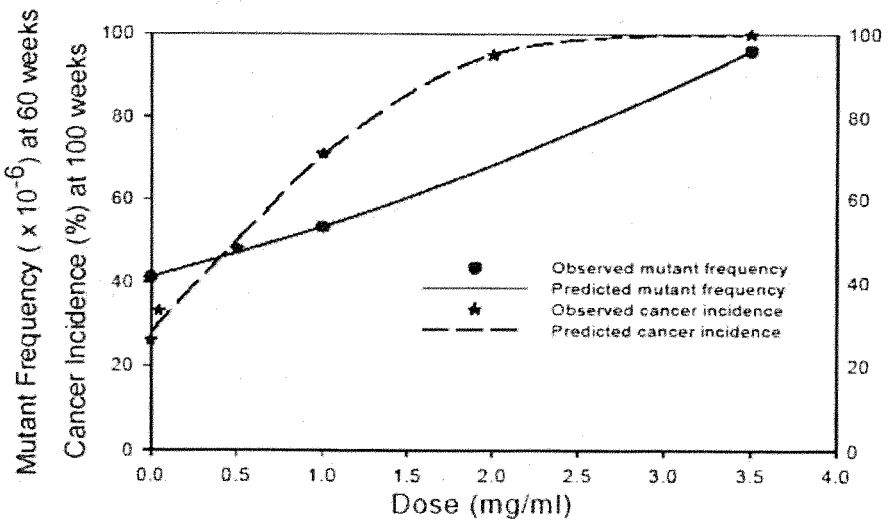


Beyond Science and Decisions: Problem Formulation to Dose Response



National Center for Toxicological Research: CRADA

Case study 2: Dose-Response Analysis for Dichloroacetic Acid

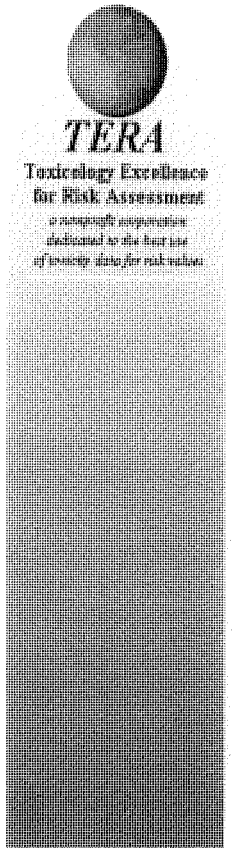


Genomics in Risk Assessment

Bowyer et al., 2008. Subchronic acrylamide exposure in Fischer 344 rats.

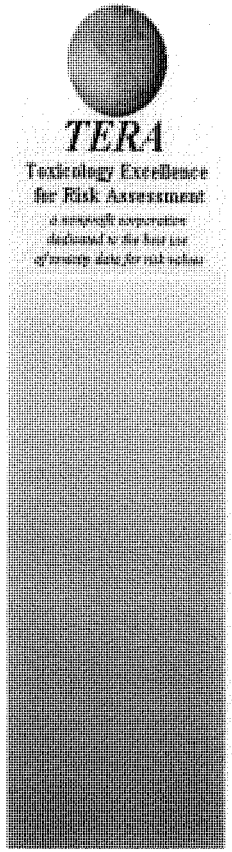
Region	Gene Expressed	Expression Levels		
		% Relative to Control[a]	Relative to GADPH	P value[d]
Thyroid	Glyceraldehydephosphate dehydrogenase (GAPDH)	83±12%	NA	NA
Thyroid	Thyroglobulin	102±18%	54.6-fold	0.97
Thyroid	Thyroid peroxidase	102±18%	0.278-fold	0.77
Thyroid	Sodium iodide symporter	142±22%	0.0218-fold	0.12
Thyroid	Type I 5′-deiodinase	142±38%	0.295-fold	0.48
Thyroid	Type II 5′-deiodinase	189±33%	0.0181-fold	0.034
Thyroid	Type III 5′-deiodinase	113±18%	0.00139-fold[b]	0.53
Thyroid	Mki67	109±14%	0.0619-fold	0.71
Pituitary	Thyroid stimulating hormone β	108%	12.31	0.30
Pituitary	Thyroid hormone receptor α	103%	8.53	0.57
Pituitary	Thyroid hormone receptor β	109%	8.74	0.73

Statistically significant



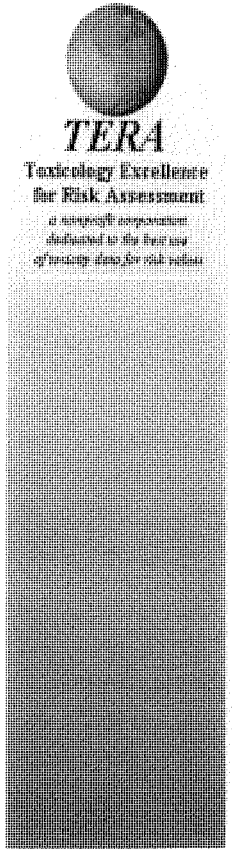
Science and Decisions:
Advancing Risk Assessment (NAS 2009)

- Gave suggestions on hiring, training and planning
- Suggests incorporation of background exposures, stressors, and/or diseases in modeling efforts
- Suggests common dose response approach for all endpoints; default is a no threshold model
- These latter two suggestions are controversial
  - Background exposures and diseases are included in control groups
  - Including background exposures/stressors obviates tier the "Component" part of EPA mixtures guidelines
  - Ignoring thresholds is not consistent with most toxicology
- Several current methods were overlooked



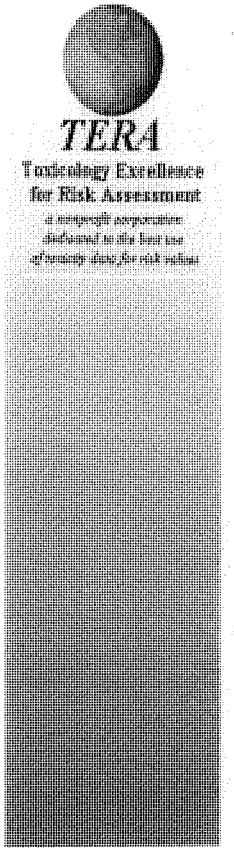
Risk Assessment Peer Review

- Cornerstone principles
  - Scientific robustness
  - Selection of appropriate panel expertise
  - Transparency
  - Independence
- Distinguish conflict-of-interest from bias
  - Avoid COI
  - Balance biases
- Rule of thirds; ~1/3 of the panel should be
  - Experience risk assessors
  - Chemical or related-chemical experts
  - Effect experts
- Balanced affiliations

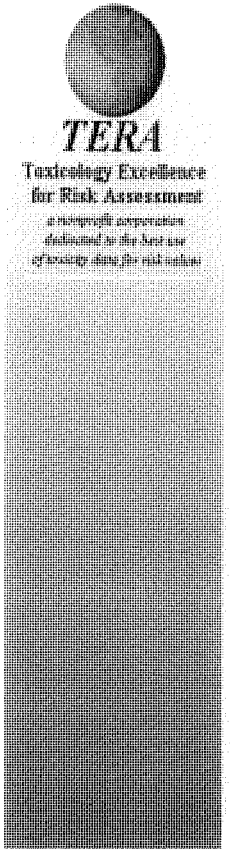


Summary

- Know traditional risk methods cold
  - Involve clinicians
  - Challenge non-experts
- Use contemporary methods often
  - BMD, Categorical Regression, CSAF, PBPK
- Create future by collaboration and research
  - Hang together, or hang separately
  - Focus on collaboration among agencies



- Extra slides



Thresholds

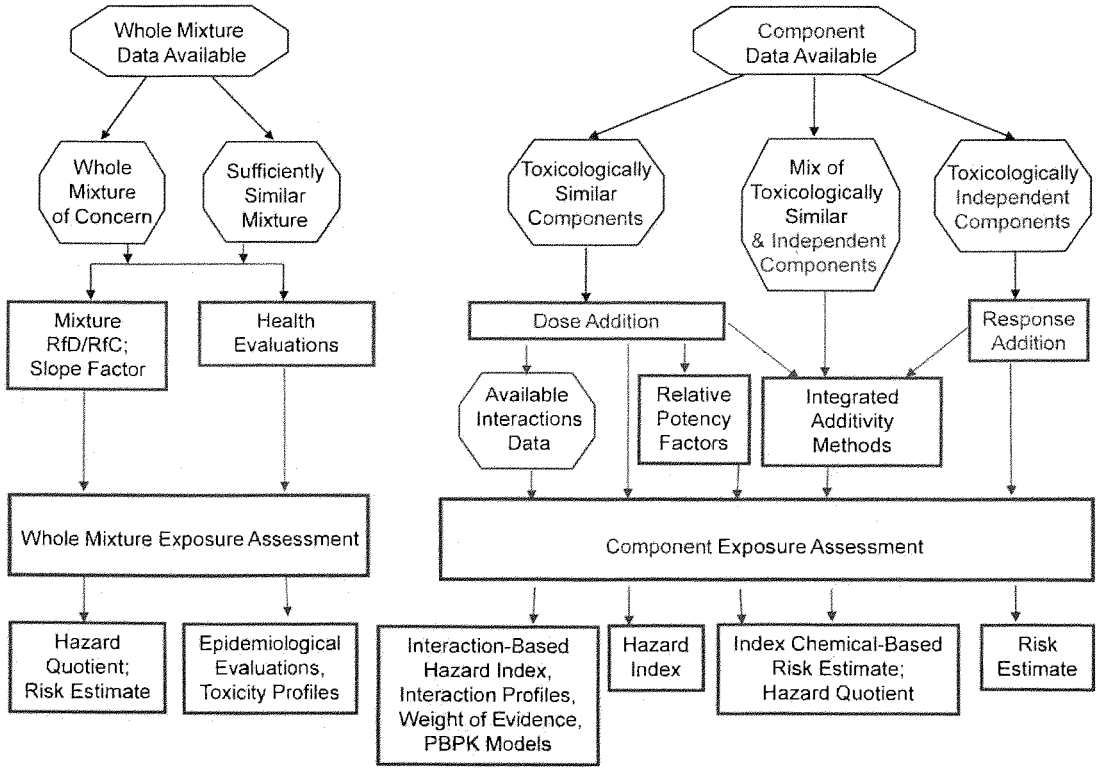
Wikipedia: Point where one mentally or physically is vulnerable in response to provocation or to particular things in general, as in emotions, stress, or pain.

Word software: Level at which effect starts

Casarett & Doull (2008—page 23): …some dose below which the probability of an individual responding is zero.

The question is not whether a chemical has a threshold for an adverse effect---since all chemicals do---but rather can it be that this threshold is one molecule.

Flow Charts for Evaluating Chemical Mixtures

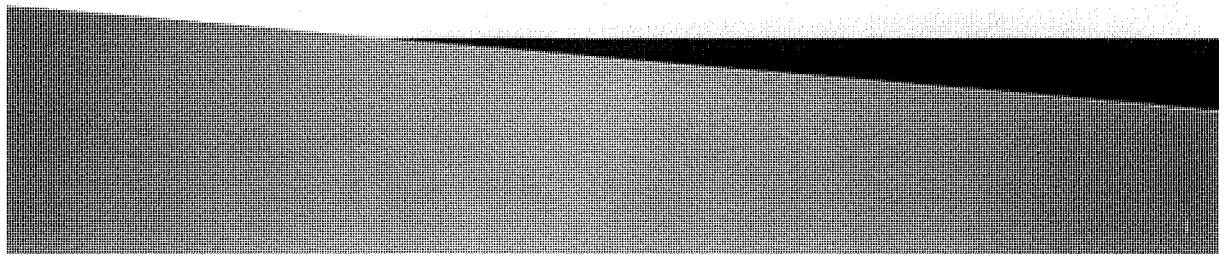


Defining the range of the reference dose: imprecision versus uncertainty.

Dourson ML, Gadagbui B, Pfau E, Thompson R, Lowe J*



** Alliance for Risk Assessment (ARA); Toxicology Excellence for Risk Assessment; Hull & Associates, Inc.; Alliance for Site Closures; CH2M-Hill*



Hazard Range and Problem Formulation

- The development of a hazard range should help to address the following problems:
  - Hazardous waste site remedial objectives for chronic exposures
  - Communicating risk/hazard of exposure above RfC
  - Prompt/short term exposure action levels
  - Inform the confounding effects of assessing ambient background concentrations in air

TCE Residential Indoor Air Acceptable Exposure Levels

- Based on CalEPA values (2000)
  - HQ = 1: 630 $\mu g/m^3$
  - ELCR = 1 x 10^{-6}: 1.2 $\mu g/m^3$
  - ELCR = 1 x 10^{-5}: 12 $\mu g/m^3$
  - ELCR = 1 x 10^{-4}: 120 $\mu g/m^3$

- Based on US EPA IRIS (October 2011)
  - HQ = 1: 2.1 $\mu g/m^3$
  - ELCR = 1 x 10^{-6}: 0.48 $\mu g/m^3$
  - ELCR = 1 x 10^{-5}: 4.8 $\mu g/m^3$
  - ELCR = 1 x 10^{-4}: 48 $\mu g/m^3$

Risk Assessment and Risk Management

- Excess Lifetime Cancer Risk (ELCR) Range: 10^{-6} to 10^{-4}
  - Provides risk managers flexibility to balance acceptable exposure levels with closure needs:
    - Technical feasibility
    - Implementability
    - Timeliness
    - Economic considerations
    - Cultural or other concerns
- **How may a similar evaluation be performed with respect to the non-cancer endpoint?**

Problem Response: Alliance for Risk Assessment (*ARA*)

- *ARA* TCE Workgroup formed in the Fall of 2012
  - Open invitation, broad interest and participation
  - Trichloroethylene (TCE) Risk Assessment Guidance for Contaminated Sites (April 2013)
  - Webcast: Practical Guidance for Contaminated Sites: TCE Risk Assessment Case Study (November 4, 2013)
  - Observers: over 300 scientists from multiple international organizations, including government, industry, academia and NGOs, on 6 conference calls and one webinar.

NAS (2014) & IRIS Process

- "**Finding:** EPA could improve documentation and presentation of dose-response information.

- **Recommendation:** EPA should clearly present two dose-response estimates: **a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a POD from which a toxicity value is derived.** The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value." [emphasis added]

NAS (2014) & IRIS Process

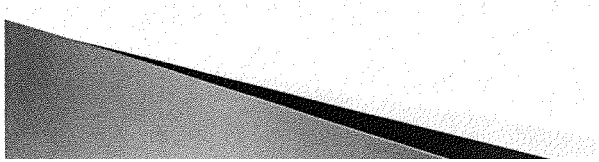
- "**Finding**: IRIS-specific guidelines for consistent, coherent, and transparent assessment and communication of uncertainty remain incompletely developed. The inconsistent treatment of uncertainties remains a source of confusion and causes difficulty in characterizing and communicating uncertainty.

- **Recommendation**: Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty communication. Moreover, uncertainty analysis should become an integral component of the IRIS process."

Reference Dose (IRIS)

- "The RfD (expressed in units of mg of substance/kg body weight-day) is defined as an estimate (**with uncertainty spanning perhaps an order of magnitude**) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." [emphasis added]

- That is, the RfC/RfD is expected to be below the actual threshold for adverse effect in a sensitive subgroup.

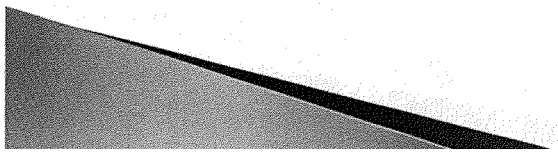


Uncertainty vs. Imprecision

- Alternative interpretations:
  - Imprecision of a RfC is on both sides of the RfC. This is because a 2nd expert group might estimate a RfC higher or lower than the 1st group, if given the same information.
  - Uncertainty in a RfC, in contrast, lies mainly above the RfC. This is because RfCs are based on lower bounds on PODs and UFs are known to be protective.
  - For risk management decisions, uncertainty in the RfC is generally more important than imprecision.
  - Managers are interested in making decisions that protect public health and uncertainties in a RfC are generally more informative.

Hazard Range Development

- Hazard Range
  - Floor
  - Intermediate value (Midpoint)
  - Ceiling

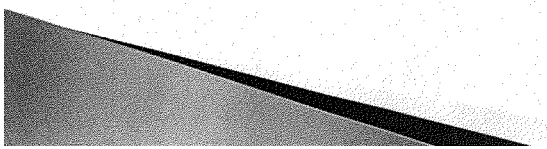


Floor of the Hazard Range

- Identified as the RfC/RfD based on a single candidate value
- In the case of an RfC/RfD based on two or more candidate values
  - identified as the candidate RfC/RfD with the higher(est) confidence.
    - The reference value is not likely to change with further testing, except for mechanistic studies that might affect the interpretation of prior test results.
    - RfC could be modified if refined data are obtained to modify uncertainty factors – e.g., kinetic data for chemical-specific adjustment factors.

Floor of the Hazard Range

- The RfC/RfD is developed:
  - using UFs that are protective based on the observed behaviors of a typical toxicant
    - so that the RfC/RfD is an underestimate of the expected threshold value.
  - The floor of the hazard range may be denoted as a point below which risk managers are unlikely to recommend remedial action or exposure control.



Ceiling of the Hazard Range

- Is defined as the adjusted point of departure (POD_{adj})
- POD based on the critical concentration/dose of chosen study.
- Managers likely to take regulatory action above this ceiling since specific toxic effects can sometimes be seen.

Ceiling: Adjusted POD

- Adjustments for the dosing regime in the critical study, such as...

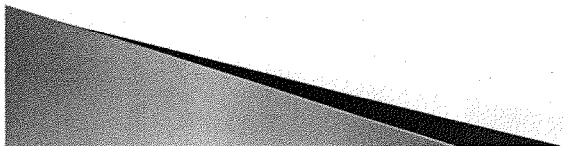
- Toxicokinetic differences between the test organism and humans
- Database quality, lack of NOAEL, and study duration; reductions are based on available data, or a factor of 3 used as a default for each area.
- The intent of these adjustments and reductions is to estimate the likely ceiling of the RfD/C by using the median value of the Ufs.

Midpoint of the Hazard Range

- Unlikely to be associated with adverse effects in a human population, based on…
  - Greater understanding of the range of uncertainty associated with RfC/RfD development and
  - Consistent with the definition of "uncertainty of up to an order of magnitude" impacts the RfC/RfD
- It is a plausible estimate of the upper concentration or dose that is likely to be protective of the general population, including sensitive subpopulations

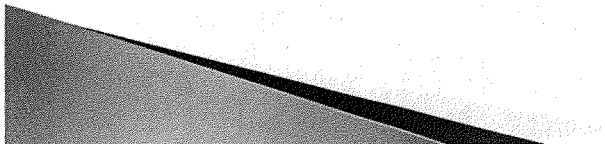
Midpoint of the Hazard Range

- Is a judgment that meshes four considerations:
  - Collective magnitude of the UFs
  - Steepness of the hazard slope describing exposures above the RfC/RfD
  - The confidence in the selection of the critical effect
  - The confidence in the POD

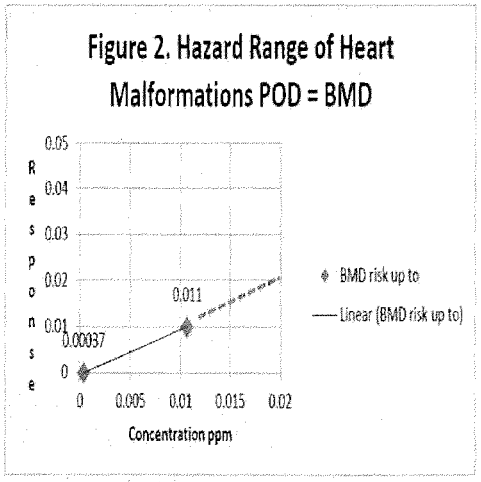


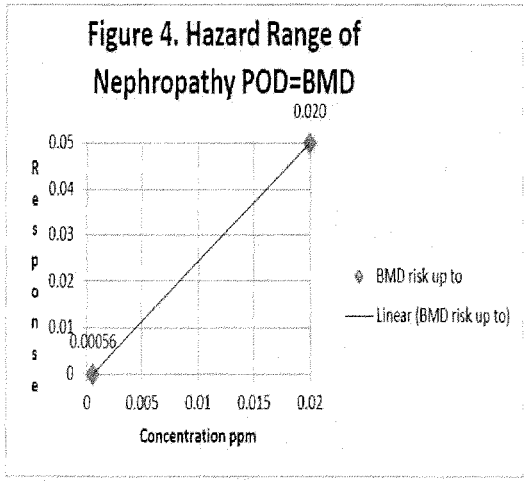
Johnson et al., 2003
RfC = 2 μg/m^3

- Fetal malformation endpoint
  - Intermediate value of 10 μg/m^3 is judged to be 5-fold above the candidate RfC due to:
    - Its small UF of 10,
    - Shallower hazard slope,
    - Low confidence in the critical effect, and
    - Low confidence in the choice of a benchmark response of 1% ($BMDL_{01}$)



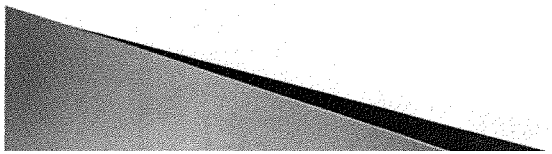
Hazard Ranges of Two Candidate RfCs for TCE (as per Gentry et al.)





NTP, 1988
RfC = 3 μg/m^3

- Toxic nephropathy endpoint
  - Intermediate value of 9 μg/m^3 is judged to be 3-fold above the candidate RfC due to:
    - Its small UF of 10,
    - Steeper hazard slope,
    - Medium confidence in the critical effect, and
    - Medium to low confidence in the choice of a benchmark response of 5% ($BMDL_{05}$)



Keil et al., 2009
RfC = 2 μg/m^3

- Decreased thymus weight endpoint
  - Intermediate value of 20 μg/m^3 is judged to be 10-fold above the candidate RfC due to:
    - Its larger UF of 100,
    - The effect shown by Keil et al. (2009) does not lend itself to dose-response modeling, so steepness of the slope was not assessed
    - Medium confidence in the critical effect, and
    - Medium to low confidence in its choice of a LOAEL as the POD

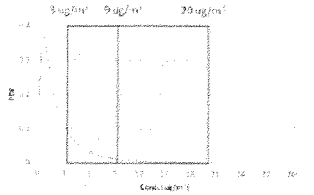
TCE as an Example

Table 7. Different uncertainty ranges for different TCE RfCs. All values are in $\mu g/m^3$. Shaded areas indicate best **overall uncertainty range** for risk management purposes.

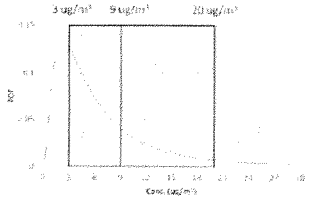
Study	Endpoint	IRIS UF [a]	Steep [b] Slope	Confidence		Uncertainty Ranges		
				Critical [c] Effect	Point of [d] Departure	Floor	Intermediate	Ceiling
Johnson et al (2003)	Fetal malformation	10	Lower	Low	Low	2	10	20
NTP (1988)	Toxic nephropathy	10	Higher	Medium	Medium to Low	3	9	30
Keil et al. 2009	Decreased thymus weight	100	NA	Medium	Medium to Low	2	20	60

a. Size of the uncertainty factor as on IRIS
b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.
c. Confidence in the choices of critical effect, as per Section 4.
d. Confidence in the POD, as per Section 4.

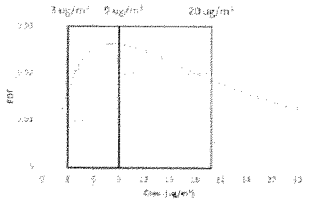
Practical Application of the Hazard Range for TCE



ES Figure 1a. Exposure distribution of indoor air concentrations primarily below the 3 $\mu g/m^3$ to 20 $\mu g/m^3$ hazard range. Relatively small proportion of exposures is higher than 3 $\mu g/m^3$. Nominal actions or no further action may be warranted for risk management.



ES Figure 1b. Exposure distribution of indoor air concentrations falling within the 3 $\mu g/m^3$ to 20 $\mu g/m^3$ hazard range. Relatively small proportion of exposures is higher than 9 $\mu g/m^3$. Limited action may be warranted for risk management

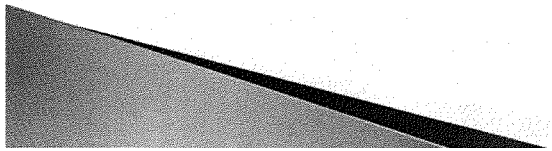


ES Figure 1c. Exposure distribution of indoor air concentrations primarily above the 3 $\mu g/m^3$ to 20 $\mu g/m^3$ hazard range. Actions to reduce exposures may be warranted for risk management.

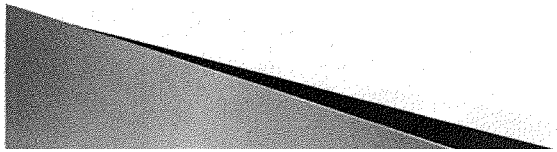
For more information http://www.allianceforrisk.org/Projects/TCE.html

Guidance for Contaminated Sites: Trichloroethylene Case Study. Gadagbui, et al., SOT, 53rd Annual Meeting & ToxExpo, 23-27 March 2014, Phoenix, AZ.

Development of a Non-cancer Hazard Range for Effective Risk Assessment and Risk Management of Contaminated Sites: A Case Study with TCE and Other Chemicals, Beyond Science & Decisions: Problem Formulation to Dose-Response Assessment, Workshop VIII, 21-22 May 2014, Austin, TX.



Thank You!

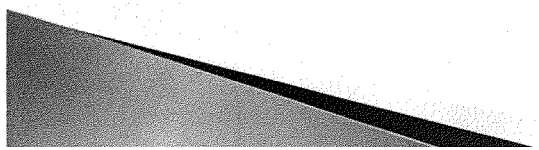


TCE Criteria: *Through the Years*

- Withdrawn US EPA IRIS (1989)
  - Inhalation Unit Risk = 1.7×10^{-6} $(\mu g/m^3)^{-1}$
- CalEPA values (2000)
  - Chronic inhalation REL = 600 $\mu g/m^3$
  - Inhalation Unit Risk = 2×10^{-6} $(\mu g/m^3)^{-1}$
- Draft US EPA TCE Assessment (2001)
  - Prov. RfC = 0.04 mg/m^3 = 40 $\mu g/m^3$
  - Prov. Inhalation Unit Risk = 5.7×10^{-6} $(\mu g/m^3)^{-1}$ to 1.1×10^{-4} $(\mu g/m^3)^{-1}$
- US EPA IRIS (October 2011)
  - RfC = 0.002 mg/m^3 = 2 $\mu g/m^3$
  - Inhalation Unit Risk = 4.1×10^{-6} $(\mu g/m^3)^{-1}$

Consequences of the New TCE Toxicity Values (Problem Formulation)

- Risk-based indoor air levels now based upon non-cancer endpoint (RfC)
- The RfC is based on both chronic and developmental endpoints
- Prompt/short term exposure action levels based on the RfC
  - Prompt action exposure concentrations
  - Application of lifetime RfC to acute and subchronic exposures
- Confounding effects of assessing ambient background concentrations of TCE in air



NAS *Science and Decisions: Advancing Risk Assessment* (2009)

- "For noncancer end points, it is assumed that homeostatic and defense mechanisms lead to a **dose threshold** (that is, there is low-dose nonlinearity), below which effects do not occur or are extremely unlikely. For these agents, risk assessments have focused on defining the reference dose (RfD) or reference concentration (RfC), a putative quantity that is 'likely to be without an appreciable risk of deleterious effects' (EPA 2002a, p. 4-4)." [emphasis added]

- That is, the RfC/RfD is expected to be below this actual threshold for adverse effect.

NAS *Science and Decisions: Advancing Risk Assessment* (2009)

"The "hazard quotient" (the ratio of the environmental exposure to the RfD or RfC) and the "hazard index" (HI)... An HI less than unity is generally understood as being indicative of lack of appreciable risk, and a value over unity indicates some increased risk.

The larger the HI, the greater the risk, but the index is not related to the likelihood of adverse effect except in qualitative terms: 'the HI cannot be translated to a probability that adverse effects will occur, and is not likely to be proportional to risk' (EPA 2006a)." [emphasis added]

NAS (2009) & Hazard Assessment

- NAS (2009):
  - Suggested that methods for assessing non-cancer toxicity have the capability of determining hazard ranges.
- ARA project "Beyond Science and Decisions: From Problem Formulation to Dose Response"
  - Built on NAS (2009) report
  - Six of its cases studies are about evaluating noncancer *risk* (at different doses)
    - Each was vetted by a Science Panel
- We focus on:
  - modeling risk above the RfC/RfD using the benchmark dose method (Gentry *et al.*, 2011).

Problem Response: Alliance for Risk Assessment (ARA)

- *Guidance for Contaminated Sites: Trichloroethylene Case Study.* Gadagbui, *et al.*, SOT, 53rd Annual Meeting & ToxExpo, 23-27 March 2014, Phoenix, AZ.

- *Development of a Non-cancer Hazard Range for Effective Risk Assessment and Risk Management of Contaminated Sites: A Case Study with TCE and Other Chemicals,* Beyond Science & Decisions: Problem Formulation to Dose-Response Assessment, Workshop VIII, 21-22 May 2014, Austin, TX.

Yes, "Thresholdable" Carcinogens are Still Delaney Carcinogens

Michael Dourson, PhD, DABT, ATS
TERA Center
University of Cincinnati

Life is Chemistry…

- We are all exposed to a sea of chemicals daily.
  - Coffee with ~1000 chemicals; 20 to 30 of them known to be either mutagenic or carcinogenic
  - No pure water anywhere
  - Acrylamide, a known carcinogen, in ~40% of our cooked food
  - Pharmaceuticals in our waterways
  - Mixtures of diverse chemicals in our air due to just living in a house, working in a city, or playing soccer on artificial turf
  - Soils are a complex mixtures of living and dying organisms each with its own stew of chemistries…

Adding to this Complexity are Four Things to Remember

- Dose matters
- Timing is critical
- People differ
- Things change

[Hayes, Kruger, and Clemens, 2016]

Fortunately...

- These 1000+ chemicals each have a safe or virtually safe dose.
  - For noncancer toxicity this can be an ADI, RfD, MRL, TDI, DNEL, OEL, TLV, PEL, REL, etc... based on a NOAEL, LOAEL, BMD, or HED, HEC with associated SF, UF, CSAF, DDEF, or AF, etc.
  - For cancer toxicity this can be a VSD or RSD, with associated CIs, based on a POD, SF, or Q1*, etc.
- These doses can be use with exposure assumptions to determine for either cancer or noncancer toxicity a...
  - MRL, HQ, MOE, MOS, HI, DWEL, etc...
- ***Fortunately...?***

So What of All This Science?

- The overriding goal of federal policies governing the use of chemicals is- *and should be*- consumer safety.
- Fess up. Doesn't your family only want to know at dinner whether the chemical highlighted in the daily news is safe?
- And isn't this question asked everywhere else in the country?
- And somehow do you think that US Congress is any different?
- *Au contraire*! And this is why the **Delaney amendment** was passed. Science is complex and safety is paramount.

So…Is It safe?

- For some toxicities the answer is easy… For example, one chemical is:
  - A well known flame retardant
  - An established neurotoxin
  - An endocrine disruptor for sure…
- *And a macronutrient*… a Reference Dose (RfD) is appropriate

- But for other toxicities like cancer…

US has 7th-highest-cancer-rate-in-world

- Jan 24, 2011 -- About 300 of every 100,000 Americans develop cancer each year, earning us 7th place!
  - The new rankings were compiled using World Health Organization (WHO) estimates.
- We are higher than we should be, and it's not the type of list on which you want to be on top, says Alice Bender, MS, RD.
  - Due to lifestyle? Americans are more likely overweight from eating too much food, drinking to much alcohol and being less active.
- So has the "war on cancer" reduced our rates?

And What About Idiopathic disease?

one that exists without any connection with any known cause.

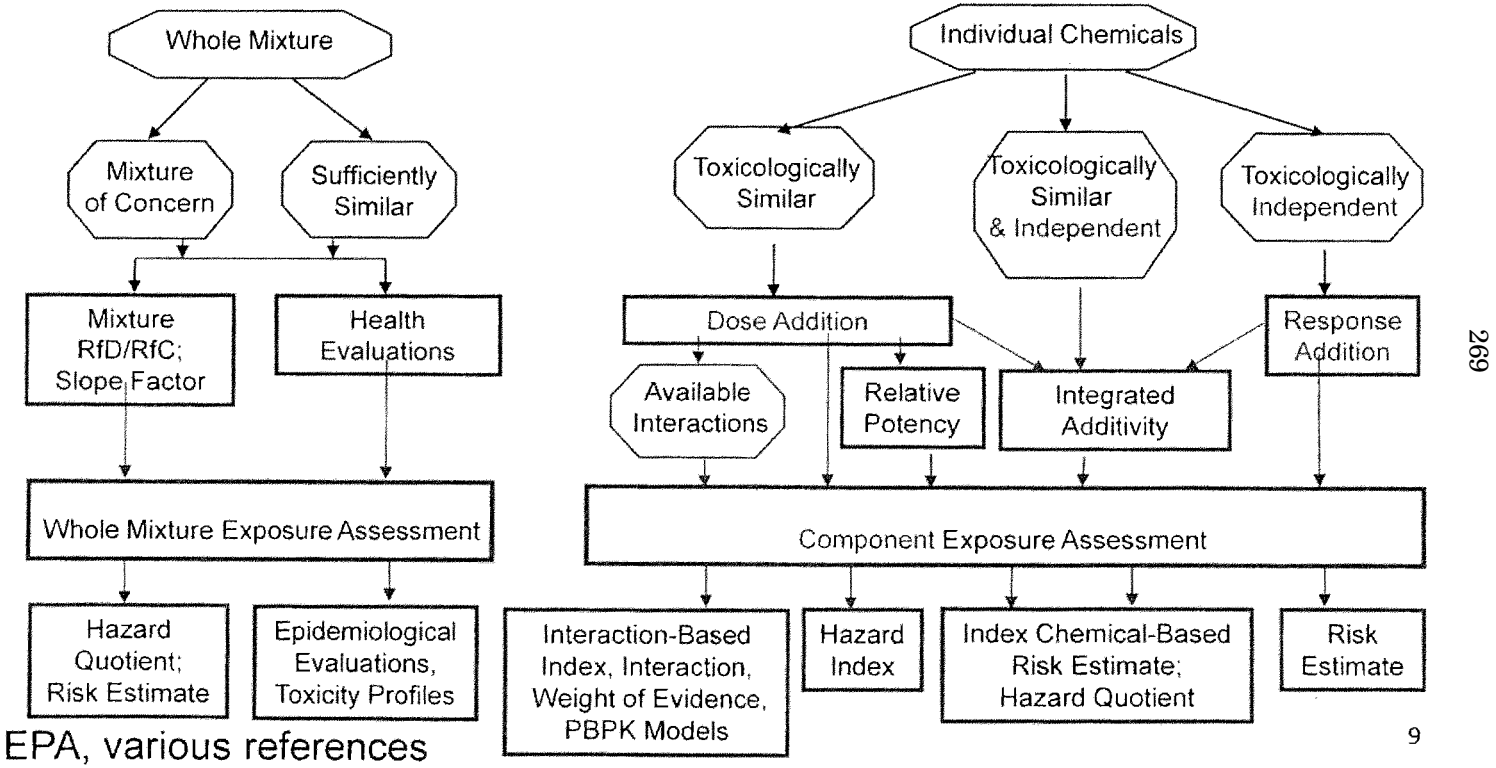
[http://medical-dictionary.thefreedictionary.com/idiopathic+disease]

Idiopathic Diseases (partial listing):

- Alabama rot
- Condylar resorption
- Diffuse idiopathic skeletal hyperostosis
- Idiopathic giant-cell myocarditis
- Idiopathic infantile arterial calcification
- Inflammatory demyelinating diseases of the central nervous system
- Idiopathic interstitial pneumonia
- Idiopathic pulmonary fibrosis
- Immune thrombocytopenic purpura
- Juvenile idiopathic arthritis
- Multifocal fibrosclerosis
- Pellucid marginal degeneration
- Systemic-onset juvenile idiopathic arthritis

[https://en.wikipedia.org/wiki/Category:Idiopathic_diseases]

Or Evaluating Chemical Mixtures?



EPA, various references

Legislative Answer? Chemicals are not Safe Unless Proven Otherwise

- Repeal Delaney? One needs to find a legislative replacement.
  - Perhaps an 95% upper-bound, one in a million, lifetime, excess, cancer risk, where the risk is unlikely greater, but likely lower and perhaps 0.
- Delaney prevents beneficial product development?
  - A simple walk around the grocery store readily disputes this claim.
- But opposition to Delaney may be based on misunderstanding
  - Allows discretion if substance induces cancer when ingested in tests which are appropriate. Expert judgment needed here.
  - Once "induced" limit of science is reached. Delany assures safety.

To the Rescue!

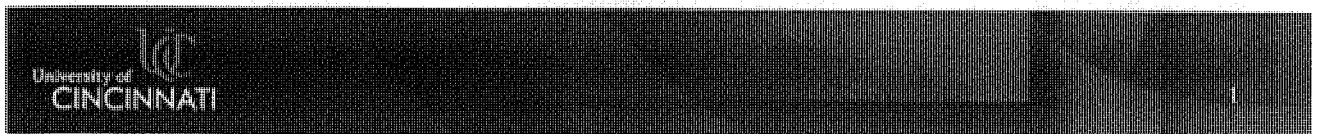
- The Society of Toxicology (SOT) mission is to create a safer and healthier world by advancing the science of toxicology and increasing the impact on society from these advances.

- Specialty Sections are formed to help with understanding risk assessment and regulatory and safety evaluation.

- Better communication to the public and Congress is needed.

Health Risk Assessment for Perchlorate: New Direction in EPA's Modeling Approach for Establishing Standards

Michael Dourson, Ph.D., DABT, FATS, FSRA
John Reichard, PhD, PharmD
University of Cincinnati, College of Medicine



EPA (2016) Perchlorate Model

- EPA's Science Advisory Board (SAB, 2013) recommended crafting a model on perchlorate's effects on sensitive lifestages to assist the agency in determining an appropriate maximum contaminant level goal (MCLG).
- In an effort to fulfill the recommendations of this panel, EPA (2016) showcased a model, which is the first step in a two step process to develop an MCLG.
- EPA choose hypothyroxinemia as the critical effect, that is the first adverse effect or its known precursor, as part of this modeling effort.

EPA's External Peer Review

- The peer reviewers identified a number of areas for improvement of the proffered model:
  - Develop a plan for further actions in order to maximize the benefit of any model revisions.
  - Develop a model that is fit for the intended purpose. Specifically, how the model outputs would be used in developing the MCLG.
- Changes in hormones are precursors of the critical effect that leads to neurotoxicity. Models should facilitate:
  - Linkages between perchlorate exposure and iodine handling and impacts on thyroid hormone levels, and
  - Relationships between thyroid hormone status and neurodevelopment in critical fetal, especially 1st trimester, and post-natal periods.

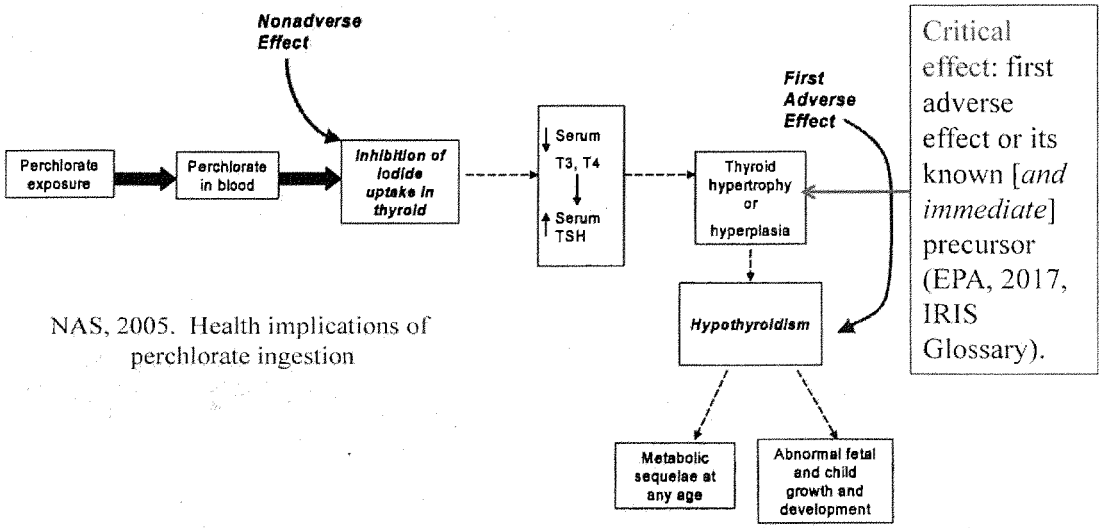
EPA's External Peer Review

- EPA should establish an interaction with clinicians and epidemiologists with expertise in thyroid function and neurodevelopment.
- EPA should clearly convey the scope of the modeling effort, the biology the model addresses, and the model applications.
- EPA needs to clearly state why the current model, which likely could always be improved given additional time and resources, represents a fit-for-purpose solution applicable to current efforts to develop regulatory standards for perchlorate.

External Comments

- The physiologically-based pharmacokinetic/pharmacodynamic (PBPK/PD) model of EPA accounts for differences in exposure and biology across life stages, and is a good start at understanding iodine nutrition and perchlorate exposures.
- However, EPA needs to explain thyroid changes as critical effects, in contrast to NAS (2005) and its own definition.
- EPA also needs to support its assumption of 2.5th to 10th percentile of fT4 as a hypothyroxinemia range, and incorporate symporter up-regulation in the model.

The Critical Effect as per NAS/EPA



NAS, 2005. Health implications of perchlorate ingestion

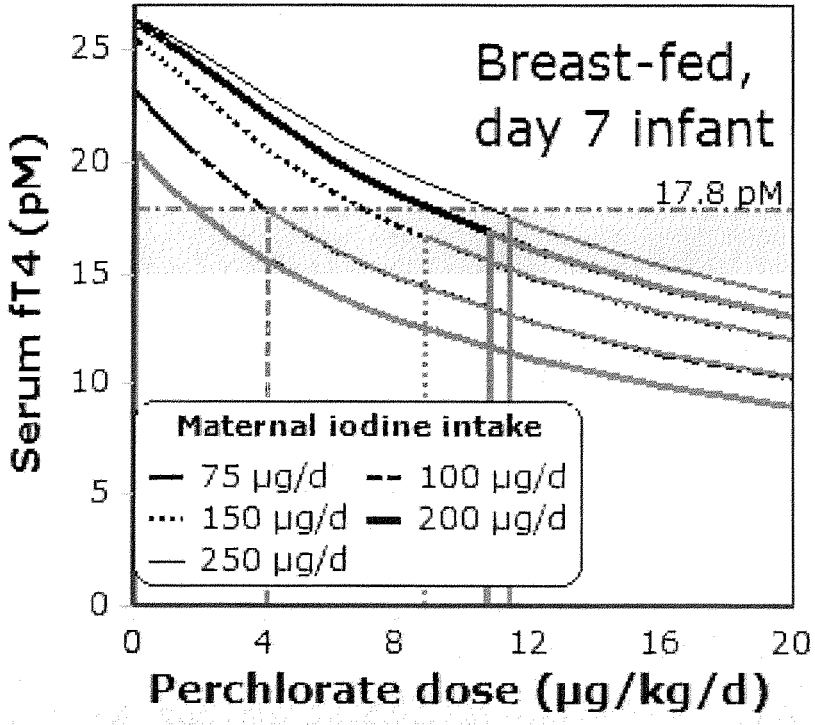
FIGURE 5-2 Committee's suggested mode-of-action model for perchlorate toxicity in humans indicating first adverse effect in the continuum.

One Way Forward?

- EPA could select as the critical effect a lower 2.5th percentile of free T4 in the chosen sensitive population.
- Although not technically the critical effect, this percentile may be a reasonable surrogate for increase in TSH, which would be necessary for thyroid hyperplasia and hypertrophy, which are the known precursors to the first adverse effect from perchlorate, and therefore the critical effect (NAS, 2005, page 111).

EPA, 2016, page 75

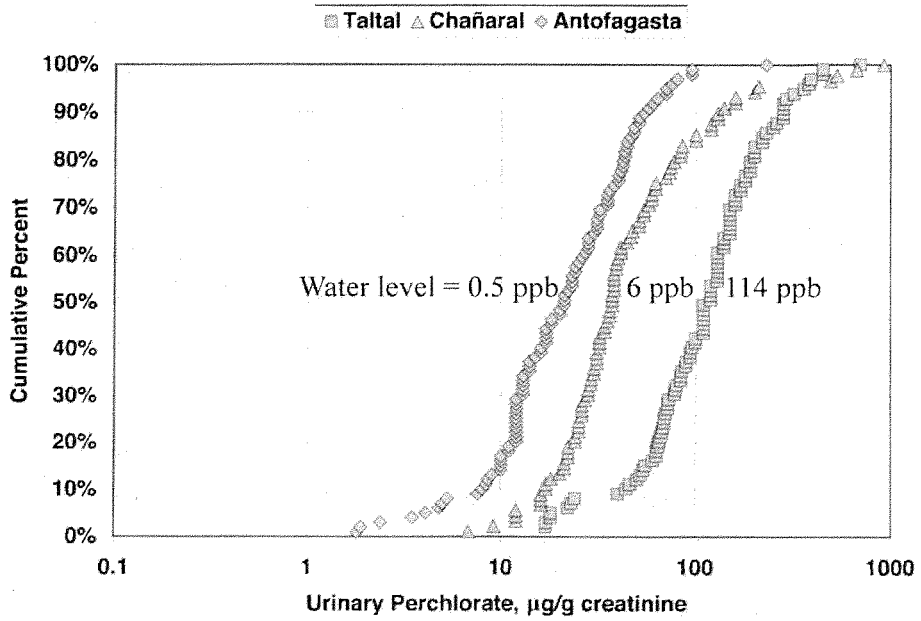
Biologically Based Dose Response Models for the Effect of Perchlorate on Thyroid Hormones in the Infant, Breast Feeding Mother, Pregnant Mother, and Fetus: Model Development, Revision, and Preliminary Dose-Response Analyses



University of CINCINNATI

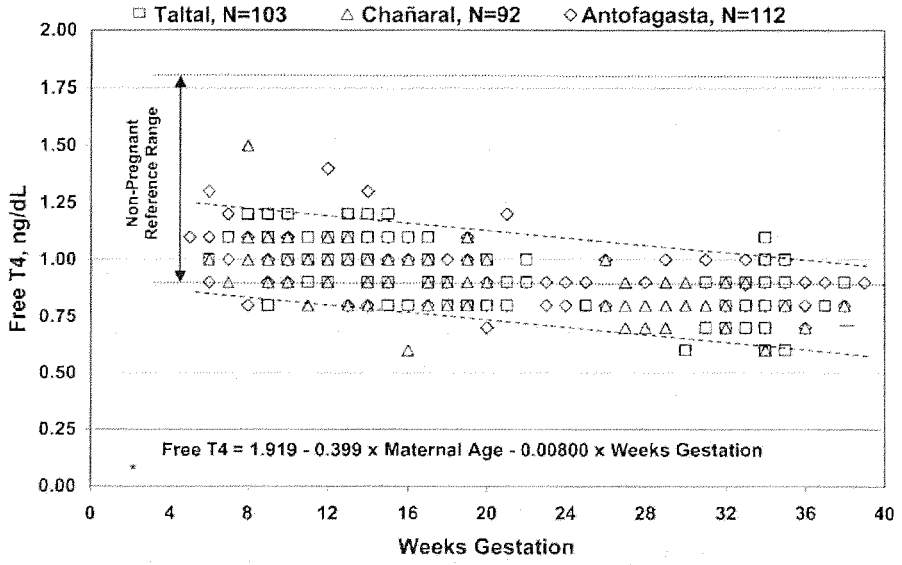
One Way Forward

- If EPA selects an iodine-deficient subpopulation as the basis for its MCLG, then this choice reduces the need for an uncertainty factor for within human variability.
- EPA should consider observations from prospective epidemiology studies, specifically Tellez et al. (2005) for applicability to the US, consistent with NAS (2005, page 69).
- EPA should consider how the model might be modified by up-regulation of symporter expression in the perchlorate dose range of interest, or if not possible, then un-modeled up-regulation leads to a more conservative or MCLG.



Tellez et al., 2005. Long-Term Environmental Exposure to Perchlorate Through Drinking Water and Thyroid Function During Pregnancy and the Neonatal Period . THYROID Volume 15, Number 9, 2005.

MATERNAL PERCHLORATE EXPOSURE DURING PREGNANCY



Tellez et al., 2005. Long-Term Environmental Exposure to Perchlorate Through Drinking Water and Thyroid Function During Pregnancy and the Neonatal Period . THYROID Volume 15, Number 9, 2005.

One Way Forward

- From a clinical perspective lactation is associated with iodine uptake in the breast, and, there is a well-documented clinical increase in thyroid hormone requirements during pregnancy.
- However, colleagues of the University of Cincinnati are unaware of any clinically increased rate of hypothyroidism in breast-feeding women compared to those choosing to feed their children formula. Thus, pregnancy and its increased thyroid hormone requirements appear to have a far greater impact on the mother than breast-feeding.
- EPA should explore the clinical relevance of the breast-feeding maternal population prior to choosing it for any point of departure in developing an MCLG.

Summary

- EPA's biologically based dose response model addresses many of the challenges the Agency has faced in establishing causality and uncertainty with perchlorate exposure.
- EPA's peer review panel highlights important limitations in the model that impact its viability in developing of an MCLG, the most important perhaps is whether the "critical effect" should be multiple steps before any adverse effect, and whether a 1st trimester fetus is more sensitive. A second peer review is planned for later this summer.
- However, EPA has a good basis for the sensitive population; thus, the need for uncertainty factor for within human variability is lessened.

Extra Slides

Practical Guidance on a Non-cancer Hazard Range for Effective Risk Management of Contaminated Sites: A Case Study with Trichloroethylene and other Chemicals

Tri-Service Environmental Risk Assessment Work Group January 21, 2015

Pfau EJ, Thompson R, Gadagbui BK, Gillay D, Lowe J, Dourson M;*

**Hull & Associates, Inc.; Alliance for Site Closures; TERA; Barnes & Thornburg, LLP; CH2M-Hill; Alliance for Risk Assessment*

NAS (2009) & Hazard Assessment

- NAS (2009):
  - Suggested that methods for assessing non-cancer toxicity have the capability of determining hazard ranges.
- *ARA* project "Beyond Science and Decisions: From Problem Formulation to Dose Response"
  - Built on NAS (2009) report
  - Six of its cases studies are about evaluating noncancer *risk* (at different doses)
    - Each was vetted by a Science Panel
- We focus on:
  - modeling risk above the RfC/RfD using the benchmark dose method (Gentry *et al.*, 2011).

NAS (2014) & IRIS Process

- "**Finding:** EPA could improve documentation and presentation of dose-response information.

- **Recommendation:** EPA should clearly present two dose-response estimates: **a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a POD from which a toxicity value is derived.** The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value."
[emphasis added]

NAS (2014) & IRIS Process

- **"Finding:** IRIS-specific guidelines for consistent, coherent, and transparent assessment and communication of uncertainty remain incompletely developed. The inconsistent treatment of uncertainties remains a source of confusion and causes difficulty in characterizing and communicating uncertainty.
- **Recommendation:** Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty communication. Moreover, uncertainty analysis should become an integral component of the IRIS process."

Reference Dose (IRIS)

- "The RfD (expressed in units of mg of substance/kg body weight-day) is defined as an estimate (**with uncertainty spanning perhaps an order of magnitude**) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime."
  [emphasis added]
- That is, the RfC/RfD is expected to be below the actual threshold for adverse effect in a sensitive subgroup.

Uncertainty vs. Imprecision

- Alternative interpretations:
  - Imprecision of a RfC is on both sides of the RfC. This is because a 2nd expert group might estimate a RfC higher or lower than the 1st group, if given the same information.
  - Uncertainty in a RfC, in contrast, lies mainly above the RfC. This is because RfCs are based on lower bounds on PODs and UFs are known to be protective.
  - For risk management decisions, uncertainty in the RfC is generally more important than imprecision, because managers are interested in making decisions that protect public health.

Hazard Range Development

- Hazard Range
  - Floor
  - Midpoint
  - Ceiling

Floor of the Hazard Range

- Identified as the RfC/RfD based on a single candidate value
- In the case of an RfC/RfD based on two or more candidate values
  - identified as the candidate RfC/RfD with the higher(est) confidence.
    - The reference value is not likely to change with further testing, except for mechanistic studies that might affect the interpretation of prior test results.
    - RfC could be modified if refined data are obtained to modify uncertainty factors – e.g., kinetic data for chemical-specific adjustment factors.

Floor of the Hazard Range

- The RfC/RfD is developed:
  - using UFs that are protective based on the observed behaviors of a typical toxicant
    - so that the RfC/RfD is an underestimate of the expected threshold value.
  - The floor of the hazard range may be denoted as a point below which risk managers are unlikely to recommend remedial action or exposure control.

Ceiling of the Hazard Range

- Is defined as the adjusted point of departure (POD_{adj})
- POD based on the critical concentration/dose of chosen study.
- Managers likely to take regulatory action above this ceiling since specific toxic effects can sometimes be seen.

Ceiling: Adjusted POD

- Adjustments for the dosing regime in the critical study, such as…

- Toxicokinetic differences between the test organism and humans
- Database quality, lack of NOAEL, and study duration; reductions are based on available data, or a factor of 3 used as a default for each area.
- The intent of these adjustments and reductions is to estimate the likely ceiling of the RfD/C by using the median value of the Ufs.

Midpoint of the Hazard Range

- Unlikely to be associated with adverse effects in a human population, based on…
  - Greater understanding of the range of uncertainty associated with RfC/RfD development and
  - Consistent with the definition of how "uncertainty of up to an order of magnitude" impacts the RfC/RfD

- It is a plausible estimate of the upper concentration or dose that is likely to be protective of the general population, including sensitive subpopulations

Midpoint of the Hazard Range

- Is a judgment that meshes four considerations:
  - Collective magnitude of the UFs
  - Steepness of the hazard slope describing exposures above the RfC/RfD
  - The confidence in the selection of the critical effect
  - The confidence in the POD

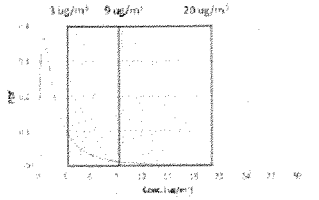
TCE as an Example

Table 7. Different uncertainty ranges for different TCE RfCs. All values are in $\mu g/m^3$. Shaded areas indicate best **overall uncertainty range** for risk management purposes.

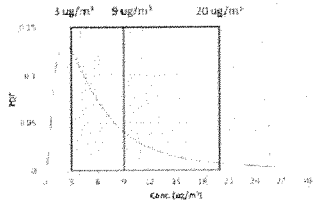
Study	Endpoint	IRIS UF [a]	Steep [b] Slope	Confidence		Uncertainty Ranges		
				Critical [c] Effect	Point of [d] Departure	Floor	Intermediate	Ceiling
Johnson et al (2003)	Fetal malformation	10	Lower	Low	Low	2	10	20
NTP (1988)	Toxic nephropathy	10	Higher	Medium	Medium to Low	3	9	30
Keil et al. 2009	Decreased thymus weight	100	NA	Medium	Medium to Low	2	20	60

a. Size of the uncertainty factor as on IRIS
b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.
c. Confidence in the choices of critical effect, as per Section 4.
d. Confidence in the POD, as per Section 4.

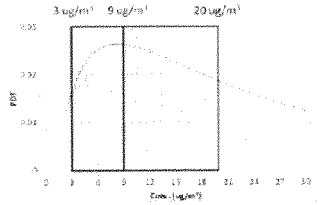
Practical Application of the Hazard Range for Noncancer Effect (e.g., TCE)



ES Figure 1a. Exposure distribution of indoor air concentrations primarily below the 3 µg/m^3 to 20 µg/m^3 hazard range. Relatively small proportion of exposures is higher than 3 µg/m^3. Nominal actions or no further action may be warranted for risk management.



ES Figure 1b. Exposure distribution of indoor air concentrations falling within the 3 µg/m^3 to 20 µg/m^3 hazard range. Relatively small proportion of exposures is higher than 9 µg/m^3. Limited action may be warranted for risk management



ES Figure 1c. Exposure distribution of indoor air concentrations primarily above the 3 µg/m^3 to 20 µg/m^3 hazard range. Actions to reduce exposures may be warranted for risk management.

Summary of data for the Development of the Hazard Range for the Arsenic

Chemical	IRIS RfD	IRIS POD	IRIS UF[a]	Steep Slope[b]	Confidence		Hazard Ranges (mg/kg-day)		
	(mg/kg-day)				Critical Effect[c]	POD[d]	Floor	Midpoint (Inter-mediate)	Ceiling
Arsenic*	3E-4	8E-4	3	Low	High	Medium	1E-4*	3E-4	8E-4*

a. Size of the uncertainty factor as on IRIS
b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.
c. Confidence in the choices of critical effect, as per Section 4.
d. Confidence in the POD, as per Section 4.

Summary of data for the Development of the Hazard Range for the Chromium (VI)

Chemical	IRIS RfD (mg/kg-day)	IRIS POD (mg/kg-day)	IRIS UF[a]	Steep Slope[b]	Confidence		Hazard Ranges (mg/kg-day)		
					Critical Effect[c]	POD[d]	Floor	Midpoint (Inter-mediate)	Ceiling
Chromium (VI)	3E-3	2.5	300 x 3	Low	Low	Low	3E-3	3E-2	3E-1***

a. Size of the uncertainty factor as on IRIS
b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.
c. Confidence in the choices of critical effect, as per Section 4.
d. Confidence in the POD, as per Section 4.

***Range judged to be 100 (see text under *"Evaluation"*)

Summary of data for the Development of the Hazard Range for the Tetrachloroethylene

Chemical	IRIS RfD	IRIS POD	IRIS UF[a]	Steep Slope[b]	Confidence		Hazard Ranges (mg/kg-day)		
	(mg/kg-day)				Critical Effect[c]	POD[d]	Floor	Midpoint (Inter-mediate)	Ceiling
Tetrachloroethylene	6E-3	6E-0	1000	Low	High	Low	6E-3	6E-2	6E-1**

a. Size of the uncertainty factor as on IRIS
b. Steepness of the hazard slope (*i.e.*, the slope of the line describing hypothetical population responses at concentrations above the RfC), as per Section 3.
c. Confidence in the choices of critical effect, as per Section 4.
d. Confidence in the POD, as per Section 4.

**Range judged to be 100 (see text under *"Evaluation"*)

Panel and Audience Comments

- Midpoint" may not be an appropriate term, but rather a best estimate of the sensitive human LOAEL. The authors noted the intent for the "midpoint" was to identify a value that will protect sensitive populations, based upon greater understanding of uncertainty.
- When greater uncertainty exists, one might want the "midpoint" to be closer to the RfD, rather than farther. The authors noted that larger uncertainty suggests a larger range between the floor and the ceiling.
- Regardless, all agreed that it is important to clearly communicate that the value is a judgment.

More comments at:
http://www.allianceforrisk.org/Workshop/WS8/DR8_Meeting_Report_and_Appendices.pdf

Hazard Range and the Problem Formulation

- Does the development of a hazard range help to address the following problems:
  - Hazardous waste site remedial objectives for chronic exposure levels
  - Communicating risk/hazard of exposure above RfC/RfD
  - Prompt/short term exposure action levels
    - Prompt action exposure concentrations
    - Application of lifetime RfC/RfD to acute and subchronic exposures
  - Confounding effects of assessing ambient background concentrations in air (TCE, Petroleum)

Summary

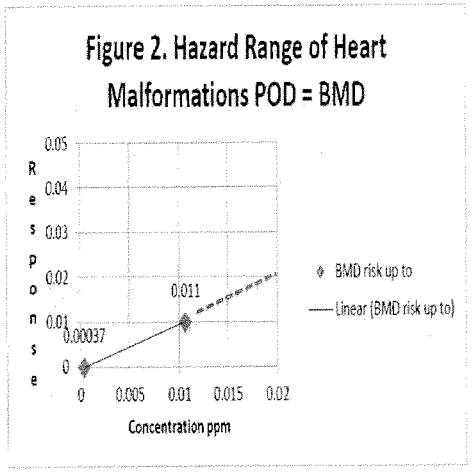
- The suggested method allows the development of a range in a non-cancer health risk value based on readily available information.
- The development of floor, midpoint and ceiling of the suggested range is consistent with the problem formulations of risk managers at waste sites. This range may be helpful with other contaminated media.
- Science Panel comments suggested several improvements including the possible integration with the work offered by Dr. Nancy Beck in the presentation on "Understanding Uncertainties and Confidence in Hazard Databases: An Example Using IRIS."

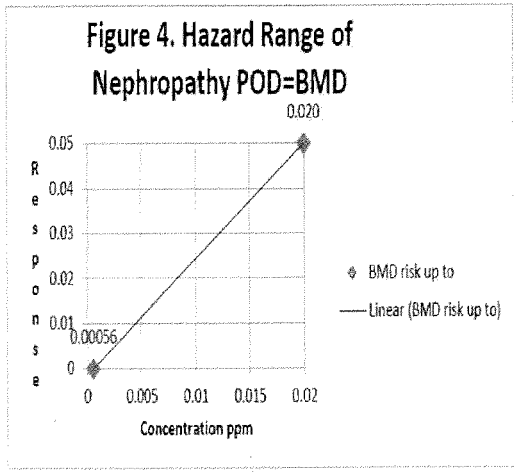
Extra Slides

Johnson et al., 2003
RfC = 2 μg/m^3

- Fetal malformation endpoint
  - Midpoint of 10 μg/m^3 is judged to be 5-fold above the candidate RfC due to:
    - Its small UF of 10,
    - Shallower hazard slope,
    - Low confidence in the critical effect, and
    - Low confidence in the choice of a benchmark response of 1% ($BMDL_{01}$)

Hazard Ranges of Two Candidate RfCs for TCE (as per Gentry et al.)





NTP, 1988
RfC = 3 μg/m^3

- Toxic nephropathy endpoint
  - Midpoint of 9 μg/m^3 is judged to be 3-fold above the candidate RfC due to:
    - Its small UF of 10,
    - Steeper hazard slope,
    - Medium confidence in the critical effect, and medium to low confidence in the choice of a benchmark response of 5% ($BMDL_{05}$)

Keil et al., 2009
RfC = 2 μg/m^3

- Decreased thymus weight endpoint
  - Midpoint of 20 μg/m^3 is judged to be 10-fold above the candidate RfC due to:
    - Its larger UF of 100, medium confidence in the critical effect, and medium to low confidence in its choice of a LOAEL as the POD
    - The effect shown by Keil et al. (2009) does not lend itself to dose-response modeling, so steepness of the slope was not assessed

Arsenic as an Example

Oral RfD Summary (after IRIS)

Critical Effect	Experimental Doses	UF	MF	RfD
Hyperpigmentation, keratosis and possible vascular complications Human Chronic oral exposure Tseng, 1977; Tseng *et al.*, 1968	NOAEL: 0.009 mg/L, converted to 0.0008 mg/kg-day LOAEL: 0.17 mg/L, converted to 0.014 mg/kg-day	3	1	3E-4 mg/kg-day

Chromium (VI)

Oral RfD Summary (after IRIS)

Critical Effect	Experimental Doses	UF	MF	RfD
None Reported Rat, 1-year drinking water study MacKenzie et al., 1958	NOAEL: 25 mg/L of chromium as K_2CrO_4 2.5 mg/kg-day (adj.)	300	3	3E-3 mg/kg-day

Tetrachloroethylene

Oral RfD Summary (after IRIS)

Principal Study/Critical Effect	POD (mg/kg-day)*	UF	Candidate RfDs (mg/kg-day)	RfD (mg/kg-day)**
Echeverria *et al.* (1995): neurotoxicity (reaction time, cognitive effects) in occupationally-exposed adults	LOAEL = 9.7	1,000[a]	0.0097	0.006
Cavalleri *et al.* (1994): neurotoxicity (color vision) in occupationally-exposed adults	LOAEL = 2.6	1,000[a]	0.0026	

*Derived by route-to-route extrapolation from inhalation exposure using PBPK model of Chiu and Ginsberg (2011).

**The RfD is supported by the two principal studies, as a midpoint of the range of available values (then rounded to one significant figure).

[a]Judged to be 100 (see text under "*Evaluation*")

Table 1. Summary of data for the Development of the Hazard Range for the Arsenic, Tetrachloroethylene and Chromium (VI) RfDs on IRIS (2014).

(All values for these ranges are in mg/kg-day).

Chemical	IRIS RfD	IRIS POD	IRIS UF[a]	Steep Slope[b]	Confidence		Hazard Ranges (mg/kg-day)		
	(mg/kg-day)				Critical Effect[c]	Point of Departure[d]	Floor	Midpoint (Intermediate)	Ceiling
Arsenic*	3E-4	8E-4	3	Low	High	Medium	1E-4*	3E-4	8E-4*
Tetrachloroethyl-ene	6E-3	6E-0	1000	Low	High	Low	6E-3	6E-2	6E-1**
Chromium (VI)	3E-3	2.5	300 x 3	Low	Low	Low	3E-3	3E-2	3E-1***

*The floor to ceiling range as found on IRIS

**Range judged to be 100 (see text under *"Evaluation"*)

***Range judged to be 100 (see text under *"Evaluation"*)

a. Size of the uncertainty factor, as per IRIS

b. Steepness of the hazard slope (*i.e.*, the slope of a hypothetical line describing population responses at concentrations above the RfD), as per Section 3 of eth case Study Report.

c. Confidence in the choices of critical effect, as per Section 4 of the Case Study Report.

d. Confidence in the point of departure, as per Section 4 of eth Case Study Report.

The concept of hormesis and application in risk assessment

Michael Dourson with help from Ed Calabrese
Risk Science Center (aka, TERA Center)
University of Cincinnati, College of Medicine

UNIVERSITY OF Cincinnati

Abstract

- Low dose non-monotonic (LDNM) behavior occurs routinely in biological systems. Such behavior can be due to essentiality, toxicology masking or hormesis.
- Hormeisis is characterized by low-dose adaptive effect and high-dose adverse effect.
- As with other LDNM, hormesis depends on endpoint measured and chemical mode of action (MOA).
- Because the hormetic biphasic dose response may represent a general pattern of biological responsiveness, or is otherwise part of the adverse outcome pathway of many chemicals, it should become progressively more significant within risk assessment practice.

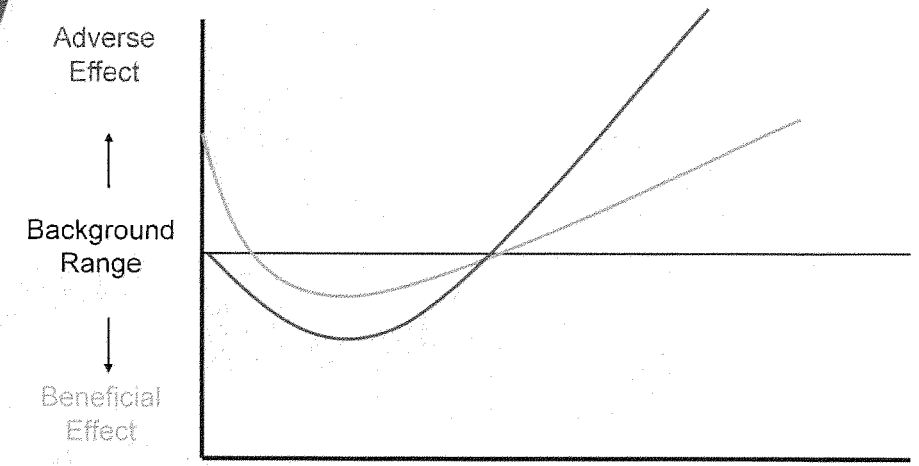
UNIVERSITY OF Cincinnati

HORMESIS CONCEPT

- Low doses of numerous stressors (e.g. exercising, intermittent fasting, hypoxia, heat, cold, ionizing/non-ionizing radiation, electricity, toxins, chemicals/drugs) can stimulate a wide range of adaptive responses
- Calabrese, numerous citations

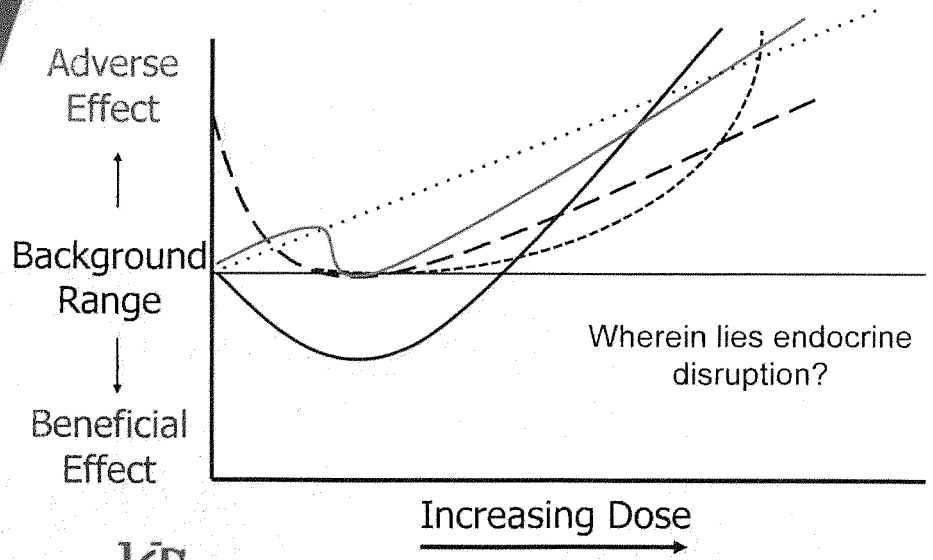
UNIVERSITY OF Cincinnati

General Form of the Essentially/Hormesis Curves



UNIVERSITY OF Cincinnati

A Variety of Possibilities
Essentially (– –), Hormesis (–), Toxicity (---), Cancer (…) LDNM (red)



UNIVERSITY OF Cincinnati

Mechanisms for LDNM (partial)

- Essential nutrients – such as chromium & copper
- Overcompensation & induction of protective responses – increased heat shock proteins from mild heat stress or gutathione from oxidative stress
- Benefits and risks to different organs---low dose ethanol benefits in heart, but high dose problems in CNS & liver
- Shifts in response spectrum – cyclophosphamide increased resistance to flu; decreased resistance to tumors.
- Stimulatory and inhibitory receptors within same organ (apomorphine)
- Masking---antimicrobial stimulation of growth masking overall toxicity measured by changes in body weight

A Way Forward?

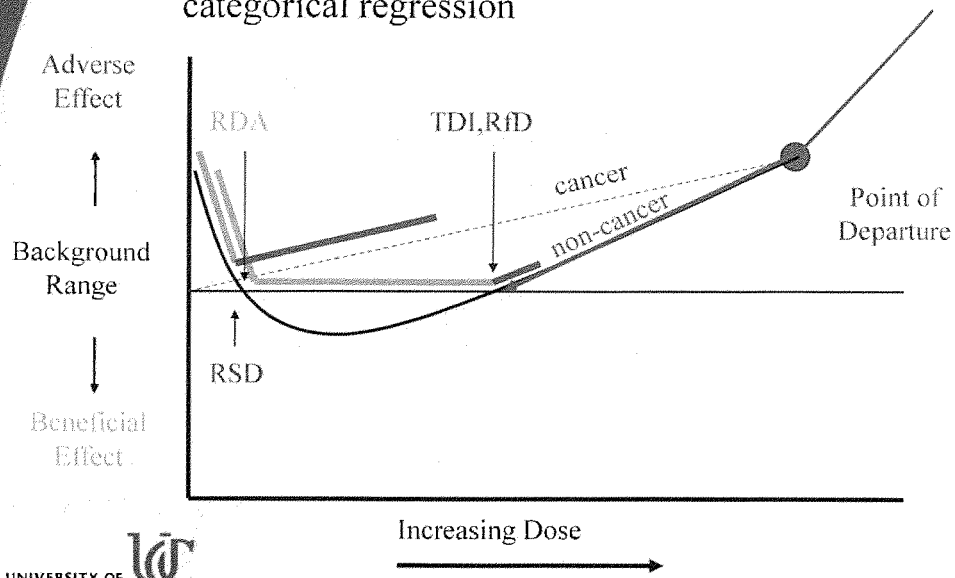
Case by Case (current approach for essential nutrients)

A Mode of Action (MOA) approach: Are MOAs the same and effect severities similar?

- No and No? Develop "RDA" and RSD/RfD, allow overlap if biology indicates, or plot composite effect/benefit curve by categorical regression
- No and Yes? Plot composite data using new models, determine nadir
- Yes and No? Plot composite effect/benefit curve by addressing severity via categorical regression
- Yes and Yes? Plot with new models, determine nadir

Is mechanism the same? Effect severity similar?

No and No: Develop RDA, and RSD, TDI or RfD; combine curves (as below) or model via categorical regression

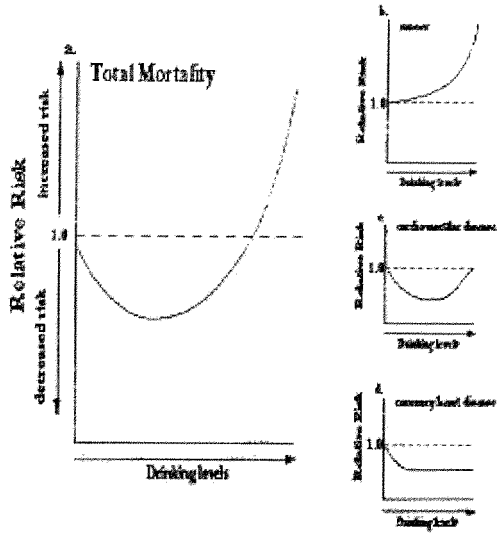


UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

No and Yes: Plot composite data using new models, determine nadir

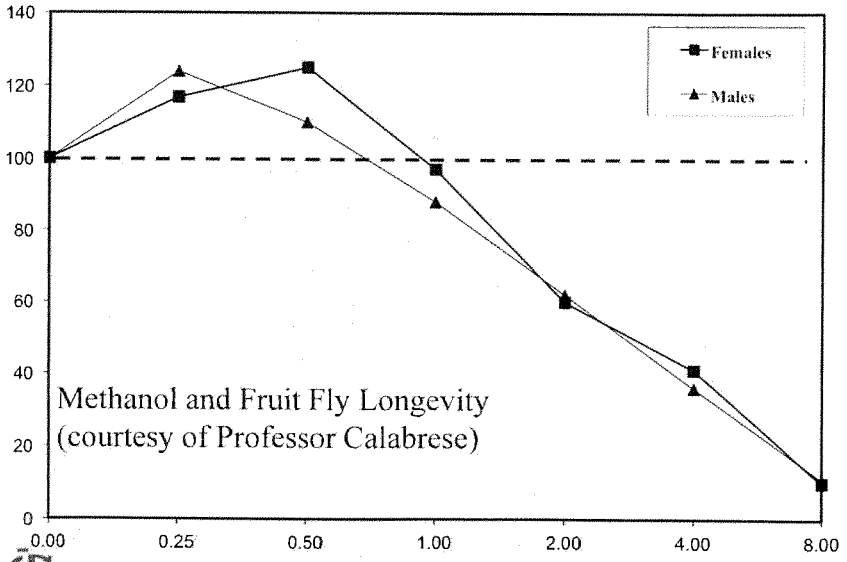
- Total mortality: J-shape response for ethanol intake
- Cancer: no apparent increase until higher drinking levels
- Cardiovascular: U-shaped response
- Coronary Heart Disease: L-shaped threshold effect



UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

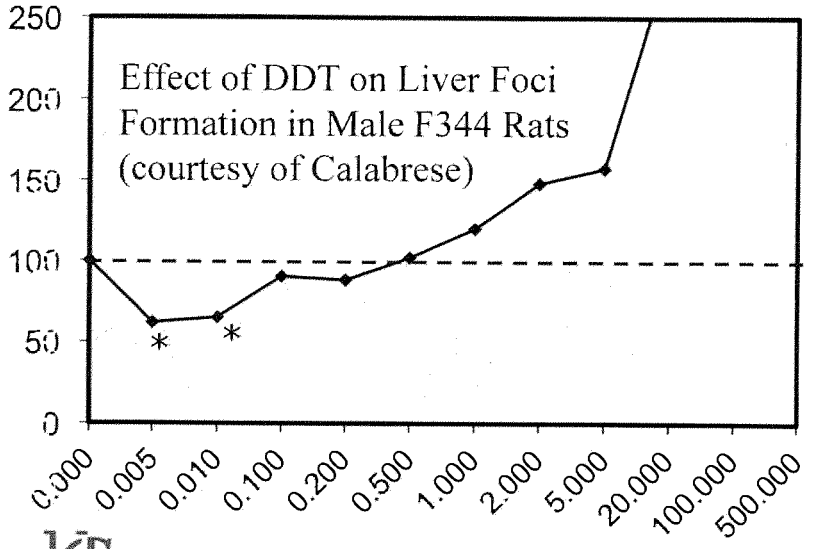
No and Yes.* Plot composite data using new models, determine nadir



UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

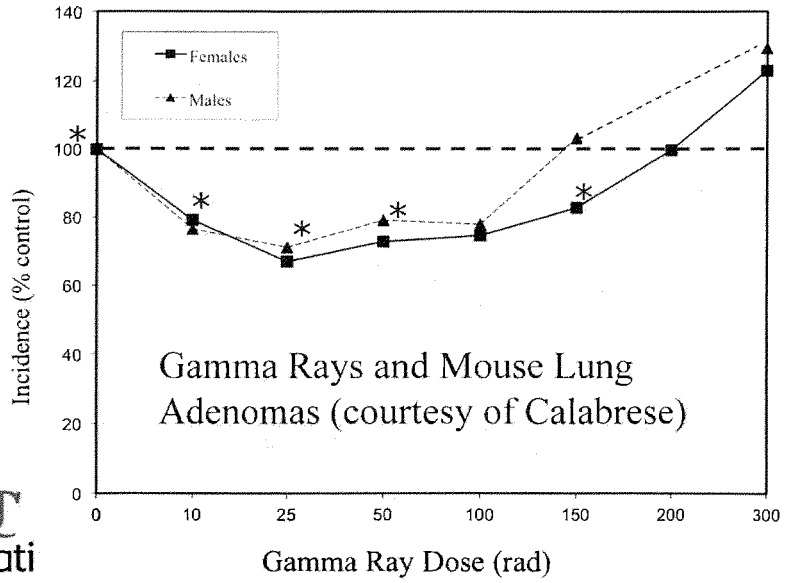
Yes and No: Plot composite effect/benefit curve by addressing severity via categorical regression.



UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

Yes and No: Plot composite effect/benefit curve by addressing severity via categorical regression.

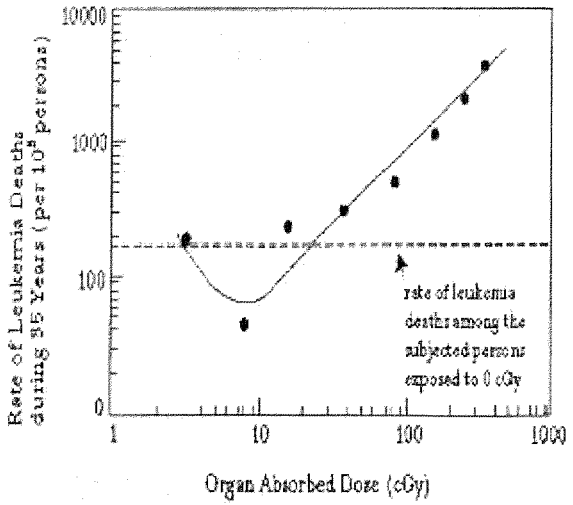


UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

Yes and Yes: Plot using new models and determine nadir

- Survivors of Hiroshima and Nagasaki
- Radiation hormesis
- 8 cGy is optimum for suppression of leukemia
- Dr. Luckey's claim that "low dose radiation is stimulating and essential for life!"

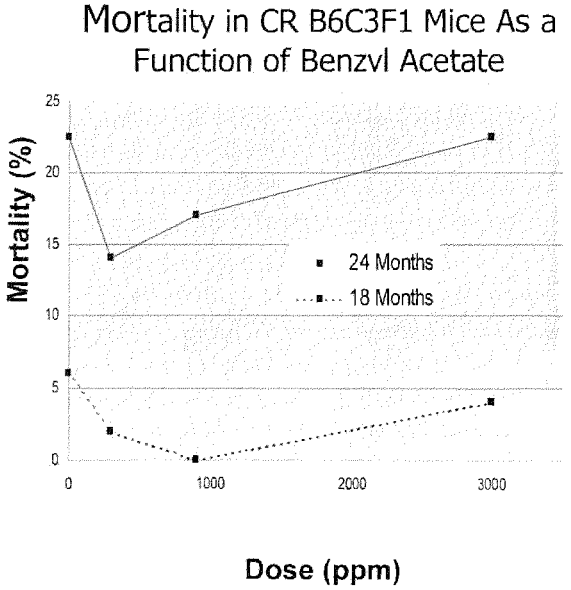


UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

Yes and Yes: Plot using new models and determine nadir

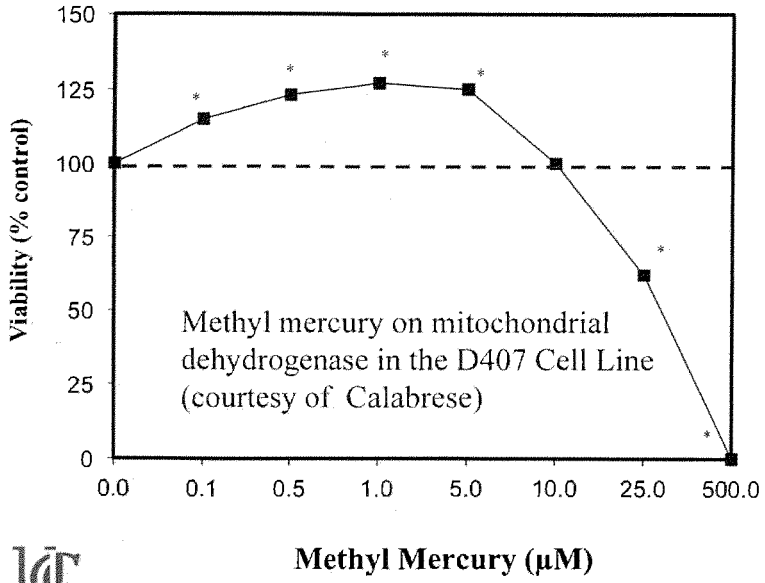
- DR curve with minima at the middle dose at 18 mos. And a minima at the low does at 24 mos.
- Survival at 0 dose keeps deteriorating with age.
- Mortality is inhibited at the medium doses of compound.



UNIVERSITY OF Cincinnati

Is mechanism the same? Effect severity similar?

Yes and Yes: Plot using new models and determine nadir



UNIVERSITY OF Cincinnati

Current Issues and Activities:

Critical Effect & Point of Departure

Trend: better characterizing dose response of critical effect in low-dose region. For example,

- Benchmark dose (BMD), categorical regression and Markov-Chain Monte Carlo for toxicokinetic models (Andersen and Clewell, multiple publications).
- Cooperative agreements to address dose-response approaches for mutagenic chemicals (Moore and Haber, 2006).
- Evaluation of severity, adversity, adaptation, compensation, hormesis and essentiality in critical effect.

Current Issues and Activities:

Use of Precursor Data and Adverse Outcome Pathways

Trend: increasing use of precursor data to judge mode of action. For example,

- Meek et al. (2008, 2014) Mode of action frameworks for evaluating experimental animal evidence in relationship to humans.
- U.S. National Institute for Occupational Safety and Health research for evaluating biomarkers; includes Bayesian network for using biomarker data.
- U.S. Environmental Protection Agency (EPA) research on the pathology-physiological progression to develop criteria to categorize endpoints (AOPs).

Current Issues and Activities:

Uncertainty Factors

Trend: using chemical data to move from default values of 10-fold. For example,

- International Programme on Chemical Safety (Meek et al., 1994; IPCS, 2005; EPA, 2013) methods for using chemical-specific adjustment factors (CSAFs).
- SOT Award-winning papers on implications of genetic polymorphisms for development of uncertainty factors and CSAFs (Nauman et al., 1998; Haber et al., 2002).
- The default is to use data; use 10-fold reluctantly.

Implications for Essentiality Risk Characterization

A Risk Assessment Definition for Essential Elements…

> Statistical or biological significant increases in adverse effects at both lower and higher doses from an optimal or background point in the dose response curve.

A Risk Assessment Definition for Hormesis…

> Statistical or biological significant decreases in adverse effects below background in the low dose region.

With either definition, low, but yet still measurable doses, exhibit a positive, beneficial effect.

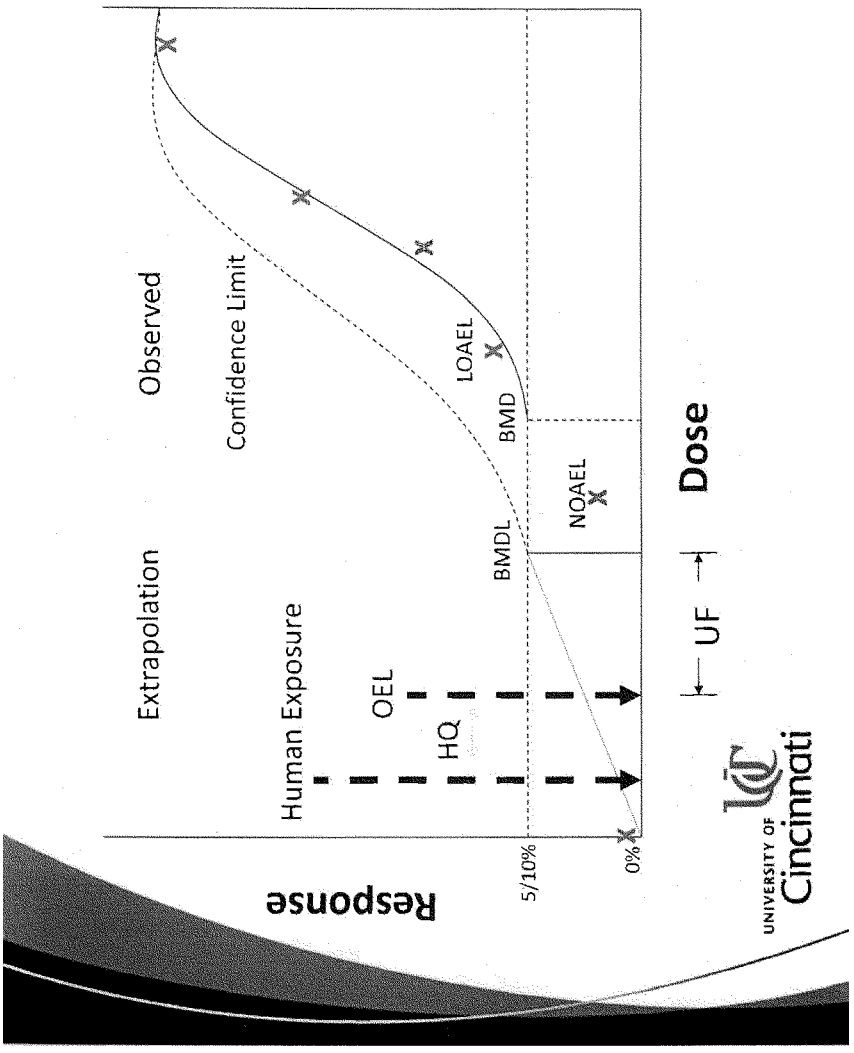
UNIVERSITY OF Cincinnati

Conclusions

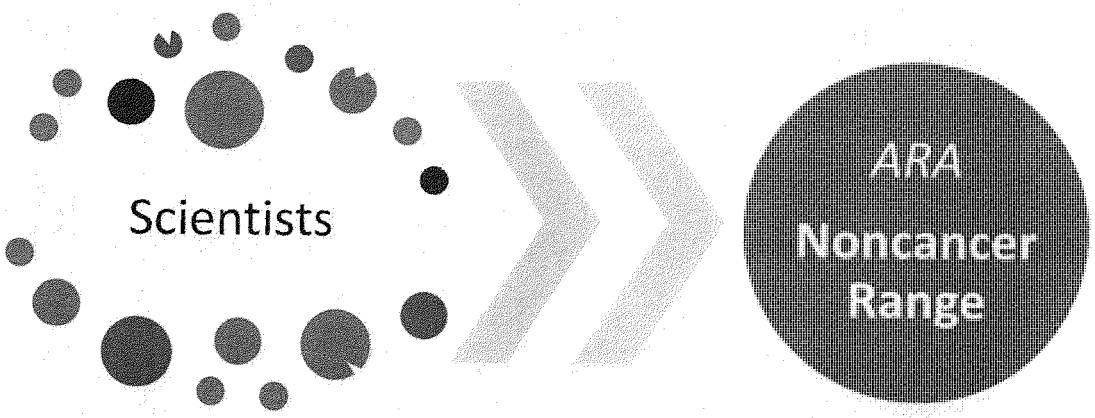
- The existing risk assessment & management model is general and can incorporate essential elements, but it lacks precision.
- Hormesis is a general biological concept. It represents an adaptive strategy through which biological performance is enhanced and mediated.
- A mode of action framework may provide approaches for characterizing risk and benefit of hormetic and other LDNM elements, but must address the differing severity of effects, perhaps through categorical regression.



Extra Slides


Response
Dose
Extrapolation
Observed
Confidence Limit
Human Exposure
OEL
HQ
LOAEL
BMD
BMDL
NOAEL
5/10%
0%
UF
UNIVERSITY OF Cincinnati

Managing the Non-Cancer Risks at Hazardous Waste Sites: Trichloroethylene (TCE) as a Case Study



Michael Dourson, Risk Science Center, U.Cin.
Rod Thompson, Risk Options, LLC
Edward Pfau, Hull and Associates

Abstract

- The 2011 EPA reference concentration (RfC) TCE presents risk managers evaluating vapor intrusion with two challenges:
  - Discerning TCE concentrations that are attributable to subsurface contamination, and
  - Selecting remedial objectives that result in acceptable indoor TCE levels.
- RfCs exhibit several precautionary adjustments, but do not show a range as for cancer (i.e., 10^{-4} to 10^{-6}). Thus, risk managers do not often consider an RfC range when deciding.
- A method for determining the safety range for noncancer hazard is presented:
  - Comparable to the cancer risk range
  - Consistent with the uncertainty inherent in EPA's RfC calculation.
  - TCE Safety range was judged to be 3 to 30 ($\mu g/m^3$).

State's Relocation or Immediate Response Action Levels

Problem Formulation: So which "safe" levels are correct?

State	Urgent/Immediate Action Residential	Urgent/Immediate Action Commercial	Imminent Action Residential	Imminent Action Commercial
Alaska	2	8.4		
California	6	(24)		
Connecticut	5	8		
Indiana	20			
Massachusetts	6	24	20	60
New Hampshire	2	8.8		
New Jersey	4	18		
New York	20			
Ohio	6.3	26	20	60
Region 09	6	24		
Region 10	2	8		
Region 7	2	8		

State's Very Rapid Response Action Levels

All of these are in the safe range for the appropriate group!

State	Urgent/Immediate Action Residential	Urgent/Immediate Action Commercial	Imminent Action Residential	Imminent Action Commercial
Alaska	2	8.4		
California	6	(24)		
Connecticut	5	8		
Indiana	20			
Massachusetts	6	24	20	60
New Hampshire	2	8.8		
New Jersey	4	18		
New York	20			
Ohio	6.3	26	20	60
Region 09	6	24		
Region 10	2	8		
Region 7	2	8		

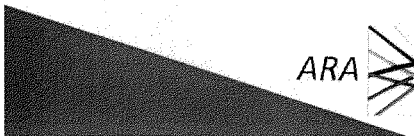
Problem Response: Alliance for Risk Assessment (*ARA*)

- *ARA* Steering Committee accepts proposal Summer 2012
  - United States Army Corps of Engineers, Oregon Department of Environmental Quality, Indiana Department of Environmental Management, U.S. Environmental Protection Agency (EPA), University of Cincinnati, College of Medicine, Texas Commission on Environmental Quality, Agency for Toxic Substance & Disease Registry, Neptune & Company, Inc.
- TCE Workgroup formed in the Fall of 2012
  - Open invitation, broad interest and participation
  - Trichloroethylene (TCE) Risk Assessment Guidance for Contaminated Sites (April 2013)
  - Webcast: Practical Guidance for Contaminated Sites: TCE Risk Assessment Case Study (November 4, 2013); over 300 scientists from multiple international organizations, including government, industry, academia and NGOs, on 6 conference calls and one webinar.
  - Alliance for Risk Assessment (*ARA*) review Summer of 2015
  - Publication in the Spring of 2016

ARA Science Panel
Thoughts and Response

Purpose: Guidance for Noncancer Range at Contaminated Sites

- Develop a range in noncancer risks, similar to the range used for cancer risks in management of waste sites, using readily available information from U.S. EPA and elsewhere.
- Create range to enable evaluation of uncertainty in the noncancer benchmark.
- Demonstrate confidence in this range so that the range can be considered in the determination of management choices.



NAS (2014) & IRIS Process

- **Finding:** EPA could improve documentation and presentation of dose-response information.

- **Recommendation:** EPA should clearly present two dose-response estimates: **a central estimate (such as a maximum likelihood estimate or a posterior mean) and a lower-bound estimate for a POD from which a toxicity value is derived.** The lower bound becomes an upper bound for a cancer slope factor but remains a lower bound for a reference value."

NAS (2014) & IRIS Process

- **Finding**: IRIS-specific guidelines for consistent, coherent, and transparent assessment and communication of uncertainty remain incompletely developed. The inconsistent treatment of uncertainties remains a source of confusion and causes difficulty in characterizing and communicating uncertainty.

- **Recommendation**: Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty communication. Moreover, uncertainty analysis should become an integral component of the IRIS process.

Developing the Range

An RfC is an estimate (**with uncertainty spanning perhaps an order of magnitude**) of a daily oral (for RfD) or continuous inhalation (for RfC) exposure to the human population (**including sensitive subgroups**) that is likely to be without an appreciable risk of deleterious effects during a lifetime.

- Arsenic RfD on IRIS.
  - There was not a clear consensus among Agency scientists on the oral **RfD of 0.3 ug/kg-day**. Applying the Agency's RfD methodology, strong scientific arguments can be made for various values within a factor of 2 or 3 of the currently recommended **RfD value, i.e., 0.1 to 0.8 ug/kg-day**. It should be noted, however, that the RfD methodology, by definition, yields a number with inherent uncertainty spanning perhaps an order of magnitude.

Developing the Range (con't)

- In the IRIS Summary for TCE, U.S. EPA identified three candidate RfC values from principal and supporting studies for the noncancer inhalation toxicity of TCE. These are:
  - Candidate RfC of 2 μg/m^3 based on decreased thymus weight in female mice (Keil *et al.*, 2009);
  - Candidate RfC of 2 μg/m^3 based on fetal heart malformations in rats (Johnson *et al.*, 2003); and
  - Candidate RfC of 3 μg/m^3, based on toxic nephropathy in female rats (NTP, 1988).
- Each of these candidate RfCs may be evaluated with respect to the imprecision and the uncertainty inherent in its derivation.

Imprecision Versus Uncertainty

- **Imprecision** of a RfC is on both sides of the RfC. This is because a 2nd expert group might estimate a RfC higher or lower than the 1st group, if given the same information.
- **Uncertainty** in a RfC, in contrast, lies mainly above the RfC. This is because RfCs are based on lower bounds on points of departure & uncertainty factors are known to be protective.
- For risk management decisions, uncertainty in the RfC is generally more important than imprecision. Managers are interested in making decisions that protect public health and uncertainties in a RfC are generally more informative.

Different Uncertainty Ranges for TCE RfCs

Table 7. Uncertainty ranges for different TCE RfCs in $\mu g/m^3$. Shaded areas indicate best **overall uncertainty range** for risk management.

Study	IRIS UF [a]	Steep Slope [b]	Confidence		Uncertainty Ranges		
			Critical Effect [c]	Point of Departure [d]	Floor	Intermediate	Ceiling
Johnson et al (2003)	10	Lower	Low	Low	2	10	20
NTP (1988)	10	Higher	Medium	Medium to Low	3	9	30
Keil et al. 2009	100	NA	Medium	Medium to Low	2	20	190

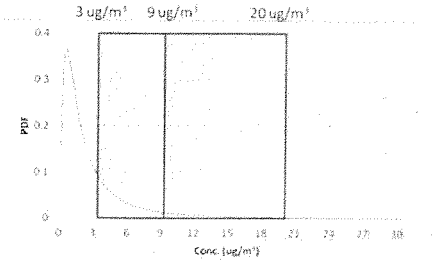


Figure 3a. Exposure distribution of indoor air concentrations primarily below the 3 µg/m^3 to 20 ug/m^3 hazard range. Relatively small proportion of exposures is higher than 3 µg/m^3. Nominal actions or no further action may be warranted for risk management.

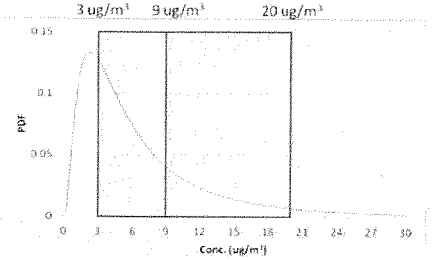


Figure 3b. Exposure distribution of indoor air concentrations falling within the 3 µg/m^3 to 20 µg/m^3 hazard range. Relatively small proportion of exposures is higher than 9 µg/m^3. Limited action may be warranted for risk management.

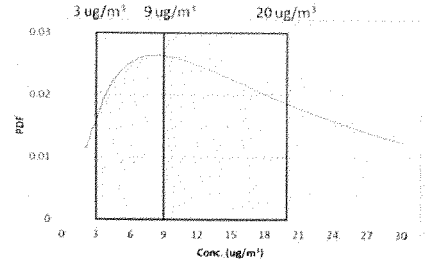


Figure 3c. Exposure distribution of indoor air concentrations freqeuently above the 3 µg/m^3 to 20 µg/m3 hazard range. Actions to reduce exposures may be warranted for risk management.

TCE Action Level Decision Matrix

Exposure Scenario	Chronic Response ug/m^3	Accelerated Response ug/m^3	Prompt Action ug/m^3
Residential	>3.2 but < 9.4	> 9.4 but < 21	> 21
Commercial (8 hr)	> 13 but < 39	> 39 but < 88	> 88
Response Action	Within months coordinate with local or state personnel to communicate risk from long-term exposures.	Within weeks coordinate with local and state personnel to communicate risk from short term exposure.	Within days coordinate with local and state personnel to communicate risk from several days exposure.
	Based on chronic exposures, remedial objectives can be based anywhere in the range of 3.2-9.4 ug/m^3 (residential) or 13-39 ug/m^3 (commercial) within 6 months.	Based on short term exposures, remedial objectives can be based anywhere in the range of 3.2-9.4 ug/m^3 (residential) or 13-39 ug/m^3 (commercial) within 10 days to 3 months.	Based on acute exposures, remedial objectives can be based anywhere in the range of 3.2-9.4 ug/m^3 (residential) or 13-39 ug/m^3 (commercial) within a matter of days.

Summary: Noncancer Range at Contaminated Sites

- A noncancer range was developed for the TCE RfCs. Range included floor, midpoint and ceiling.
- Range for EPA's TCE RfC was judged to be ***3 to 30 µg/m³***.
  - The results of the NTP study-based RfC were used to determine the floor and midpoint of this uncertainty range.
  - The highly controversial results from the Johnson et al. (2003) study-based RfC, while associated with low confidence, were considered for the ceiling level, but journal peer review recommended against this.
  - This 3 µg/m³ to 30 µg/m³ range was entirely within the wider individual uncertainty range from the Keil et al. (2009) study; therefore, this latter study was considered to be confirmatory.

Need for Further Effort

- Continue this dialogue regarding vapor intrusion risk assessment issues, including agencies and responsible parties.
- Study the proposed method for the noncancer risk range.
- Resolve discrepancies in TCE fetal heart findings from one lab compared with negative findings in all other labs.
- Determine appropriate TCE safe range & averaging time.

For more information go to:

http://www.allianceforrisk.org/Projects/TCE.html

Michael Dourson, michael.dourson@uc.edu
513 558-7949




Collaboration thru *ARA* brings:
Credibility
Publicity
Efficiency
Trust
ARA – Building a Risk Assessment Community

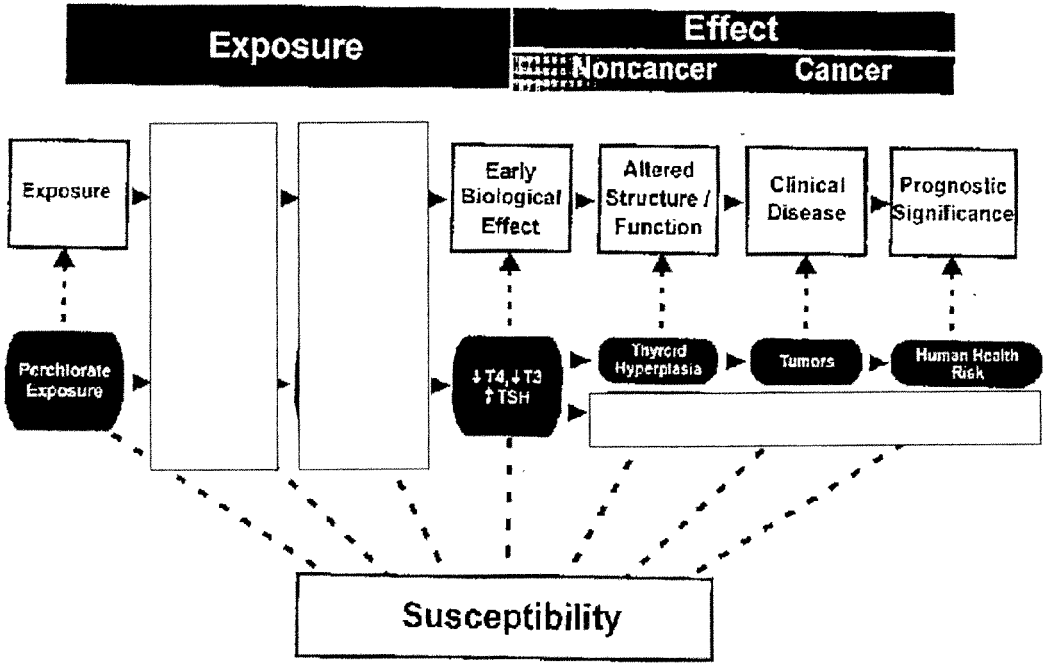
Perchlorate Reference Dose (RfD)

Joan Dollarhide
Jay Zhao
Mike Dourson

Toxicology Excellence for Risk Assessment
(*TERA*)

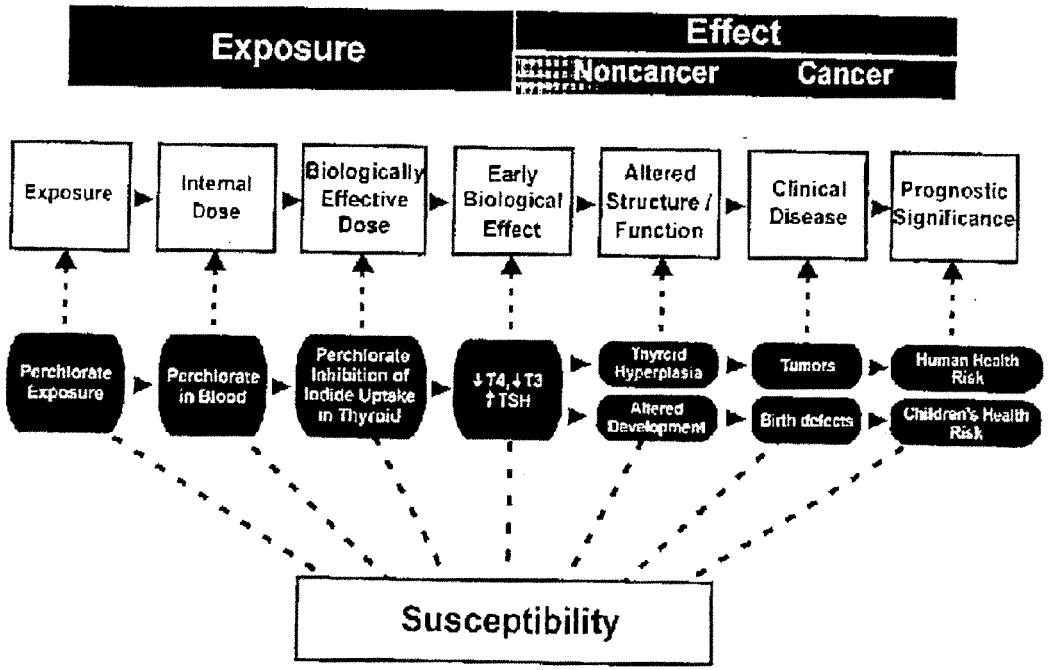
Perchlorate Response Continuum

(EPA, 1992)



Perchlorate Response Continuum

(EPA, 2002)

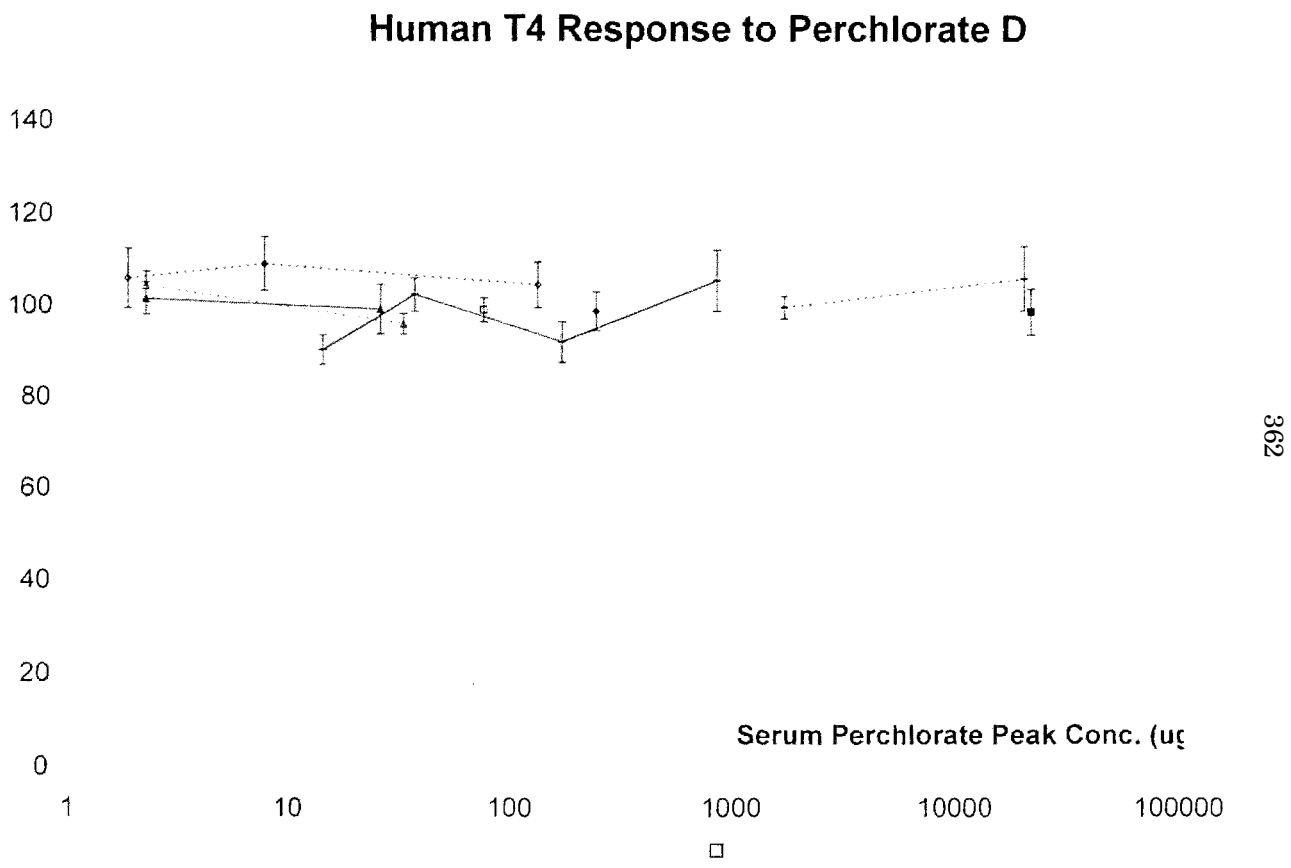


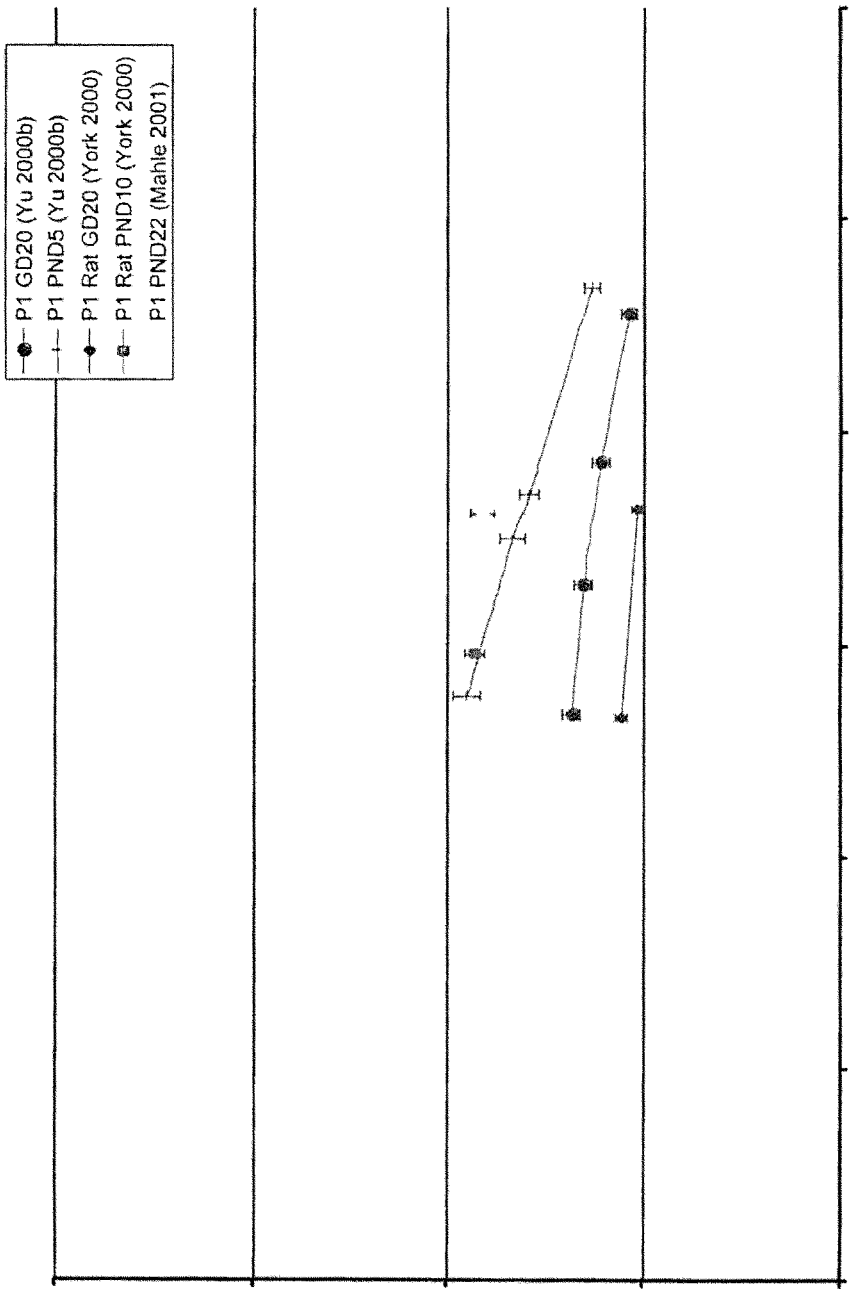
Decreased T4 is Critical Effect

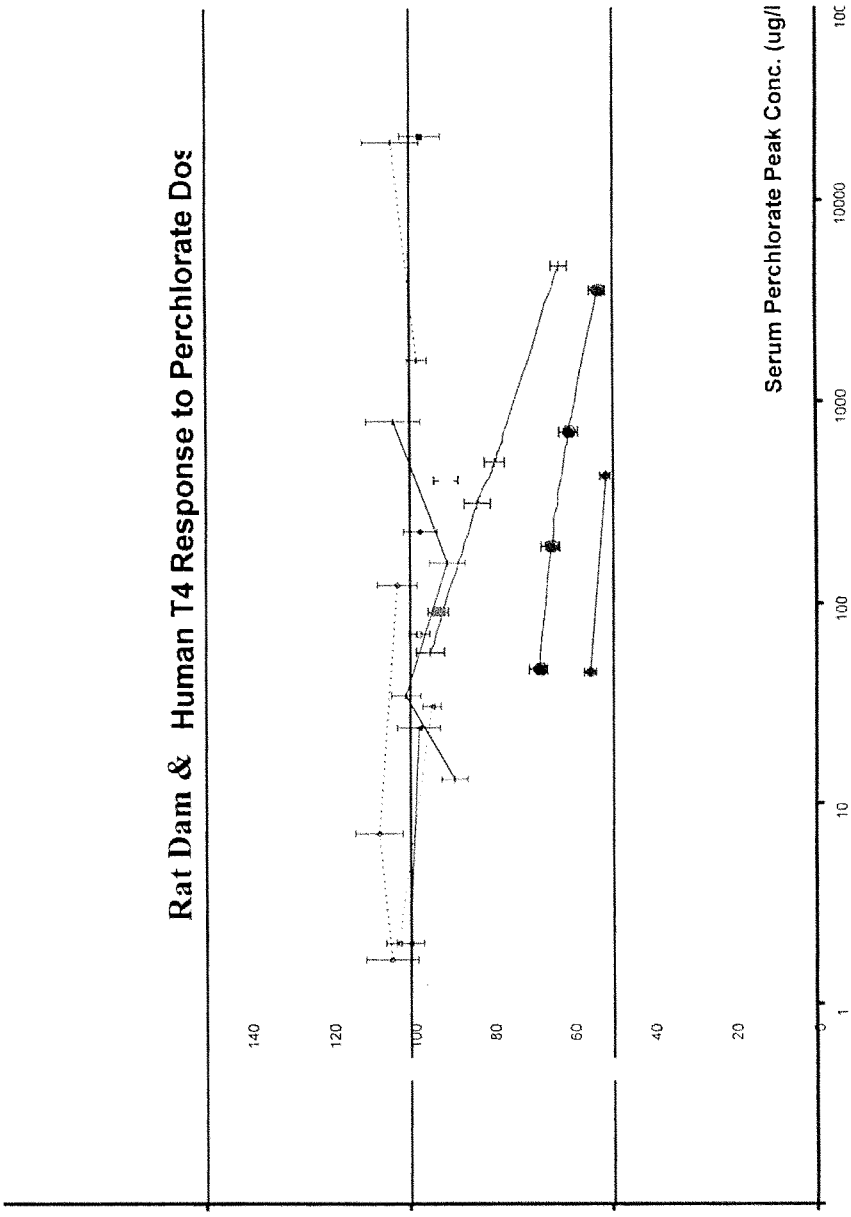
- Mode of action analysis shows inhibition of iodine uptake is biologically effective dose and altered hormones early biological effect
- In humans, decreased T4 in both pregnancy and infancy known to increase potential for thyroid and nervous system toxicity; no such knowledge for iodine inhibition
- In perchlorate rodent studies, altered hormones occur at lower doses than other thyroid and nervous system effects. Pregnant rats have most dramatic response.
- Decreased T4 not adverse itself – changes in this hormone occur every day. Rather decreased T4 is a precursor to an adverse effect.
- Basing an RfD on decreased T4 will prevent all subsequent potential adverse effects.

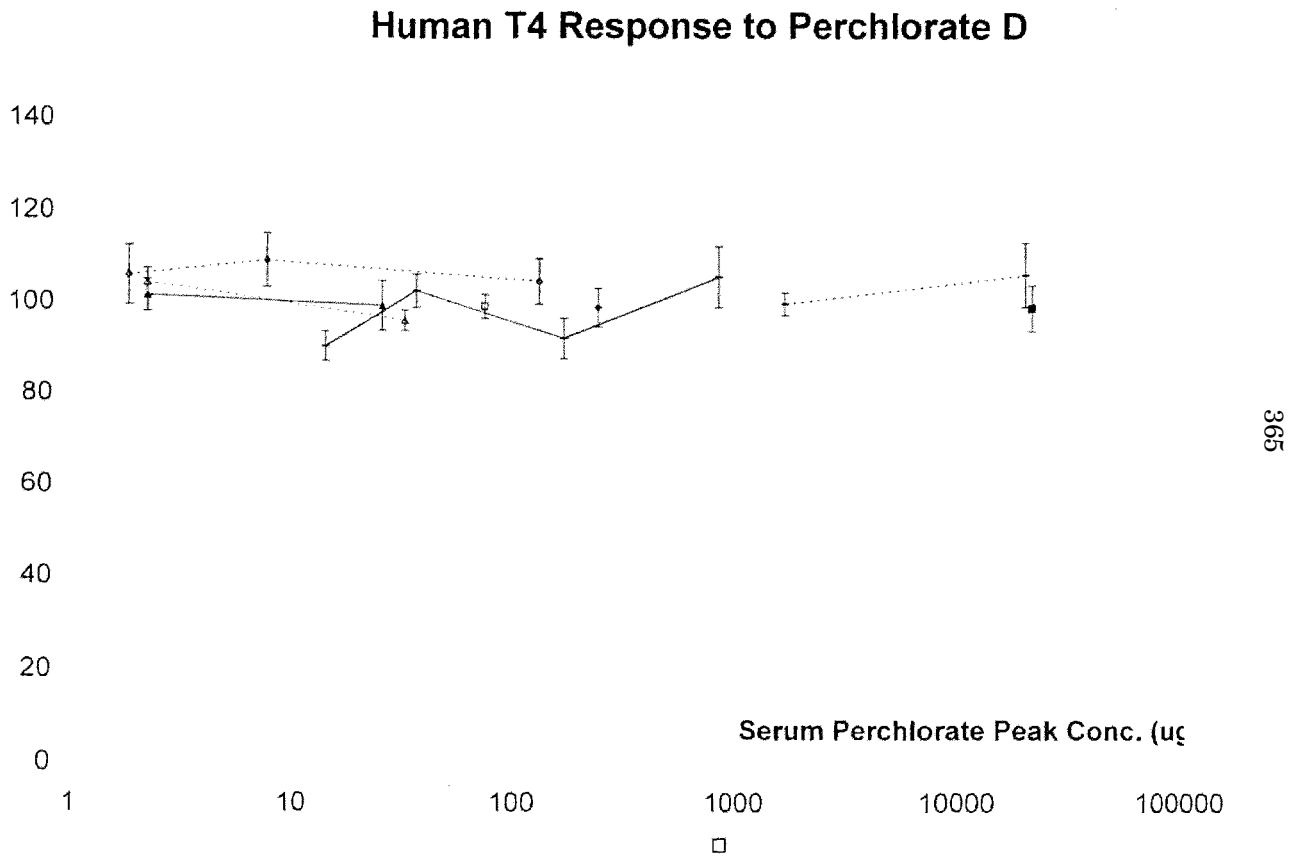
Human Studies Most Appropriate Critical Studies

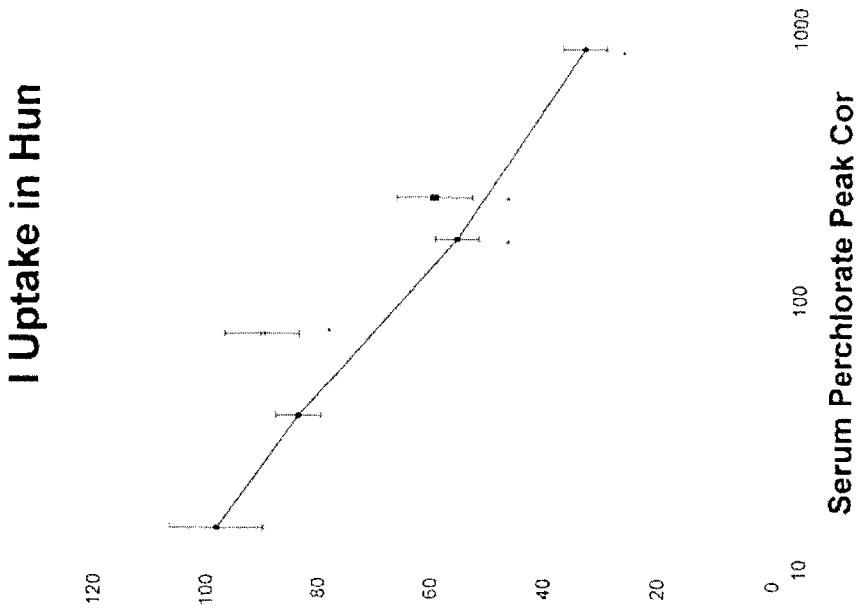
- Several well-conducted human studies available, including occupational, epidemiology, clinical studies.
- One of the sensitive subpopulations, neonates/children, well studied.
- Although kinetics appear similar between rodents and humans, dynamics dramatically different (i.e., 10-fold)
- In humans, no decrease in T4 observed at any dose tested, even when serum perchlorate levels sufficient to result in up to 70% iodine uptake inhibition, compared to rats.
- Iodine uptake inhibition different in humans and rats.

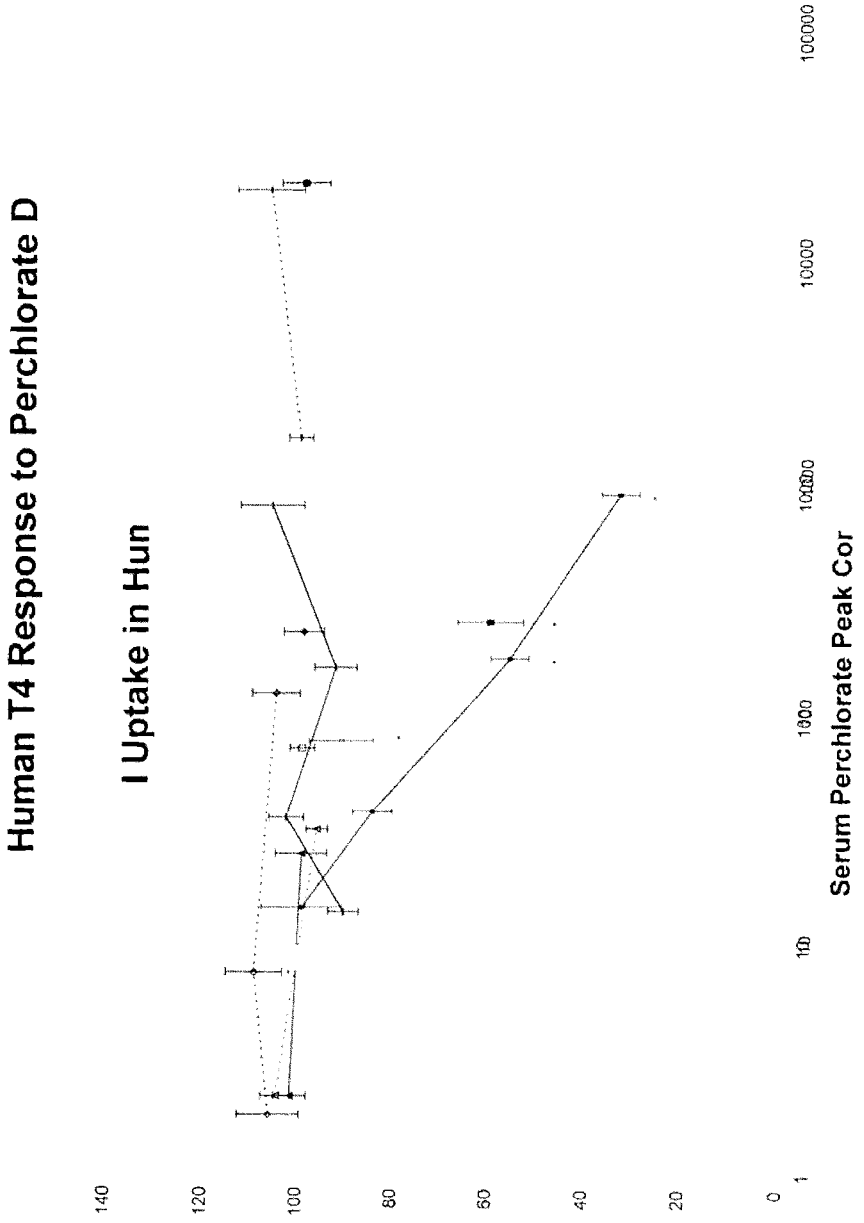

Human T4 Response to Perchlorate D
140
120
100
80
60
40
20
0
1
10
100
1000
10000
100000
Serum Perchlorate Peak Conc. (uç


P1 GD20 (Yu 2000b)
P1 PND5 (Yu 2000b)
P1 Rat GD20 (York 2000)
P1 Rat PND10 (York 2000)
P1 PND22 (Mahle 2001)


Rat Dam & Human T4 Response to Perchlorate Dos
140
120
100
80
60
40
20
0
1
10
100
1000
10000
Serum Perchlorate Peak Conc. (ug/l


Human T4 Response to Perchlorate D
140
120
100
80
60
40
20
0
1
10
100
1000
10000
100000
Serum Perchlorate Peak Conc. (uç


I Uptake in Hun
120
100
80
60
40
20
0
10
100
1000
Serum Perchlorate Peak Cor


Human T4 Response to Perchlorate D
I Uptake in Hun
140
120
100
80
60
40
20
0
1
100000
10000
Serum Perchlorate Peak Cor

Co-critical Study: Crump et al., 2000

- Epidemiology study of 9784 neonates and 162 school-age children.
- TSH and free T4 measured compared in residents of 3 cities in Chile. Measured perchlorate concentrations:

  Taltal – 100-120 ug/L

  Chanaral – 5-7 ug/L

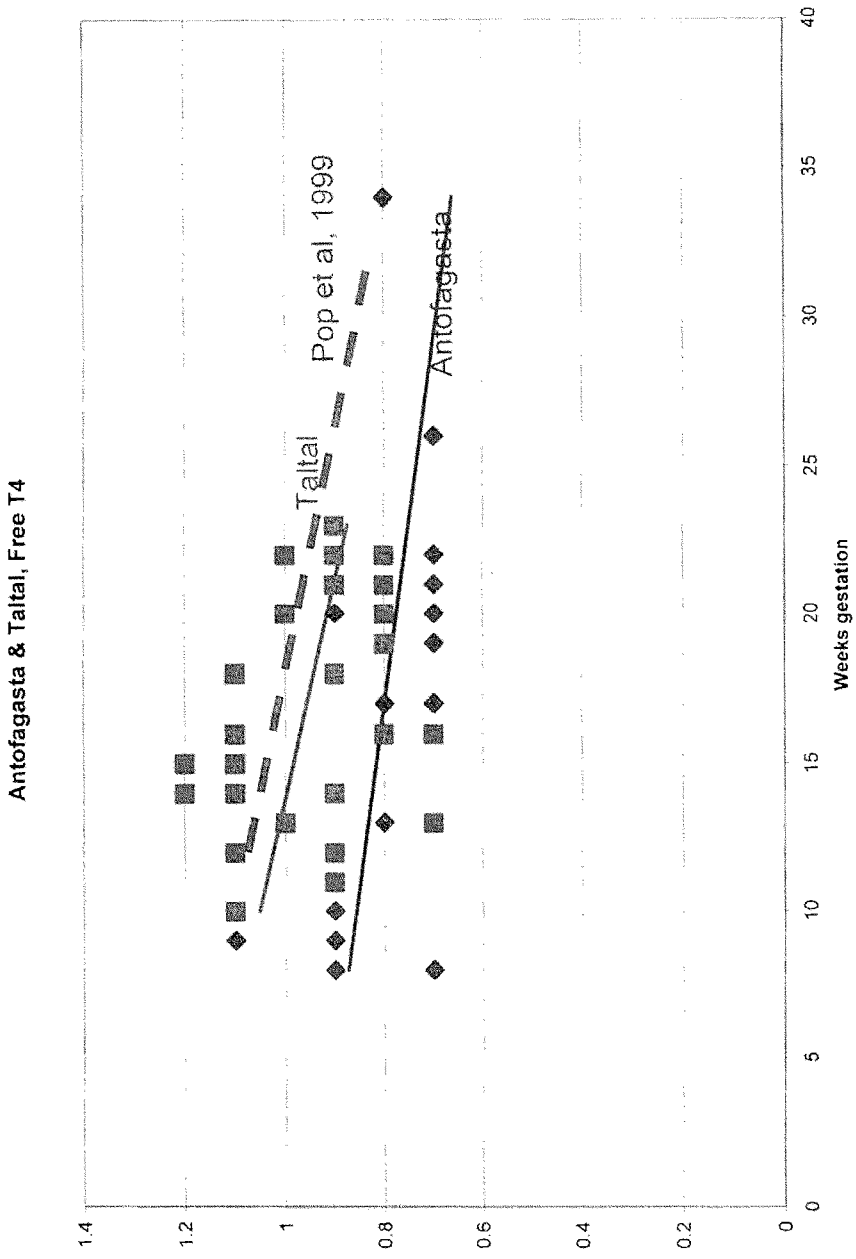
  Antofagasta - <4ug/L
- No effect on TSH or T4 observed in neonates or children in any city.
- Freestanding NOAEL of 0.006 mg/kg-day estimated based on estimated child drinking water consumption of 1.5 L/day and body weight of 28 kg.

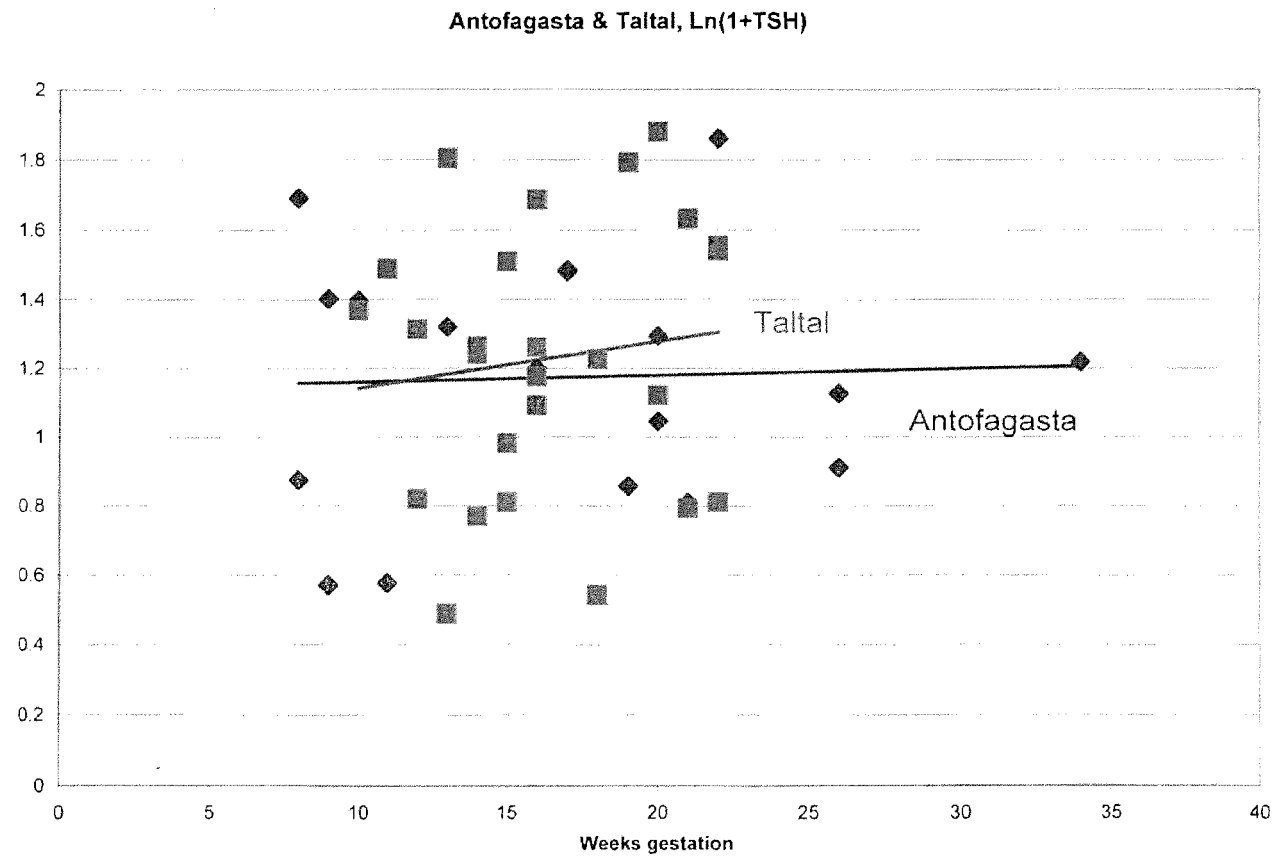
Co-critical Study: Greer et al., 2002

- Clinical study of 37 male and female healthy volunteers exposed for 14 days
- Perchlorate in drinking water at doses of 0.007, 0.02, 0.1 and 0.5 mg/kg-day
- Iodine uptake and thyroid parameters evaluated.
- No statistically significant effects on T4; good dose-response for inhibition of iodine uptake.
- Identifies a NOAEL of 0.5 mg/kg-day.
- BMD analysis of iodine uptake inhibition ($BMDL_{20}$ = 0.02 mg/kg-day) selected as conservative, quantitative NOAEL surrogate for RfD development

Different Perchlorate RfDs

Item \ Group	*TERA* 2002 proposed	*TERA* 2002 supporting	EPA 2002 proposed	OEHHA 2002 proposed
Critical Effect	T4 decrease in children	Adult iodine inhibition	Several effects	Adult iodine inhibition
Study	Crump et al., 2000	3 human clinical studies	PSG, 2001	Greer et al., 2002
BMDL, NOAEL, or LOAEL (mg/kg-day)	Human NOAEL 0.006	Human $BMDL_{20}$ 0.02	Rat LOAEL 0.01	Human BMDL05 0.0037
Total Factor	3	10	300	30
RfD (mg/kg-day)	0.002	0.002	0.00003	0.0001
Confidence in RfD	High	High	Medium	NA


Antofagasta & Taltal, Free T4
Taltal
Pop et al, 1999
Antofagasta
Weeks gestation
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
40


Antofagasta & Taltal, Ln(1+TSH)
2
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
5
10
15
20
25
30
35
40
Weeks gestation
Taltal
Antofagasta

Acknowledgement

TERA wishes to thank the Perchlorate Study Group for its support over a number of years to study perchlorate's toxicology and assess its risk.

However, support for the development of this manuscript was provided only by internal developmental reserve funds of *TERA*, and not by any outside party.

Furthermore, our deliberations shown in this paper have not been influenced by discussions with outside parties.

History of TERA Coordinated Public/Private Partnership on Perchlorate Research

Mike Dourson, Ph.D., DABT

Toxicology Excellence for Risk Assessment (*TERA*)



T*oxicology*
E*xcellence for*
R*isk*
A*ssessment*



TERA is a non-profit 501(c)(3) corporation dedicated to the best use of toxicity data for risk assessment.



One of TERA's Activities

- Improve the practice of risk assessment by industry and government through informed and neutral guidance and advice



History of Perchlorate RfD

- EPA Superfund provisional Reference Dose 1992, revised 1995
- *TERA* RfD and expert peer review 1997 - data are inadequate, suggest specific studies
- 1997-1999 Air Force and PSG complete recommended studies
- 1999 EPA draft document and RfD based on new data peer reviewed/ peer review
- 2000-2002 Air Force and PSG completed additional studies
- 2002 EPA revised draft risk assessment and RfD/ peer review



EPA Provisional RfD 1992

- EPA Superfund Technical Support Center
- Based on acute study in patients with Graves' Disease (Stanbury and Wyngaarden, 1952)
- NOAEL 0.14 mg/kg-day - release of iodine in thyroid followed by incomplete inhibition of iodine uptake
- Uncertainty factor 1000 (10 each Uf_H, UF_S, UF_D)
- RfD of 0.0001 mg/kg-day = ground water screening level of 4 ppb



EPA Provisional RfD 1995

- EPA Superfund Technical Support Center
- Based on acute study in patients with Graves' Disease (Stanbury and Wyngaarden, 1952)
- NOAEL 0.14 mg/kg-day - release of iodine in thyroid followed by incomplete inhibition of iodine uptake
- Uncertainty factor 300 to 1000 (10 each Uf_H, UF_S, 3 to 10 for UF_D)
- RfD of 0.0001 to 0.0005 mg/kg-day = ground water screening level of 4 to 18 ppb



TERA Expert Peer Review 1997

- Additional literature search to answer outstanding questions from EPA provisional RfD
- Considered Caldwell study, not available to EPA
- Developed a RfD based on similar database as EPA's RfD, peer reviewed in 1997



TERA Expert Peer Review 1997

Conclusion:

Perchlorate database insufficient to develop any RfD

Major unanswered questions:

- » shape of dose-response curve in humans
- » effects from long-term exposure
- » possibility of effects in organs/systems other than thyroid



Recommended Studies

- Neurobehavioral developmental
- 90-day subchronic oral bioassay
- Segment II developmental
- Two-generation reproductive
- ADME
- Genotoxicity assays
- Immunotoxicity studies
- Mechanism studies



TERA Coordinated Studies

- TERA, in association with the U.S. Air Force, U.S. EPA, the Perchlorate Study Group and others, has helped in developing a research program and protocols for studies that will fill in the data gaps that existed in the toxicology database.
- Studies were funded by the U.S. Department of Defense and Perchlorate Study Group.
- TERA monitored these studies.



EPA 1999 RfD

- Minimal LOAEL of 0.1 mg/kg-day for thyroid hypertrophy and decreased lumen size in PND5 pups (Neurodevelopmental study, Argus 1998)
- Experimental dose of ammonium perchlorate adjusted by 0.85 to estimate dose of perchlorate ion.
- RfD of 0.0009 mg/kg-day = DWEL of 32 ppb in water



Studies Conducted In Response to 1999 Peer Review Recommendations

- PWG reevaluation of all thyroid histopathology
- Predictive immunotoxicity studies
- Developmental toxicity study in rats
- "Effects study"
- Motor activity study
- Epidemiology and clinical human studies
- PBPK modeling



EPA 2002 RfD

- MOA – any transient decrease of T4 can have effect on neurodevelopment
- LOAEL of 0.01 mg/kg-day based on decreased T4 in rat dams and brain morphometry in rat pups (Effects Study, Argus, 2001)
- Supported by BMDL analysis of colloid depletion and thyroid hypertrophy in multiple studies and novel statistically analysis of motor activity studies
- LOAEL adjusted by 0.85 to estimate dose of perchlorate ion



Summary of RfDs

	EPA 1992	EPA 1995	EPA 1999	EPA 2002	TERA
Critical Study	Stanbury and Wyngaarden, 1952	Stanbury and Wyngaarden, 1952	Argus 1998, Neurodevelopmental study	Argus 2001, "Effects Study"	Crump et al., 2000 and Greer et al., 2002
Species	Human	Human	Rat	Rat	Human
Critical Effect	Release of iodine from thyroid	Release of iodine from thyroid	Thyroid histopathology in PND5 pups*	Decreased T4 in dams, brain morphometry in pups**	Decreased T4 in pregnant women. BMDL for iodine uptake inhibition used as NOAEL surrogate
NOAEL/ LOAEL	NOAEL, 0.14 mg/kg-day	NOAEL, 0.14 mg/kg-day	LOAEL, 0.1 mg/kg-day	LOAEL, 0.01 mg/kg-day	NOAEL, 0.006 or 0.02 mg/kg-day
UF	1000	300-1000	100	300	3-10
RfD	0.0001 mg/kg-day	0.0001 – 0.0005 mg kg-day	0.0009 mg kg-day	0.00003 mg kg-day	0.002 mg kg-day
DWEL	4 ppb	4 ppb 18 ppb	32 ppb	1 ppb	70 ppb

*EPA conducted a "weight-of-evidence" analysis, and noted that this effect was supported by BMD analysis of hormone levels and motor activity results, but that thyroid histopathology occurred at lower doses than the other effects.

** More focus by EPA on the potential for neurodevelopmental effects. Mode of action – transient decrease of T4 can result in neurodevelopmental effects. Weight-of-evidence analysis found support for LOAEL in BMD analysis of hormones, novel statistical evaluation of two motor activity studies, tumors in 2-gen study, and immunotoxicity study.

TERA Provides Public Access to These New Study Results

- *TERA* website: www.tera.org
- Presentation at Scientific Conventions: SRA & SOT
- Provides comments on EPA's assessment
- Publications in peer reviewed journals.



TERA Website Provides Public Access to PSG Study Results

- 1997 peer review comments,
- Study designs,
- Study results,
- Data analysis,
- Related publications,
- TERA independent assessment.



New Manuscript

- Reference dose for perchlorate based on human studies.
- Submitted for publication, peer reviewer's comments received, under revision.



Data-Derived Replacement of Default Uncertainty Factor

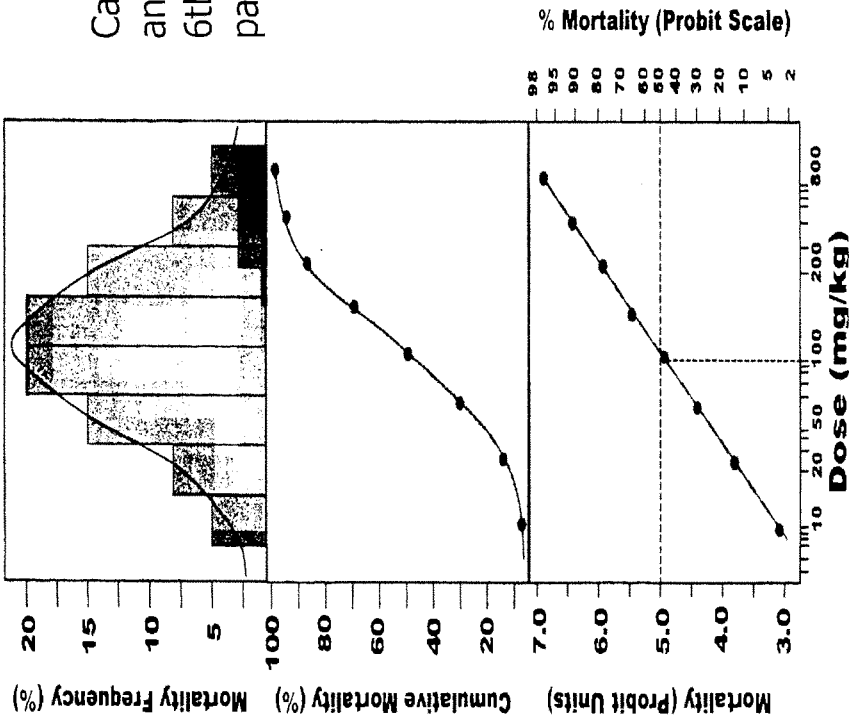
Michael Dourson

and

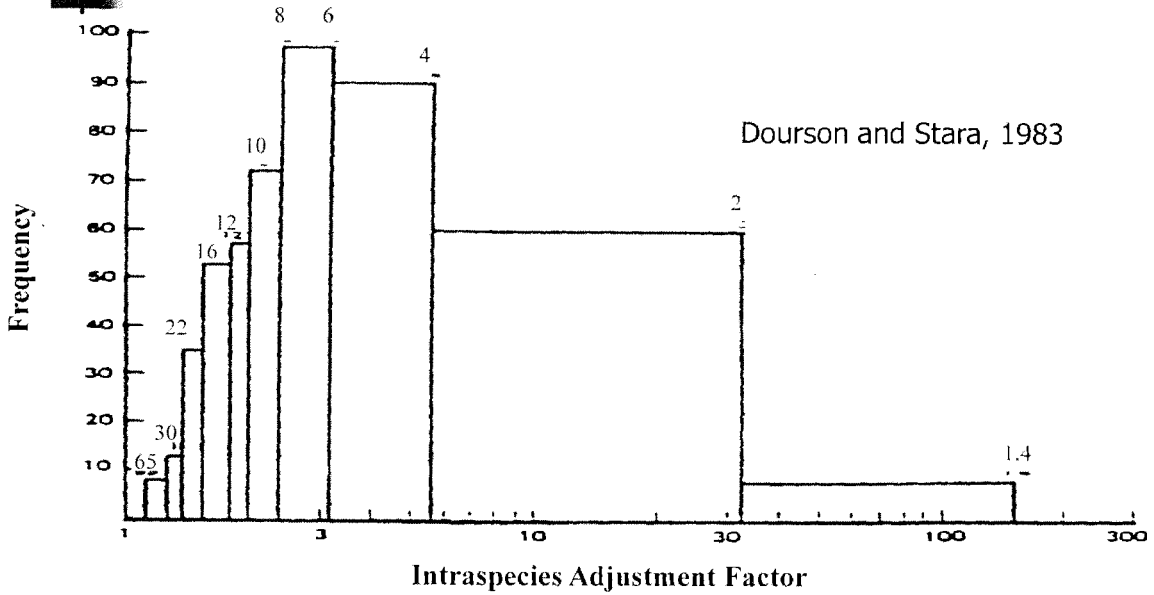
Patricia Nance

Toxicology Excellence for Risk Assessment
(*TERA*)

Casarett and Doull, 6th Edition, page 19

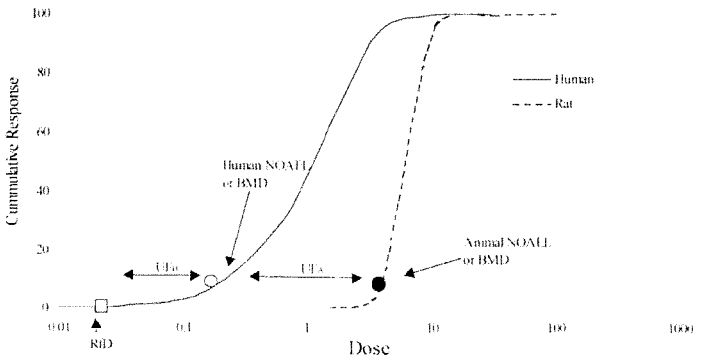


Intraspecies Variability

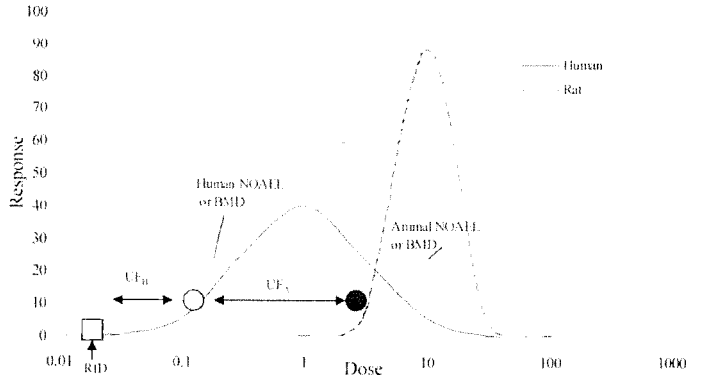


Frequency vs an intraspecies adjustment factor obtained by raising 10 to the power (3 standard deviations ÷ the probit, log-dose slope). Probit, log-dose slopes are shown within the figure

Cumulative response as a function of dose for humans and rats



Response as a function of dose for humans and rats



Dourson et al, 2002, In review

Response as a function of dose for humans of different sensitivities

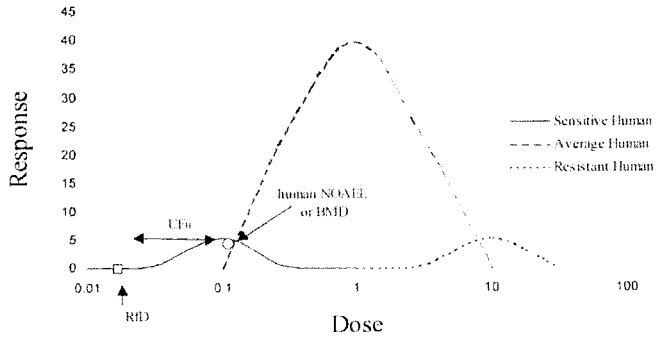
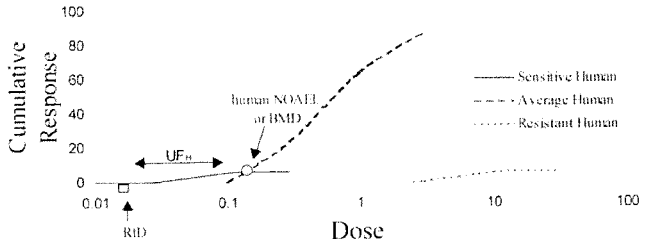


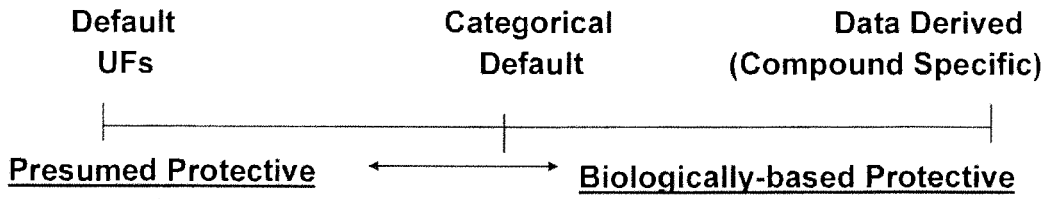
Figure 6b. Cumulative Response as a function of dose for humans of different sensitivities. Data are the same as in Figure 6a.



Dourson et al, 2002, In review

Evolution of Uncertainty Factors

- Over the last several years, scientists have begun using more data when choosing uncertainty factors
- Scientists use a number of approaches
- Methods range from default ("presumed protective") to those incorporating more biological data ("biologically-based protective")



Meek et al, 2001

Example of Default UF: Methyl Hg Oral RfD

Critical Effect	Experimental Doses*	UF	MF	RfD
Developmental neuropsychological impairment	Benchmark Dose: $BMDL_{05}$ range of 46-79 ppb in maternal	10	1	1E-4 mg/kg-day (0.0001 mg/kg-day)
Human epidemiological studies (Grandjean et al., 1997; Budtz-JØrgensen et al., 1999a)	blood for different neurological effects in the offspring at 7 years of age, corresponding to a range of maternal daily intakes of 0.857-1.472 µg/kg-day			

EPA, 2001

Dose Conversion for Methyl Hg

$$d = (\mu g/kg/day)\ \frac{c \times b \times V}{A \times f \times bw}$$

d = daily dietary intake (expressed as μg of methylmercury)
c = concentration in blood (expressed as μg/L)
b = elimination constant (expressed as days-1)
V = volume of blood in the body (expressed as liters)
A = absorption factor (expressed as a unitless decimal fraction
f = fraction of absorbed dose taken up by blood (unitless)
bw = body weight (expressed in kg)

EPA, 2001

Example of Categorical Default

- Renwick (1993) proposed breaking the interspecies and intraspecies UFs into toxicokinetic (TK) and toxicodynamic (TD) components
- This approach was modified by World Health Organization- International Programme on Chemical Safety as follows:

	Kinetics	Dynamics
*Inter*species	4.0	2.5
*Intra*species	3.2	3.2

IPCS, 1994

Interindividual Variability in Ingested MeHg

Study	Maternal Medium	50th percentile[a] (μg/kg-d)	50th percentile/5th percentile[b]	50th percentile/1st percentile[c]
Stern (1997)	hair	0.03-0.05[d] (mean = 0.04)	1.8-2.4 (mean = 2.1)	2.3-3.3 (mean = 2.7)
	blood	0.01	1.5-2.2 (mean = 1.8	1.7-3.0 (mean = 2.4)
Swartout and Rice (2000)	hair	0.08	2.2	Data not reported
	blood[e]	0.02	2.1	2.8
Clewell et al. (1999)	hair	0.08	1.5	1.8
	blood[f]	0.07	1.4	1.7

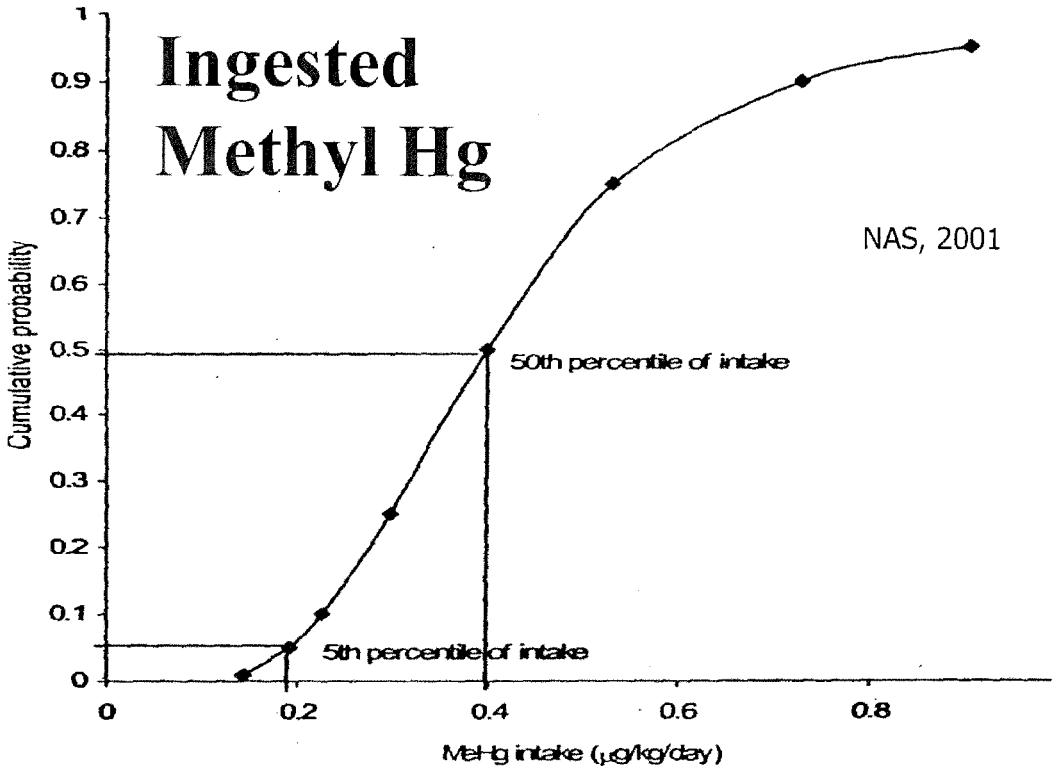
[a] Corresponding to either 1ppm Hg in hair or 1ppb in blood

NAS, 2001

Example of Data-Derived & Categorical Default for Hg

	Kinetics	Dynamics
*Inter*species	1	1
*Intra*species	1.8	3.2

Total UF = 5.8
Methyl Hg RfD = 2 E-4 mg/kg-day



Predicted mean probability of MeHg intake corresponding to 11ppm MeHg in hair.

Example of Data-Derived (or Compound Specific: Monte Carlo

- Plasma Flows
  - fraction of cardiac output
  - e.g., cardiac output, brain, kidney, liver
- Tissue Volumes
  - fraction of body weight
  - e.g., body weight, brain, plasma, kidney
- Partition Coefficients for MeHg
  - e.g., brain/blood, brain blood/plasma, gut/blood
- Kinetic Parameters
  - L/hr for 1 kg animal
  - e.g, conversion of brain MeHg to inorganic Hg, MeHg to inorganic Hg in intestine
- Fetal Kinetic Parameters
  - L/hr
  - placenta/embryo diffusion of MeHg, RBC to plasma diffusion on HeMg in Fetus

Comparison of ingestion rates (μg/kg/day) estimated using a deterministic approach to rates estimated using a Monte Carlo approach

Percentile	Monte Carlo	Deterministic
1	0.82	0.6-0.9 (Stern, 1997)
5	0.99	
10	1.10	
25	1.25	
50	1.5	1.7 (ATSDR, USEPA MC)
75	1.8	2.0 (USEPA)
90	2.19	
95	2.47	
99	3.15	

Comparison of Predicted Variability of Ingestion Rate from Monte Carlo Analysis

Ratio of Median to 5th Percentile of Distribution		
USEPA	Stern (1997)	PBPK
2.0	2.0	1.5

RfD Based on a Monte Carlo

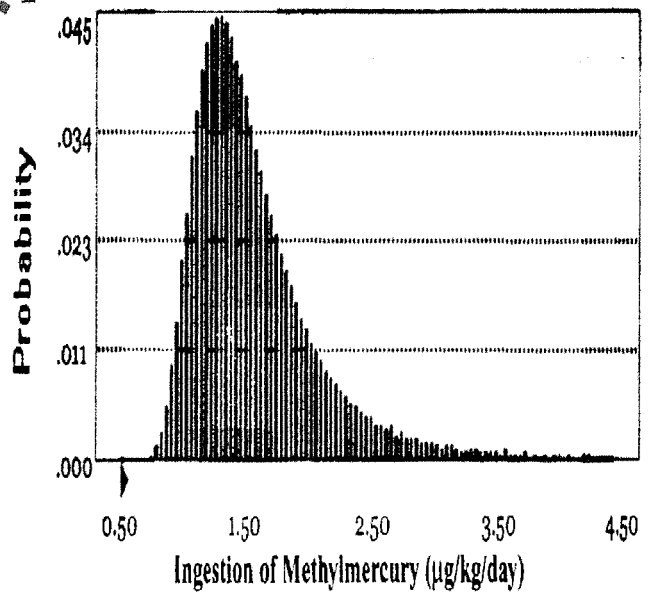
1

÷ 3 UF

2

Distribution of RfD Values

Percentile	RfD(μg/kg/day)
1	0.29
5	0.35
10	0.38
25	0.44
50	0.53
75	0.63
90	0.77
95	0.86
99	1.10



Methylmercury ingestion associated with BMDL in Seychelles population.

Summary

- Limited scientific data supports use of default uncertainty factor for intra-species variability of 10. (Hg RfD = 1 E-4)
- Newer methods on categorical defaults allow replacement of defaults with compound specific data. (Hg RfD = 2 E-4)
- Monte Carlo Analysis requires more data but allows probabilistic approach to RfD determination. (Hg RfD = 4 E-4)

Category	Date	Creditor	Credits
Awards and Grants	8/3/2015	US EPA	10,000.00
Awards and Grants	4/6/2016	US EPA	10,000.00
Awards and Grants	2/22/2017	US EPA	10,000.00
Alex Malaspina:Grant	1/20/2017	Community Fdn for Greater Atlanta	50,000.00
Contributians	9/25/2015	Am. Chemist	5,000.00
Contributions	10/13/2015	Am Beverage Assn	10,000.00
Contributions	11/30/2015	TPN Associates,LLC	25.00
Contributions	11/30/2015	The Coca-Cola Company	10,000.00
Contributions	11/30/2015	The Coca-Cola Company	10,000.00
Contributions	3/23/2016	Am Beverage Assn	5,000.00
Contributions	7/8/2016	Am Beverage Assn	5,000.00
Contributions	7/28/2016	Society of Toxicology	1,000.00
Contributions	7/22/2016	CropLife America	1,000.00
Contributions	7/14/2016	Am. Chemistry Council	5,000.00
Contributians	8/26/2016	The Coca-Cola Company	10,000.00
Contributions	8/26/2016	The Coca-Cola Company	5,000.00
Contributions	1/31/2017	The Coca-Cola Company	10,000.00
Contributions	1/31/2017	The Coca-Cola Company	10,000.00
Corporate Sponsors	7/15/2015	Procter & Gamble Company	10,000.00
Corporate Sponsors	7/31/2015	Givaudan Flavors Corporation	10,000.00
Corporate Sponsors	1/28/2016	Givaudan Flavors Corporation	10,000.00
Corporate Sponsors	1/29/2016	Firmenich Inc	10,000.00
Corporate Sponsors	1/29/2016	Intertek Scientific & Regulato	3,000.00
Corporate Sponsors	1/1/2016	Am Beverage Assn	1,000.00
Corporate Sponsors	1/1/2016	ToxStrategies Inc	3,000.00
Corporate Sponsors	1/1/2016	The Hamner Inst for Hlth Scien	1,000.00
Corporate Sponsors	1/1/2016	Novartis	10,000.00
Corporate Sponsors	1/1/2016	Procter & Gamble	10,000.00
Corporate Sponsors	1/1/2016	Am. Chemistry Council	1,000.00
Corporate Sponsors	1/1/2016	Exxon Mobil	20,000.00
Corporate Sponsors	2/23/2016	Monsanto Company	10,000.00
Corporate Sponsors	2/8/2016	Merck	3,000.00
Corporate Sponsors	2/23/2016	The Coca-Cola Company	10,000.00
Corporate Sponsors	3/9/2016	Church & Dwight Co., Inc	10,000.00
Corporate Sponsors	3/9/2016	Pepsico Inc	10,000.00
Corporate Sponsors	9/16/2016	SRC, Inc	333.00
Corporate Sponsors	9/23/2016	Mars Inc	20,000.00

Corporate Sponsors	1/3/2017	NSF International	1,500.00
Corporate Sponsors	1/10/2017	ToxStrategies, Inc	1,500.00
Corporate Sponsors	1/19/2017	Exxon Mobil	20,000.00
Corporate Sponsors	1/25/2017	Am. Chemistry Council	1,500.00
Corporate Sponsors	2/3/2017	Intertek Scientific and Regula	1,500.00
Corporate Sponsors	2/24/2017	Firmenich Inc	10,000.00
Corporate Sponsors	3/24/2017	Pepsico Inc	10,000.00
Corporate Sponsors	3/2/2017	Mars Inc	10,000.00
Corporate Sponsors	3/14/2017	Procter & Gamble	10,000.00
Corporate Sponsors	5/31/2017	Merck	3,000.00
Corporate Sponsors	5/11/2017	Givaudan Flavors Corporation	10,000.00
Grants	11/30/2015	The Coca-Cola Company	7,500.00
Grants	11/30/2015	The Coca-Cola Company	7,500.00
Mouse Liver Tumor	12/30/2015	Exxon Mobil	10,000.00
Mouse Liver Tumor	2/29/2016	BASF	10,000.00
Mouse Liver Tumor	3/23/2016	Am Beverage Assn	2,000.00
Mouse Liver Tumor	3/9/2016	The Coca-Cola Company	5,000.00
Mouse Liver Tumor	3/14/2016	Am. Chemistry Council	3,000.00
Mouse Liver Tumor	3/21/2016	Procter & Gamble	10,000.00
Mouse Liver Tumor	5/18/2016	Bayer	2,000.00
Mouse Liver Tumor	7/7/2016	Am. Chemistry Council	2,000.00
Mouse Liver Tumor	11/9/2016	USFDA	5,000.00
Mouse Liver Tumor	5/9/2017	EPA	4,125.00

Senator CARPER. Unfortunately, though, the bad news is that his answers did not alleviate my concerns about his nomination and his suitability to serve.

I regret to say that my second concern with our nominees today before us is the nomination of Bill Wehrum, whose mom is here today, his wife is here today, sisters-in-law are here today, and we welcome you. He asked me to introduce him, and I have declined to do that, respectfully. I think my doing that might hurt you more than help you, and I don't want to make the situation more difficult for you or for me.

He is a Delawarean. This is a little State, and you know, in Delaware you know just about everybody. We run many races together. I usually have to see him run from behind. He is always running far ahead of me; he is a great runner. Sometimes we ride the same train together from Wilmington to Washington. I think he is a good person. I think he is a good person, but he is not, in my judgment, a good choice for this particular job.

In 2005 Bill was nominated for the very same post, and I opposed his nomination then due to concerns that he deferred too frequently to industry rather than to protecting our public, public health. Moreover, he has suppressed scientific information and was not responsive to congressional requests. Mr. Wehrum's nomination failed to receive Senate approval. Though unconfirmed, he served for 2 years as the head of the Air Office. Sadly, I fear that too little has changed since he last appeared before this Committee.

I just want to take briefly—and then I will close, a look at some numbers. One of the numbers is 31, 31, the number of times that Mr. Wehrum has represented industry in lawsuits against EPA since 2009. Against EPA.

Twenty-seven, the number of times that public health groups prevailed in court when challenging clean air regulations that Mr. Wehrum helped to craft at EPA because the rules didn't follow the law or protect public health. Twenty-seven.

Ten, the number of additional years that children were exposed to toxic power plant emissions due to regulatory delays that Mr. Wehrum put in place while he was at EPA.

And one, the number of times that industry supported language from Mr. Wehrum's old law firm and made it verbatim into a clean air regulation that he helped to write at EPA.

As best we can tell, zero is also the number of times that Mr. Wehrum advocated in court for stronger clean air regulations since leaving the EPA, an especially troubling number for those in downwind States like Delaware. Zero is also the number of times that Mr. Wehrum expressed a desire to protect public health when he and I met prior to this hearing in my office.

My time is short. Thank you for being generous with it, Mr. Chairman, but I would ask unanimous consent to submit my full statement for the record, including my views on the other three nominees before us who I hope to support.

I look forward to hearing from all of you. Again, welcome.

Thank you.

[The prepared statement of Senator Carper was not received at time of print.]

Senator BARRASSO. Thank you very much, Senator Carper.

Senator Inhofe.

OPENING STATEMENT OF HON. JAMES M. INHOFE, U.S. SENATOR FROM THE STATE OF OKLAHOMA

Senator INHOFE. Thank you, Mr. Chairman. I am delighted to join Congressman Chabot and Dunn in making introductions of nominees.

I will be introducing Bill Wehrum. I am his second choice for an introduction. However, I am honored to do so. He has been a friend during the years I chaired this Committee. I just know his knowledge and expertise is second to none. His career spans more than 31 years in the environmental field, including work as an environmental engineer, a public servant with the EPA, and an environmental lawyer. As a result, he is known across the field as an expert on the issues he will be overseeing at the EPA when he is confirmed.

He has consistently been recognized as a leader and top lawyer in environmental laws for such groups as the Chambers USA, Legal 500 United States, and Washingtonian Magazine. Those who have worked with Bill praise him, like his former EPA boss, Jeff Holmstead, who said, "There is no better person to serve as the Assistant Administrator of the EPA's Office of Air and Radiation."

Former EPA Deputy Administrator Marcus Peacock said, "Bill Wehrum, his understanding of the Clean Air Act may be second to none. His desire to pull up his sleeves and actually make the Clean Air Act work as a practical matter is second to none."

And that gets to what we are doing here. Congress and our other agencies should not be in the business of creating laws and regulations that are unworkable and impossible to implement, and I trust that Bill will be able to navigate the line between the healthy environment and ensuring standards and regulations are achievable and practical without undue harm to our economy, and that is the law, I would remind you.

So, Mr. Wehrum, thank you for your willingness to do this tough job, and I look forward to many more year of service with you.

Senator BARRASSO. Thank you, Senator Inhofe.

We have two members of the House who have joined us today, Congressman Chabot from Ohio and Congressman Dunn from Florida, to introduce two of the nominees.

I would like to welcome both of you to the Senate and invite Congressman Chabot to introduce Dr. Dourson.

STATEMENT OF HON. STEVE J. CHABOT, U.S. REPRESENTATIVE FROM THE STATE OF OHIO

Representative CHABOT. Thank you very much, Chairman Barrasso and Ranking Member Carper and all the members of this Committee for inviting me here today to introduce a fellow Cincinnatian, Dr. Michael Dourson.

As everyone on the Committee is aware, Dr. Dourson has been nominated to be the Assistant Administrator for the EPA's Office of Chemical Safety and Pollution Prevention.

I am sure that most of you are also aware that Dr. Dourson's impressive credentials and distinguished career, so I won't delve into

every aspect of his resume, but I would like to mention just a few highlights.

Currently, Dr. Dourson is a professor in the Risk Science Center at the University of Cincinnati College of Medicine, which is located in my congressional district in Cincinnati. Prior to his current position he founded and led the Center's predecessor for 21 years, the non-profit corporation Toxicology Excellence for Risk Assessment. And these two positions occurred following the 15 years Dr. Dourson worked at the U.S. EPA, where he held numerous leadership positions.

Throughout his career, Dr. Dourson has served on numerous government panels and authored or co-authored an impressive array of publications, including more than 150 papers on risk assessment methods or chemical specific analyses, and over 100 government risk assessment documents. And he has been elected as a fellow or an officer for numerous professional organizations, including the Academy of Toxicological Sciences, the Society for Risk Analysis, the American Board of Toxicology, and the Society of Toxicology. Currently, Dr. Dourson is the President of the Toxicology Education Foundation.

Dr. Dourson's excellence in his field of expertise has been recognized time and time again. Over the years, he has received four bronze medals from the EPA, the Arnold A. Lehman Award from the Society of Toxicology, and the International Achievement Award from the International Society of Regulatory Toxicology and Pharmacology.

In addition to his stellar qualifications, I would be remiss if I did not also mention that Dr. Dourson is a fellow graduate of La Salle High School. And I would also be remiss if I didn't mention that La Salle has won the Ohio Division II State football championship the last 3 years, and we hope they win it again this year.

Dr. Dourson, thank you for being here today, and congratulations on your distinguished career and this prestigious nomination. I wish you the best as this process moves forward, and again I want to thank Chairman Barrasso and Senator Carper and all the Committee members for allowing me to be here today. And if I could be excused, I have the parents of Otto Warmbier, who was kidnapped and brutalized by North Korea, waiting for a meeting.

[The prepared statement of Representative Chabot follows:]

Thank you, Chairman Barrasso and Ranking Member Carper, for allowing me to be here today to introduce a fellow Cincinnatian, Dr. Michael Dourson.

As everyone on the Committee is aware, Dr. Dourson has been nominated to be the Assistant Administrator for the EPA's Office of Chemical Safety and Pollution Prevention.

I am sure that most of you are also aware of Dr. Dourson's impressive credentials and distinguished career. So, I won't delve into every aspect of his resume, but I would like to mention a few highlights.

Currently, Dr. Dourson is a professor in the Risk Science Center at the University of Cincinnati, College of Medicine, which is located in my district. Prior to his current position, he founded and led the Center's predecessor for 21 years, the nonprofit corporation, Toxicology Excellence for Risk Assessment (TERA).

And these two positions occurred following the 15 years Dr. Dourson worked at the U.S. Environmental Protection Agency, where he held numerous leadership positions.

Throughout his career, Dr. Dourson has served on numerous government panels and authored, or co-authored, an impressive array of publications, including: more than 150 papers on risk assessment methods or chemical-specific analyses; and over 100 government risk assessment documents.

And he has been elected as a fellow or an officer for numerous professional organizations, including: the Academy of Toxicological Sciences; the Society for Risk Analysis; the American Board of Toxicology; and the Society of Toxicology. Currently, Dr. Dourson is the President of the Toxicology Education Foundation.

Dr. Dourson's excellence in his field of expertise has been recognized time and again. Over the years, he has received 4 bronze medals from EPA, the Arnold J. Lehman award from the Society of Toxicology, and the International Achievement Award from the International Society of Regulatory Toxicology and Pharmacology.

In addition to his stellar qualifications, I would be remiss if I did not also mention that Dr. Dourson is a fellow La Salle High School alum. Go Lancers!

Dr. Dourson, thank you for being here today, and congratulations on your distinguished career and this prestigious nomination. I wish you the best as this process moves forward.

And again thank you, Chairman Barrasso and Ranking Member Carper, for allowing me to be here today.

I yield back the balance of my time.

Senator BARRASSO. Well, thank you for your time. Thank you for your testimony. You are certainly excused.

Representative Dunn, welcome to the Committee, and we look forward to your introduction.

STATEMENT OF HON. NEAL P. DUNN,
U.S. REPRESENTATIVE FROM THE STATE OF FLORIDA

Representative DUNN. Thank you very much, Chairman Barrasso, Ranking Member Carper, and members of the Committee. Thank you for the opportunity to introduce Matt Leopold, President Trump's nominee to serve as the Assistant Administrator to the Office of General Counsel of the United States Environmental Protection Agency.

I have the honor of serving Matt in Congress as his representative for Florida's 2nd Congressional District. Over many years in public service to the State of Florida Matt has earned a reputation for his commitment to the rule of law and as a man of integrity.

Matt's record is well known to the members of this panel by now. He served with distinction as the General Counsel for Florida Department of Environmental Protection and is the attorney for the U.S. Department of Justice's Environment and Natural Resources Division. Along the way, he earned the high regard of his colleagues and of the diverse group of stakeholders served by those institutions.

Matt has twice been awarded the Attorney General's Award for Excellence and was awarded a prestigious James Madison Institute Leaders Fellowship during the 2015–16 years. I also know him as a champion during his legal career on behalf of Florida's coastal economies, particularly the oystermen and small businesses of Apalachicola, who depend on the bay for their livelihood.

Matt is an alumnus of the University of Florida and obtained his JD from Florida State University College of Law, so this is perhaps another indicator that he is uncommonly capable of bridging diverse interests on complicated issues.

In closing, I thank you for the opportunity to introduce a favorite son of Florida and a distinguished public servant to the Committee today. I applaud the President's recognition of Matt's unique qualifications for this critical role at the EPA, and I look forward to his continued service on behalf of our communities throughout our nation.

Thank you very much, Mr. Chair, for the opportunity.

[The prepared statement of Representative Dunn follows:]

Chairman Barrasso, Ranking Member Carper and members of the Committee, thank you for the opportunity to introduce Matt Leopold, President Trump's nominee to serve as Assistant Administrator for the Office of General Counsel of the U.S. Environmental Protection Agency.

I have the honor of serving Matt in Congress as the Representative of Florida's Second Congressional District.

Over many years in public service to the State of Florida, Matt earned a reputation for his commitment to the rule of law and as a person of integrity.

Matt's record is well known to the members of this panel by now: he served with distinction as General Counsel for the Florida Department of Environmental Protection and as an attorney for the for the U.S. Department of Justice's Environment and Natural Resources Division. Along the way, he earned the high regard of his colleagues and the diverse group stakeholders served by those institutions.

Matt has twice been awarded the Attorney General's Award for Excellence, and was awarded a prestigious James Madison Institute Leaders Fellowship during the 2015-2016 year.

I also know him as a champion during his legal career on behalf of Florida's coastal economies, particularly the oystermen and small business in Apalach who depend on the bay for their livelihood.

Matt is alumnus of the University of Florida, and obtained his Juris Doctorate from Florida State University College of Law – perhaps another indicator that he is uncommonly capable of bridging interests on complicated issues.

In closing, I thank you for the opportunity to introduce a favorite son of Florida and a distinguished public servant to the Committee today.

I applaud the President's recognition of Matt's unique qualifications for this critical role at the EPA, and I look forward to his continued service on behalf of our communities.

Senator BARRASSO. Thanks very much, Congressman Dunn, and you are excused as well. I know you have pressing items of business elsewhere, so thank you for being with us today.

I would like to introduce David Ross, who is the nominee for the Assistant Administrator of EPA's Office of Water. Mr. Ross is a graduate of the University of Wisconsin-Madison and the Vermont Law School. He currently serves as Assistant Attorney General and Director of Environmental Protection Unit for the Wisconsin Department of Justice. Before that, Mr. Ross served as Wyoming's Senior Assistant Attorney General in the Water and Natural Resources Division for the Wyoming Attorney General's Office.

Mr. Ross has a total of two decades of environmental, legal, and consulting experience in both the public and private sectors. His nomination has elicited bipartisan praise and support within my home State of Wyoming.

Dave Freudenthal, the former Democrat Governor of Wyoming, has said "Mr. Ross's private practice experience in DC, combined with his service in two State environmental protection agencies, make him uniquely qualified to implement America's nuanced structure of Federal and State environmental protection."

Likewise, Wyoming's current Governor, Matt Mead, Republican, expressed his unequivocal support for Mr. Ross, saying, "Dave is a talented attorney, an excellent advisor, and a person who can get things done. I recommend Dave without reservation for this position."

So now I would like to welcome to the Committee our nominees. Please take your seats.

Congratulations to each of you. I welcome you to the Committee. I would like to remind each of you that your full written testimony will be made a part of the record. We look forward to hearing your testimony today.

We will start first with Dr. Michael Dourson, and would you like to introduce your brother?

STATEMENT OF MICHAEL DOURSON, PROFESSOR, RISK SCIENCE CENTER, DEPARTMENT OF ENVIRONMENTAL HEALTH, UNIVERSITY OF CINCINNATI, COLLEGE OF MEDICINE

Mr. DOURSON. Yes. Chairman Barrasso, thank you very much.

My brother, David Dourson, is behind me, my younger brother. He is a Cincinnati native and a businessman extraordinaire. So, if you get a chance to talk with him, I am sure he would be happy to speak with you.

Senator BARRASSO. Thank you. Welcome to the Committee. Welcome as a guest, and please proceed with your testimony.

Mr. DOURSON. Well, thank you, Chairman Barrasso, Senator Carper, and distinguished members of the Committee. I thank you for the privilege of coming before you today as a nominee for the position of Assistant Administrator of the Office of Chemical Safety and Pollution Prevention. I am honored and humbled that President Trump, Administrator Pruitt, and this Committee are considering me for this position.

I would also like to thank my many current and former colleagues with the University of Cincinnati College of Medicine and

the independent, non-profit Toxicology Excellence for Risk Assessment, and the U.S. Environmental Protection Agency for their support and friendship.

I also wish to thank my many friends and family, and especially my much better half of 39 years, Martha Dourson, who apologizes for not being here due to a family obligation involving grandchildren.

I have worked on chemical safety and pollution prevention issues for my entire professional career as a board certified toxicologist in three different organizations and as an officer in one or more groups with five different scientific societies. The work included developing scientific positions to support the rulemaking under congressional legislation, such as the Clean Water Act, or pollution control prevention measures as in my role as EPA's first leader of its Integrated Risk Information System, or IRIS.

I have also served as a chair or member of well over 100 scientific peer review panels to review others' efforts. For example, as chair of the panel that reviewed the nine government response to the World Trade disaster, or as chair of the panel that reviewed the government response to a West Virginia river spill and recommended lowering the existing safe dose by eightfold. We made it eightfold more safe.

If confirmed as the Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, I will dedicate my mind, body, and spirit to the work of this office, to working with its dedicated staff, to the protection of the American public, including its most vulnerable, and its environment from exposure to pesticides and otherwise unregulated chemicals, and to answering any and all of your questions and those of your constituents on chemical specific matters at any time.

In contrast, I will not deviate in my decisions from the scientific principles of toxicology and risk assessment that have been taught to me by my mentors and co-workers, nor deviate from the code of ethics by my Society of Toxicology or my Society for Risk Analysis, nor ever stop listening to my colleagues whose expertise I do not have but otherwise cherish.

As you would expect, if confirmed, I will work with my Office of Enforcement and Compliance Assurance colleagues in the enforcement of environmental laws that you, the representatives or our nation, have established. I strongly support those laws and will do everything in my power to assure that they are being administered fairly and without prejudice.

Finally, I will strongly foster, without reservation, a collaborative spirit with our Federal and State colleagues, and those from other nations, organizations, and the public on pesticides and otherwise unregulated chemicals. It is through such collaboration, exemplified throughout my career with EPA, TERA, and U.C.—University of Cincinnati—it is through such collaboration that EPA's practice of safety assessment and pollution prevention will meet the needs of the 21st century and will best protect the public health and the environment.

Your passing of the Lautenberg Chemical Safety Act was a significant milestone, and I know it was celebrated here in Washington, but it was widely celebrated outside of Washington, DC, by

many folks. So congratulations on that. It was enabled by a bipartisan effort that included collection of diverse outside groups. If confirmed, nothing less should be expected of myself and the talented people of the Office of Chemical Safety and Pollution Prevention who now carry your torch.

I appreciate the time and effort you have devoted to reviewing my credentials and background materials, and look forward to questions that you or your colleagues may have regarding this or related information.

Thanks again for the opportunity to serve.

[The prepared statement of Mr. Dourson follows:]



Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Professor, Risk Science Center
University of Cincinnati, College of Medicine

Michael Dourson is a professor in the Risk Science Center at the University of Cincinnati, College of Medicine. He also founded and led the Center's predecessor of 21 years, the nonprofit corporation, Toxicology Excellence for Risk Assessment (TERA). Prior to directing TERA, he worked for 15 years in the U.S. Environmental Protection Agency in numerous leadership positions.

He has won several awards including 4 bronze medals from EPA, the Arnold J. Lehman award from the Society of Toxicology, and the International Achievement Award from the International Society of Regulatory Toxicology and Pharmacology. He has also been elected as a Fellow of the Academy of Toxicological Sciences and as a Fellow for the Society for Risk Analysis.

Dr. Dourson has co-published more than 150 papers on risk assessment methods or chemical-specific analyses. He has co-authored well over 100 government risk assessment documents, many of them risk assessment guidance texts. He has made over 150 invited presentations to a variety of organizations, and has chaired over 150 sessions at scientific meetings and independent peer reviews.

He has been elected to multiple officer positions in the American Board of Toxicology (including its President), the Society of Toxicology (including the presidency of 3 specialty sections), the Society for Risk Analysis (including its Secretary), and is the President of the Toxicology Education Foundation, a nonprofit organization with a vision to help our public understand the essentials of toxicology. In addition to numerous appointments to government panels, such as EPA's Science Advisory Board, he is also a member on the editorial board of the peer reviewed, scientific journals Regulatory Toxicology and Pharmacology and Human and Experimental Toxicology.

Statement of Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Nominated to be Assistant Administrator,
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
Before the Senate Environment and Public Works Committee
September 20th, 2017

Chairman Barrasso, Senator Carper and distinguished members of the Committee, thank you for the privilege of coming before you today as the nominee for the position of Assistant Administrator for the Office of Chemical Safety and Pollution Prevention. I am honored that President Trump, Administrator Pruitt and this Committee are considering me for this position.

I would also like to thank my many current and former colleagues with the University of Cincinnati, College of Medicine, the independent nonprofit Toxicology Excellence for Risk Assessment (TERA),[1] and the U.S. Environmental Protection Agency for their support and friendship.

I have worked on chemical safety and pollution prevention issues for my entire professional career, as a board-certified toxicologist in 3 different organizations, and as an officer in one or more groups within 5 different scientific societies. This work included developing scientific positions to support rulemaking under congressional legislation, such as the Clean Water Act, or pollution control/prevention measures, as in my role as EPA's first leader of its Integrated Risk Information System (IRIS). I have also served as a chair or member of well over 100 scientific peer review panels to review other efforts, for example, as chair of the panel that reviewed the 9 government agencies

[1] Work for TERA was 2/3rds for government sponsors and 1/3rd for industry sponsors; collaborations were fostered whenever possible.

response to the world trade disaster,[2] or as chair of the panel that reviewed the government response to a West Virginia river spill and recommended lowering the existing safe dose by 8-fold.[3]

If confirmed as the Assistant Administrator for OCSPP, I will dedicate my mind, body and spirit to the work of this office, to working with its staff, to the protection of the American public and its environment from overexposure to pesticides and chemicals, and to answering any and all of your questions and those of your constituents on chemical specific matters, at any time.

In contrast, I will not deviate in my decisions from the scientific principles of toxicology and risk assessment that have been taught to me by my mentors and co-workers, nor deviate from the code of ethics by my Society of Toxicology or my Society for Risk Analysis, nor ever stop listening to my colleagues whose expertise I do not have but otherwise cherish.

As you would expect, I will work with my Office of Enforcement and Compliance Assurance colleagues in the enforcement of environmental laws that you, the representatives of our nation, have established. I strongly support those laws and will do everything in my power to assure that they are being administered fairly and without prejudice.

Finally, I will strongly foster, without reservation, a collaborative spirit with our federal and state colleagues, and those from other nations, organizations and the public on pesticides and otherwise unregulated chemicals. It is through such collaboration that EPA's practice of safety assessment and pollution prevention will meet the needs of the

[2] See: http://www.tera.org/Peer/WTC/welcome.htm
[3] See: http://www.tera.org/Peer/WV/WV%20Expert%20Report%2012%20May%202014.pdf

21st century and will best protect public health and the environment. Your passing of the Lautenberg Chemical Safety Act was a significant milestone enabled by a bipartisan effort that included collection of diverse outside groups. Nothing less should be expected of OCSPP, which now carries your torch.

I appreciate the time and effort you have devoted to reviewing my credentials and background materials, and look forward to any questions you or your colleagues may have regarding this, or related, information.

Senate Committee on Environment & Public Works
Hearing entitled, *"Hearing on the Nominations of Michael Dourson, Matthew Leopold, David Ross, and William Wehrum to be Assistant Administrators of the Environmental Protection Agency, and Jeffery Baran to be a Member of the Nuclear Regulatory Commission."*
October 4, 2017
Questions for the Record for Mr. Michael Dourson

Chairman Barrasso:

1. Are you familiar with the Pesticide Registration Improvement Act (PRIA)?

    a. Do you believe the Act's provisions provide a predictable and effective evaluation process?

    Yes, I have some familiarity with the PRIA. My understanding is that with the collection of fees EPA then has the resources to complete necessary scientific evaluations of pesticides in a defined and predictable timeline.

Ranking Member Carper:

2. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.

    a. Do you agree that it is essential that in making decisions, EPA's OCSPP must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    b. Will you commit to restricting communications between OCSPP and the White House staff regarding specific matters under the authority of OCSPP?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    c. Will you commit to ensuring the staff of OCSPP is familiar with those restrictions?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OCSPP staff, including you, occur?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

3. Recently, EPA conducted "anti-leaking" training for its employees[1]. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

   5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

   a. If you are confirmed, will you commit to protect the rights of all career employees in OCSPP to make lawful disclosures, including their right to speak with Congress?

      If confirmed, I commit to protecting the rights of OCSPP employees and will follow the law.

   b. Will you commit to communicate employees' whistleblower rights via email to all OCSPP employees within a week of being sworn in?

      If confirmed, I commit to protecting the rights of OCSPP employees and will follow the law.

4. Recently, EPA decided not to revoke all the remaining tolerances for chlorpyrifos as had been proposed by the Obama Administration.

---

[1] https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

a. Do you believe that EPA should ever use epidemiological studies as a basis for the agency to conclude that it cannot make a determination that exposure to a substance can occur with a "reasonable certainty of no harm" under the Federal Food, Drug and Cosmetic Act (FFDCA)? If so, when? If not, please fully describe the reasons why not.

Epidemiology studies are an important part of any risk assessment and should be evaluated routinely as part of any risk management decision. I believe there will be situations where the use of epidemiological data is appropriate. This will depend on the quality of the epidemiological data and the specifics of the determination it informs.

b. One of the complicating factors surrounding the proposed Obama Administration's ban on the remaining uses of chlorpyrifos was the assertion made by some that there is uncertainty associated with the level of chlorpyrifos that causes an adverse health effect and debate about which biological endpoint should be used to define what an "adverse" health effect should be. If EPA cannot make a "reasonable certainty of no harm" finding under the FFDCA for a substance, how would you suggest EPA resolve such uncertainties in order to comply with both FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)?

Scientific approaches exist to help quantify and understand the impacts of uncertainty on a decision. If confirmed, I would use these approaches and would additionally seek further data and information to inform decision making.

5. EPA currently uses a 10-fold safety factor to account for the added risks mutagenic carcinogenic chemicals pose to vulnerable sub-populations. Will you commit to continue this approach? If not, please provide a specific explanation for when, why and how you would deviate from this approach.

I am familiar with EPA's Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens (March, 2005). If confirmed, I commit to using the best available science in considering any regulatory actions that come to me for decision making.

6. EPA often uses a safety adjustment factor when it writes rules that protect people from exposure to chemicals. That factor accounts for the interspecies variability between the effect of the chemical on an animal that is measured in laboratory tests and the predicted effect of the chemical on people.

a. If you are confirmed, will you commit to continue to support this approach?

Yes, when appropriate I will continue to use this approach.

b. If not, how would you propose to account for interspecies differences between a chemical's measured effect on an animal and its predicted effect on a human?

When sufficient data and understanding exists, physiologically based pharmacokinetic (PBPK) models can be used to inform the differences between animals and humans.

7. One argument that is often made to justify less protective chemical safety standards is to set an adverse effect end-point that is 'more adverse' than other end-points. For example, it would take higher exposure levels to a chemical for the chemical to actually cause cancer than it would for a biochemical marker that is a known precursor to cancer to be observed. Using cancer as the end-point in this scenario would allow for a less stringent safety standard for that chemical to be set.

   a. Generally speaking, if there is an end-point that is a precursor or otherwise predictive of a serious illness or risk of acute toxicity, is there ever a scenario in which EPA should regulate to protect against the precursor end-point rather than the more serious one? If so, please describe such scenarios. If not, please fully explain why not.

   There are scenarios where this is appropriate. It's use will depend on our understanding of the chemical's mechanism of action

   b. Additionally, if it is your view that safety standards should not seek to prevent effects that are known to be predictive of more serious ones, please explain your views on whether the FDA should continue to approve cholesterol-lowering medications or whether it should simply focus its efforts on ways to better treat heart attacks. If you believe that preventive medicine should continue to be developed and approved, why are your views different for chemical safety standards?

   The appropriate use of safety factors is determined by available data and our understanding of a chemical's mode of action. I do not have an opinion on FDA actions.

8. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:

   a) When EPA first submitted the proposed repeal rule to OMB, the draft stated that a the agency would undertake a new cost-benefit analysis as part of the second step of its process.

b) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction from OMB, EPA career staff reportedly changed the table included in the 2015 rule to i) reflect 2016 dollars instead of 2014 dollars, ii) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and iii) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.

c) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did[2].

The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OCSPP will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

I support the appropriate use of both written and oral guidance and would endeavor to use each in appropriate circumstances.

9. Thank you for your response to my pre-hearing questions. I have some follow-up questions. In the spreadsheet you provided that listed sponsors, project description and project type information, there are several entities that seem incorrect. For each of these, please explain the apparent discrepancy, and if any of these entries are errors, please submit a corrected version of the spreadsheet in excel format:

   i. Several entries that list the American Chemistry Council as its sponsor as "collaborative" rather than "private sector;"

      This designation is correct. The overall project was a collaboration of several organizations.

   ii. Listing an entry in which the California Chamber of Commerce is the sponsor as "non-profit" rather than "private sector;

      The non-profit designation is correct (see: https://www.calchamber.com/aboutus/Pages/default.aspx).

[2] https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf See Table 1

iii. Listing an entry in which the CEFIC is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

iv. Listing an entry in which Concurrent Technologies Corporation is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to CTC who was working for the government.

v. Listing an entry in which EPRI is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

vi. Listing an entry in which ICL-IP is the sponsor as a "collaboration" rather than "private sector";

This designation is correct. The overall project was a collaboration of several organizations.

vii. Listing an entry in which ILSI-NA is the sponsor as "non-profit" rather than "private sector";

This designation is correct. ILSI is a 501(c)(3) nonprofit organization.

viii. Listing an entry in which Lockheed Martin Corporation is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to Lockheed Martin Corporation who was working for the government.

ix. Listing an entry in which McKenna, Long and Aldridge is the sponsor as "government" rather than "private sector";

Yes, this is a mistake. A corrected spreadsheet is attached. Thank you.

x. Listing an entry in which Silicones Environment Safety & Health Council is the sponsor as "non-profit" rather than "private sector";

Yes, this is a mistake. A corrected spreadsheet is attached. Thank you.

xi. Listing an entry in which Summit Technology is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was working with Summit Toxicology and the National Library of Medicine on this task.

xii. Listing an entry in which ToxServices is the sponsor as "government" rather than "private sector";

This designation is correct. TERA was a subcontractor to ToxServices who was working for the government.

xiii. Listing an entry in which the Vinyl Acetate Council is the sponsor as a "collaboration" rather than "private sector"; and

This designation is correct. The overall project was a collaboration of several organizations.

xiv. Listing an entry in which Waste Management is the sponsor as a "collaboration" rather than "private sector".
This designation is correct. The overall project was a collaboration of several organizations.

b. Please identify the "multiple sponsors" listed for each entry on this spreadsheet and indicate the percentage of funding received from each sponsor.

Descriptions of all collaborative projects are a matter of public record, and can be found at websites associated with the Alliance for Risk Assessment (*ARA*) or Toxicology Excellence for Risk Assessment (TERA). I would be happy to direct your staff to the appropriate location if they have specific questions. Funding amounts are not specified, but sponsors who offer remuneration in excess of 2% of TERA income are designated at http://www.tera.org/about/FundingSources.html.

c. Please describe the criteria you used to designate an entity as a "non-profit," how you defined "sponsor" and how you defined "project "type".

We generally use 501(e)(3) designations as nonprofits. "Sponsors" refer to any group that supports the mission of Toxicology Excellence for Risk Assessment (TERA) whether or not they also obtain a report or opinion. "Project type" generally refers to whether the remuneration is from a government or other nonprofit, or from a private entity.

d. In the "Summary of billed hours" table, there is no designation for government-sponsored work for TERA for 1995-2015. Could you provide a new table that includes this information?

This is possible, but would take more time than permitted in answering these questions, since individual records for each year would have to be reviewed.

e. In the spreadsheet that includes this chart, you seem to have calculated the percentage of work done by sector by counting the number of projects you classified as falling under each sector and dividing by the total number of projects listed.

This is not correct. Rather, the percentage of work in the "Summary of billed hours" spreadsheet entitled "Question 2-TERA Yearly Funding 1995-2015" is based on the amount of time devoted to either nonprofit or profit areas by year. Time spent in the "collaborative" sector of the spreadsheet entitled "Question 3-Project Database January 2010 to June 2015" is evenly divided into profit and nonprofit times of the "Question 2" spreadsheet.

This does not reflect relative funding for projects in each sector, however. Please provide a detailed breakdown of the percentage of total funding received for projects included in each sector, using the corrected version of the table requested in c.

Summaries of funding amounts per sector were not developed.

f. In the chart, the work on the Kids+Chemical Safety website is described as: "Develop a kids risk webpage, in part." The project is listed as a collaborative twice, once with the American Chemistry Council (ACC) as the sponsor and once with the Combined Federal Campaign (CFC) as the sponsor. Did the CFC hire or pay TERA to develop the website?

No.

If not, what was their specific sponsorship role?

Funding by CFC was through contributions from CFC to TERA, and TERA's decision to use this funding for the kids website.

If so, how long after ACC hired TERA to develop the website did CFC contribute?

Continuously.

What percentage of the costs of developing the website were paid for by the CFC?

Various funding amounts are not given per sponsoring groups.

Did the CFC itself fund the website, or was it donations through a CFC listing?

Donations were through a CFC listing.

If so, were these donations from the federal government?

Various funding amounts are not given per sponsoring groups. However, the ACC contribution was the major part of the initial sponsorship.

10. The following questions refer to the chart I used during the hearing (attached). For each chemical listed on this chart, please provide a complete description of:

    a. The year(s) in which you, TERA or other TERA employees were funded to work on the chemical.

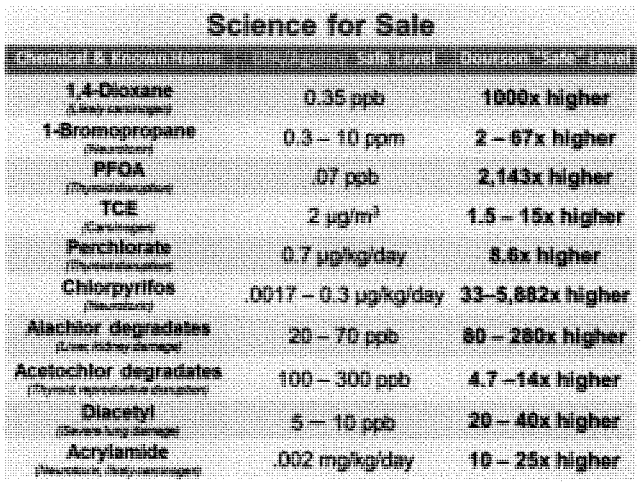
    The chart below has a number of errors. Please see attachment 1.

    b. The name of the entity or entities that provided such funding, and the funding amount. If the activity was a collaboration, please list all collaborators as well as the amount of funding each collaborator contributed to the effort.

    Please see attachment 1, but note that specific funding levels are not shown because summaries of this information were not developed. However, if funding is over 2% in any one year for any sponsor past 2010, this can be found through links to specific years at http://www.tera.org/about/FundingSources.html.

    c. The type of activity (risk assessment, peer review, research paper, presentation, litigation support, etc) that was funded and the deliverables provided to the sponsor.

    Please see attachment 1.



11. Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, with serious iodine deficiencies, and if so, what is it? Do you believe that there is a safe level of exposure to perchlorate for i) a pregnant woman, and ii) a toddler, who gets insufficient iodine according to World Health Organization guidelines, and if so, what is it?

    If confirmed, I will evaluate chemicals under the statutory authorities granted by Congress to safeguard the public.

12. On September 21, 2017, the Consumer Product Safety Commission (CPSC) approved a petition[3] that called for CPSC to write regulations requiring the removal of organohalogen flame retardants from four types of consumer products.

    a. An argument against the petition is that EPA is currently reviewing flame retardants under TSCA. Do you agree that EPA is currently undertaking a risk evaluation on only the Cyclic Aliphatic Bromide Cluster flame retardants (i.e. only one class) and that EPA is required by law to complete this risk evaluation and finishing a regulation (if needed) by November 29, 2021?

        I am aware that EPA is evaluating some flame retardants. I am unclear of the timeline.

[3] http://earthjustice.org/sites/default/files/files/FHSA-Petition%20_revised_6-30-15.pdf

b. According to EPA's website[4], "the hexabromocyclodecanes (HBCD cluster) in the cyclic aliphatic bromide cluster consists of the following chemicals: Hexabromocyclododecane; 1,2,5,6,9,10-Hexabromocyclododecane; and 1,2,5,6-Tetrabromocyclooctane. Two of these chemicals are used as flame retardants, no uses for 1,2,5,6-tetrabromocyclooctane have been identified. The primary use of the two chemicals is in expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS) in the building and construction industry for thermal insulation boards and laminates for sheathing products. They are also used in plastics (additive) and textiles (back-coating). In the United States, the HBCD cluster was historically used as a flame retardant in the back coating of textiles; however, research and information gathering indicates that the HBCD cluster is no longer used in consumer textile applications outside of the automotive industry." Do you agree that this type of flame retardant is generally not used in consumer products such as children's products, furniture, mattresses and the casings surrounding electronics? If not, why not?

Beyond the details on the EPA webpage, I am not familiar with the different types of products that different flame retardants are used with. If confirmed, I can look into this.

13. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by *any* Member of the Environment and Public Works Committee? If not, why not?

Yes

14. Before the end of the last Administration, EPA proposed to ban some uses of three dangerous chemicals using its new Toxic Substances Control Act authority. TCE is a probable carcinogen that is found in drinking water all across the country. Accidental exposures to MC, which is used in paint and furniture strippers, has killed at least 56 people since 1980. And a second chemical used in paint strippers, NMP, is dangerous for pregnant women to be exposed to. Some have suggested that these bans should not be finalized, saying instead that EPA should study the uses of these chemicals for three more years before proposing a rule. Do you disagree that more exposures, more illnesses and maybe even more deaths would probably occur as a result of a three year delay in these proposed bans? If so, on what basis? If EPA has already determined that some uses of these chemicals are dangerous, how could one justify the extra time, taxpayer dollars and risk to human health that would occur by studying these same uses for three additional years instead of acting to finalize the bans now?

I am not sufficiently familiar with EPA's proposed bans to respond to these questions. If confirmed, I will seek a briefing on the status of these proposed bans and I commit to evaluating all the scientific evidence to inform EPA's decision.

[4] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaulation-cyclic-aliphatic-bromide-cluster-hbcd

15. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily[5]. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

If confirmed, I will make my calendar available on a timely basis.

16. Section 26 of the newly enacted TSCA states that:

> "(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6."

Page 1 of Attachment 1 is an email sent by EPA on March 17, 2016, the substance of which was shared with the bipartisan and bicameral negotiators of the Toxic Substances Control Act. It states that EPA "just discovered a technical issue that will have significant policy implications for EPA's ongoing work under Section 6. As currently drafted, both Senate and House bills could frustrate EPA's ability to timely manage risks that have been (or may be) identified in our current Work Plan risk assessments." The email goes on to describe several risk assessments on chemical substances (TCE, NMP, MC and 1-BP) that had been completed or were near completion by EPA, and stated that "EPA is *not* looking at all the conditions of use for these chemicals. This approach, which might be characterized as a *partial* risk evaluation or *partial* safety determination, we see as simply not contemplated under the Senate and House bills. The section 6 structure in both bills would require EPA to assess a chemical in its entirety, based on all conditions of use – not just a subset of those uses." EPA then went on to state that if it were to move forward with rulemakings to restrict or ban some or all of these substances (which it has subsequently proposed to do), there would be some risk that the rules would be found to be inconsistent with the new statutory requirement to assess all conditions of use. EPA said that it would "welcome an opportunity to work with you on a drafting solution to this issue."

a. Do you agree with EPA's March 17, 2016 view that if it had moved forward with these partial risk evaluations and rulemakings absent explicit statutory authority to do so even though the risk evaluations had not considered all conditions of use, that EPA could have been sued for not complying with the law's requirements? If not, please provide specific reasons why not.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

[5] https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView

b. Pages 2 and 3 of Attachment 1 consist of April 2, 2016 Technical Assistance from EPA that was provided to the Senate on a drafting solution to address the problem identified by EPA on March 17, 2016. Do you agree that this language, which is also drafted as an amendment to Section 26, bears a close resemblance to the language that was enacted into law, and, like the enacted text, provides EPA with statutory authority to complete rulemakings on the chemical substances on which it completed risk assessments prior to the enactment of the new law even though the risk assessments were not undertaken for all conditions of use? If not, please provide specific reasons why not.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

17. The newly enacted TSCA, for new chemicals, states that:

"(e) REGULATION PENDING DEVELOPMENT OF INFORMATION.—(1)(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use; or (II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order."

Attachment 2 consists of a portion of EPA's Technical Assistance on an April 7, 2016 draft of Section 5 of TSCA that EPA provided to the Senate. Comment A7 provides EPA's views on section 5(e). This comment noted a change from previous drafts, observing that the draft allowed manufacture of a new chemical to proceed even if EPA did not have enough information to determine whether it posed an unreasonable risk. This is because the draft as written allowed for

manufacture to proceed if EPA *either* took steps to obtain sufficient information about the chemical substance (but before it received and evaluated that information) OR if it imposed a risk management order. EPA also suggested some edits to this draft to restore the "functionality of the prior draft," which ensured that manufacture could not proceed unless/until the information about the chemical substance was sufficient and EPA made the necessary risk determination, or in compliance with an EPA-issued order to protect against unreasonable risk under the conditions of use while the information was being developed. Do you agree that the statute requires EPA to issue an order to protect against an unreasonable risk a new chemical substance may pose under the conditions of use, either while information EPA needs to assess the chemical substance is developed, or if EPA determines that the substance may present an unreasonable risk under the conditions of use, or if such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

18. Section 5(f)(4) of TSCA states that:

> "(4) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking."

Attachment 3 is an April 9, 2016 email from EPA providing responses to questions on the April 7 draft included in Attachment 2. The email asks whether the removal of provisions 5(e)(4) and 5(f)(1)(C) in that draft would also remove EPA's requirement to consider whether to issue a Significant New Use Rule (SNUR) when it issued orders to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chose not to do so). EPA responded in the affirmative. Do you agree that the enacted law retained the April 7 draft's requirement to consider whether to issue a Significant New Use Rule (SNUR) when EPA has issued an order to a submitter of a pre-manufacturing notice (PMN) (and explain its decision if it chooses not to do so)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

19. The newly enacted TSCA requires EPA, for existing chemicals that are designated a high-priority chemical substance or otherwise designated for a risk evaluation, to:

> "conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use."

In the statute, 'conditions of use' is defined as:

> "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Attachment 4 is a December 12, 2016 (post-enactment) email conveying Technical Assistance from EPA that responded to several questions posed about how EPA was required to do risk evaluations for a chemical substance under the conditions of use. Do you agree with EPA's responses to these questions as well as the narrative that precedes the specific responses to questions? If not, please provide specific reasons why not, indicating in your response how your views are consistent with the statutory text excerpted above (or, as applicable, how EPA's responses are inconsistent with the statutory text excepted above).

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

20. Attachment 5 is a document that includes EPA's technical assistance and observations that compared an April 12 2016 Senate draft of section 5 to an April 18, 2016 House draft.

    a. On pages 2 and 15, EPA provides comments related to the 90-day period for review of a PMN. Do you agree that the enacted law includes text that reflects EPA's input in these comments? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

    If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

    b. On Page 14, EPA notes the deletion of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law retained this deletion in this subsection, but included the requirement in sections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

    If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

21. Attachment 6 consists of EPA's comments to a draft of Senate section 5 dated around April 12, 2016.

    a. EPA's comment A22 notes the absence of the requirement not to consider costs or other non-risk factors when considering section 5(h) exemption requests. Do you agree that the enacted law does not include the requirement in this subsection, but does include the requirement in subsections 5(a), 5(e) and 5(f)? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

       If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

    b. Do you agree that while this same EPA comment identifies one inconsistency between the above-described text that is absent from subsection 5(h) but appears throughout the rest of section 5, it does not identify another difference, namely the presence of the term "specific uses identified in the application" in subsection 5(h) versus the term "conditions of use" that appears throughout the rest of section 5? If not, why not?

       If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

22. Attachment 7 consists of EPA's comments to an April 3, 2016 Senate draft of section 5.

    a. On page 1, EPA observes that "5(e) requires no action on the part of the Administrator whatsoever: it is wholly discretionary authority to impose requirements on the manufacture pending development of information." Do you agree that the enacted law requires EPA to either prohibit manufacture or issue an order to mitigate against potential risk while information is being developed by a manufacturer? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

       If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

    b. On page 2, EPA responds to a question posed by Senate staff, stating "We think it is important not to limit review to the uses identified in the notice. If the identified uses seem fine, and EPA therefore does nothing, the submitter is free to submit an NOC and then manufacture in any way he or she wants. EPA often uses 5(e) orders to address uses beyond those specified in notices." Do you agree that the enacted statute requires EPA to review the conditions of use (as that term is defined in the statute) of a chemical substance when it reviews a PMN as EPA advised the Senate

in this comment? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

c. On page 9, EPA says that "It seems like the best solution, per above comment, may be to drop the limitation above that the order pertain only to the conditions of use specified in the notice." Do you agree that the enacted statute incorporated EPA's proposed 'best solution' and did not limit orders only to the conditions of use specified in the notice? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

d. A second EPA comment on page 9 states that "A possible solution would be, in line with the Senate bill and offer, to drop (e) and require EPA to issue an order under what is now (f) any time EPA either makes a may present finding or lacks sufficient info, as necessary to make the unlikely to present finding." Do you agree that the enacted text retains section 5(e) and also requires EPA to issue an order any time EPA either makes a may present finding or lacks sufficient information before manufacturing can commence? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

e. On page 16, EPA responds to a question from Senate staff about whether, in the 5(h) exemptions section, it makes sense to deviate from the rest of the section's references to 'conditions of use' and instead limit EPA's exemption determination to the uses of the chemical substance identified in the exemption request. EPA responds by stating "We agree that the reference to specific uses makes sense, but not because of anything having to do with a SNUR. It seems to us that, if a party is seeking a partial section 5 exemptions, we would consider only the uses for which they are seeking the exemption, since the exemption would limit them to those." Do you agree that the enacted statute follows EPA's advice to retain the authority for EPA to consider just the uses of a chemical substance included in an exemption request, but does not make the same limiting change anywhere else so as not to so limit its review of all conditions of use of a chemical substance subject to a PMN? If not, please provide specific reasons why not, using statutory text to explain your reasoning.

If confirmed I will commit to thorough review of the final statute and would be happy to meet with the committee to further discuss any outstanding concerns.

23. In our private meeting, you described your work on perchlorate as an example where the safety standard you suggested at the time (2004) was based on older science, and said that at that time, you actually recommended a level that was more protective than the one industry was recommending.

Yes, TERA's self-published recommendation in 2004 was 500-fold lower than the original safe dose proposed by industry.

Isn't it true that in 2012, seven years after EPA recommended its drinking water reference dose for perchlorate, you wrote a paper[6] that suggested the removal of the three-fold safety factor designed to protect pregnant women, which, if adopted, means the reference dose would be 8.6 times less protective than EPA's?

I am not certain of the paper to which you refer. However, in 2004, I coauthored a paper that judged a Reference Dose (RfD) to be 0.002 mg/kg-day based on infants. EPA later came out with a RfD of 0.0007 mg/kg-day based on adults. The TERA and EPA RfDs are less than 3-fold apart. A comparison of the underlying information for these values can be found at https://toxnet.nlm.nih.gov/newtoxnet/iter.htm.

---

6 https://yosemite.epa.gov/sab/sabproduct.nsf/F18F2B7E826BC94085257AD00053024F/$File/TERA+Perchlorate+White+Paper+12-4-12.pdf

Senator Booker:

24. In your statement and testimony, as well as on TERA's website, you tout the peer review and expert panel services you provide. Based on materials posted on TERA's website, TERA has in fact frequently been contracted to convene and manage peer review and expert panels on specific issues or specific chemicals. In the great majority of such cases, TERA has then appointed you to serve on the panel, most often as Chair. Established procedures for third-party peer reviews call for an arms-length relationship between the panel convener/manager and the members of the panel, to avoid conflicts of interest. How is it not a conflict of interest for TERA employees to appoint you, their boss, to be a member of and to chair these panels?

    When groups, including government groups, contract with TERA, they recognize that someone from TERA will chair and also manage the panel. TERA also ensures that any relationships that could create a conflict of interest or biases of panel members are disclosed.

25. You also tout TERA's vetting of panelists for potential conflicts of interest. Here again, TERA has in virtually every case found that your serving on and chairing these panels poses no conflicts of interest. How do you justify having TERA employees vetting you, their boss, for potential conflicts of interest?

    It is not clear why I would have a conflict of interest. However, if there is a conflict of interest, it would always be disclosed.

26. TERA has routinely cleared you (and in some cases other panel members) of having any conflicts of interest even in cases where you or other TERA employees (or other panelists) have conducted work for the very same companies or trade associations who are paying TERA to convene a particular panel? How do you justify this practice?

    I would need to understand better the specific situation you are referring to in order to answer this question.

27. You state in TERA slide presentations, "TERA follows the National Academy of Sciences (NAS) procedures for panel selection and conflict of interest." NAS defines a conflict of interest, in part, as "any financial or other interest which conflicts with the service of the individual because it 1) could significantly impair the individual's objectivity... The term 'conflict of interest' means something more than individual bias..." You have repeatedly served on and often chaired expert or peer review panels which TERA was paid by a company to convene and run. As the director of a company with a direct financial interest in the funding it is paid for running panels, and the possibility that future income to your company may be compromised if the panel makes recommendations counter to the interests of the company paying for the services, on what basis do you believe (and has TERA found) that your serving on those panels does not present a conflict of interest?

TERA not only follows NAS guidelines but also had a small hand in helping develop these same guidelines. TERA's mission is in running independent panels in part. All panelists are offered travel and stipend remuneration for their efforts. TERA employees are offered salary and travel expense (as needed). Again, EPA, NAS and others follow a similar practice of paying panel members.

Senator Capito:

28. EPA's Safer Choice program allows companies to add a Safer Choice logo to product labels. The Safer Choice logo informs consumers that the product uses only safest-in-class ingredients. Without imposing regulations, the program has provided incentives to companies to formulate safer products and to develop innovative new chemistries.

    Will you support continuing this program at EPA?

    I am not familiar with the details of how this program operates. If confirmed, I will seek to understand it and would then be willing to have a further discussion with you about this program.

Senator Cardin:

29. Before the end of the last Administration, EPA proposed to ban some uses of three dangerous chemicals using its new Toxic Substances Control Act authority. Trichloroethylene is a probable carcinogen that has been found in unsafe levels in household wells on Maryland's Eastern Shore. Accidental exposures to methylene chloride used in paint and furniture strippers has killed at least 56 people since 1980, including at least two Maryland residents. Exposure to a second chemical used in paint strippers, N-Methylpyrrolidone, is dangerous for pregnant women. If you are confirmed, do you commit to quickly finalize these rules and prohibit the uses of these chemicals?

If confirmed I commit to quickly getting briefed on the status of these rules so that I can better understand them and the prohibitions proposed.

Senator Duckworth:

30. The Environmental Protection Agency (EPA) has said that exposure to cancer-causing chemicals in childhood can be as much as ten times as likely to lead to cancer than the same exposure to the same chemical in an adult. EPA has specific policies in place to account for these differences when it sets safety standards for chemicals.

    You have questioned these polices claiming in your papers that, "by about 6 months of age, children are usually not more sensitive to chemical toxicity than adults" and "we are not aware of reported cases of differential harm to infants or children from low levels of regulated chemicals, like pesticides or food additives." This research was funded by the American Chemistry Council and Croplife America.

    If you are confirmed, do you commit to apply, and not to weaken, EPA's current policies that account for the greater sensitivity and risk children may have from chemical exposures?

    If confirmed, I will apply EPA policies and guidance as they are appropriate and consistent with today's best available scientific evidence.

31. During your nomination hearing you stated that you will seek guidance from EPA ethics officials on whether or not you should recuse yourself from issues for which you have previously been engaged in. However, as a regulator you can and should use your own discretion on recusal.

    Yes or no, if confirmed, will you promise to recuse yourself from any agency action that relates to petcoke?

    I will rely on the guidance from EPA's ethics officials to determine any issues for which I am to be recused.

32. As you know Administrator Pruitt, like Secretary Zinke and former Secretary Price have spent millions of dollars combined flying on private jets across the country. This is a gross waste of taxpayer dollars.

    Yes or no, as a taxpayer, do you approve of Administrator Pruitt's travel practices on the public dime, and will you commit to utilizing commercials flights in your position?

    If confirmed, I will commit to utilizing commercial flights whenever they are practical and feasible. I am not familiar with Administrator Pruitt's travel practices so I cannot comment on them.

Senator Ernst:

33. As you know, reauthorization of the Pesticide Registration Improvement Act (PRIA), was passed by the House earlier this year and we have also reported it out of the Senate Agriculture Committee. However, even though it has broad bipartisan support, it is set to expire on December 8, 2017. What would be the impact to worker protection programs and also to the EPA if this successful program is not reauthorized?

My understanding is that if PRIA is not renewed, then EPA would lose a significant amount of funds that are currently used to conduct the daily operations, including pesticide reviews, in the Office of Pesticide Programs. It is also my understanding that significant, or perhaps all, grant funding that is used to support worker protection programs would no longer exist.

34. As you know, the EPA follows a risk-based model in registration of pesticides – the gold standard for much of the world. How would you protect and defend the standard of risk-based rulemaking both domestically and on the international stage?

I would protect and defend a risk based rulemaking approach by educating our colleagues domestically and internationally about this approach. I would do this by showing them how a risk based approach relies on the strength of the scientific evidence (including information from human studies, animal studies, and in vitro toxicological evaluations) to make highly informed decisions. The work conducted by the Office of Pesticide Programs provides many high quality examples of risk based evaluations.

Senator Fischer:

35. After a registrant spends tens of millions of dollars (or $100-200 m) on development, many millions on safety data, submits often times over one hundred studies on the safety of the product, AND goes through FQPA rulemaking (special examination of children's risks, aggregate risk assessment, etc.) - can EPA actually communicate to the public that this pesticide product will not result in any unreasonable effects to the environment and human health? The Federal Food, Drug and Cosmetic Act says food must be "safe" but EPA seems reluctant to say the word – how will you ensure that EPA appropriately defends Agency decisions?

    Whether EPA can state that the pesticide product will not result in any unreasonable risk to the environment and human health will depend on the results of the tests that are conducted. If the tests are negative, or show that effects occur at levels significantly higher than levels that humans and the environment are exposed to, then we should be able to confidently say that unreasonable effects are not expected. By using high quality science, and analyzing and integrating it in an objective and transparent manner I will ensure that EPA is able to defend its decisions.

36. As you may know, agricultural innovation has been bottlenecked by the previous administration's systematic decline for proven, peer reviewed, sound science. This spring, I was pleased to see the EPA deny a petition to remove a safe and proven product, Chlorpyrifos from the market. However, more work needs to be done to provide greater certainty for applicators utilizing FIFRA approved products.

    I continue to be concerned about NPDES permit requirements for the application of pesticides in or near water. NPDES permits are duplicative and do not add any additional environmental protection beyond those provided through the FIFRA process. To the contrary, NPDES permits negatively impact the ability to protect people from mosquitoes that can vector the Zika Virus and other viruses like West Nile, to control invasive aquatic plants that contribute to flooding, impede navigation and impact public safety, and many other important uses.

    Dr. Dourson, should you be confirmed, will you uphold the rigorous FIFRA pesticide registration process and work with Congress to eliminate these costly and duplicative permits?

    Yes.

Senator Markey:

37. Dr. Dourson, according to the EPA website, the EPA Office of Chemical Safety and Pollution Prevention's mission is to prevent the public and environment from potential risks from pesticides and toxic chemicals. Do you promise to uphold this mission and take into consideration all potential risks from chemical exposures when making decisions on protecting public health and the environment?

    Yes.

38. Commercial and native bees and other pollinators play a key role in agriculture and natural ecosystems and are vital to our nation's food security, production, health, and economy. Pesticides, in particular insecticides, frequently kill these pollinators causing havoc for beekeepers and raising the alarm for environmentalists, who would like to see particular pesticides banned. What role do you think EPA should take in dealing with this issue that takes into account the various stakeholders interested in this issue?

    EPA, working with all stakeholders, should seek to understand the impact of insecticides on pollinators and based on the science should regulate appropriately to ensure protection.

39. For over two decades, EPA has failed to perform routine consultations under the Endangered Species Act on regulatory actions involving pesticides. This failure has resulted in extensive litigation. What do you see as the problems in the consultation process and what will you do to fix them?

    If confirmed, I will seek to further understand the existing process and work to improve it with the hopes of limiting future litigation.

40. For more than half a century, chlorpyrifos has been widely used as a pesticide on a variety of crops. In November 2016, the EPA released a revised human health risk assessment for chlorpyrifos confirming that there is no safe level of chlorpyrifos in drinking water and that exposure to the chemical can cause not only acute illness, but leads to many long term neurodevelopmental issues for children, including attention deficit, reduced IQ and damage to the nervous system. The 1996 Food Quality Protection Act (FPQA) requires EPA to protect children from unsafe exposures to pesticides and ensure with reasonable certainty that "no harm will result to infants and children from aggregate exposure" to pesticides. If this standard cannot be met, the pesticide must be banned. Under court order and after years of delay, the EPA recently issued a decision refusing to ban the pesticide. Please explain why the evidence created by the EPA in its revised health assessment was not sufficient to conclude this issue. How will you ensure that this credible scientific evaluation is incorporated into any revised look at this pesticide?

    If confirmed, I will work to understand this issue completely and will ensure that all decisions are based on and driven by scientific evidence.

41. One of the most significant changes made to TSCA under the LCSA was the streamlined authority for EPA to require testing of chemicals by order. However, to our knowledge that authority has not yet been used in the 15 months since the law took effect.

    Given the importance of testing to fill data gaps, which is critical to both prioritization and risk evaluation -- and fundamental to a "risk-based" system, please tell us your plans for using the section 4 testing authority and approach for filling data gaps for both prioritization and risk evaluation."

    If confirmed, I will seek to better understand the Section 4 testing authority under TSCA. With this knowledge, I will work to ensure that it is appropriately used to help fill gaps for prioritization and risk evaluation.

42. The new law requires EPA to restrict new chemicals where the available data are insufficient to address their risks. How will you evaluate the adequacy of data in PMNs? What will you do to assure that new chemicals are adequately tested?

    I will use a weight of the evidence approach that considers all scientific evidence and information to evaluate PMNs.

43. The industry has pressured EPA to accelerate the completion of the review period for PMNs in order to reduce the PMN backlog. What steps will you take to assure that EPA does not sacrifice the rigor and thoroughness of the review process in return for speed?

    If confirmed, I will work closely with staff to completely understand the PMN review process to ensure its rigor and thoroughness.

44. EPA staff has pointed to several ways industry can improve the efficiency of the review process by filing more robust PMNs that anticipate and respond to the likely concerns of EPA reviewers. What will you do to motivate industry to file more complete and accurate PMNs?

    If confirmed, I will work closely with staff to completely understand the PMN process. It seems to me that if industry had a better understanding of the EPA evaluation approach, it should incentivize them to provide more complete and accurate PMN submissions.

45. Do you agree that more transparency is needed so the public can understand what EPA is doing to protect public health and the environment in the PMN process? What specific steps will you take to increase transparency?

    I agree that transparency is always helpful and that the government should always strive to be more transparent. If confirmed, I will evaluate all the programs within OCSPP to ensure that they are sufficiently transparent and understood by all stakeholders.

Senator Merkley:

46. Please summarize the identified hazards of chlorpyrifos, and any impacts chlorpyrifos has on the brains of developing children.

Chlorpyrifos is an organophosphate insecticide, acaricide and miticide used primarily to control foliage and soil-borne insect pests on a variety of food and feed crops. Chlorpyrifos can cause cholinesterase inhibition in humans at high enough doses; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at very high exposures (e.g., accidents or major spills), respiratory paralysis and death. EPA has historically regulated chlorpyrifos on that endpoint.

47. Please summarize the identified hazards of flame-retardants, and any links to cancer or endocrine disruption.

It would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

48. Please summarize the identified hazards of alachlor, and any links between alachlor and cancer.

It would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

49. Will you defer to EPA scientists and career staff on matters of science?

If confirmed, as a scientist myself, I will work very closely with EPA scientists and other career staff to work towards consensus based on transparent, objective evaluations of scientific evidence.

50. Do you believe it is important to seek balanced input from industry perspectives and environmental and public health perspectives?

Yes.

51. In a recent public disclosure of Administrator Pruitt's calendar of meetings, only about 2-3% of his meetings were with public health and environmental advocacy organizations, whereas over 25% of his meetings were with industry representatives. Do you believe this reflects fair and balanced input from public health and environmental advocacy organizations?

Without knowing the number and nature of requests Administrator Pruitt received, it is difficult to judge if this reflects appropriate balance.

52. What do you think is a fair and balanced ratio of input from public health and environmental advocacy organizations?

A fair and balanced ratio of input would mean accepting an equal percentage of meeting requests from all stakeholder groups.

53. Will you commit to a fair and balanced ratio of input from public health and environmental advocacy organizations?

Yes, to the extent that I can control this.

54. When you and I met in my office, I asked you which chemicals you thought made sense to take off the market, and when asked about asbestos specifically, you said "yes". While I appreciate your willingness to ban asbestos in commerce, what tools could EPA use to address legacy exposures to asbestos under TSCA, such as exposure to asbestos already in many homes across the country? Will you commit to using TSCA to ban asbestos?

Although it would be inappropriate for me to prejudge the issue, if confirmed I will ensure that the issue is fully and fairly considered in a publicly transparent manner that is consistent with EPA's statutory authorities.

Senator Sanders:

Climate Change

55. President Trump has suggested in the past that climate change is a hoax. Is the President correct? Is climate change a hoax?

I believe that climate change is real and human activity contributes to climate change.

56. Do you agree with the vast majority of scientists that the combustion of fossil fuels contributes to climate change?

I believe that climate change is real and human activity contributes to climate change.

57. After Hurricane Harvey, an Arkema Inc. chemical plant exploded due to power loss and flooding. The EPA recently delayed implementation of a rule that requires hazardous chemical facilities to improve how they assess risks and prepare for potential hazardous incidents. This rule also would have required certain facilities to coordinate with local emergency response teams to ensure readiness in the case of an industrial accident, and would have provided additional information to nearby residents regarding chemical hazards.

Do you agree that communities deserve to be informed about potential chemical hazards from chemical facilities like the Arkema plant? If not, why not?

I am not familiar with the existing statutes and regulations. If confirmed, I will look into this.

Do you agree that this EPA rule could have helped mitigate environmental and chemical hazards following the Arkema plant explosion? If not, why not?

I am not familiar with the EPA rule you are referring to. If confirmed, I will look into this.

Do you agree with the decision to delay implementation of this rule? If so, why?

I am not familiar with the EPA rule you are referring to. If confirmed, I will look into this.

If confirmed, how will you work to address climate change to prevent massive toxic chemical exposure during and after climate-fueled super storms?

I am not familiar with the impacts of climate-fueled super storms. If confirmed, I will look into this.

Past Career/Conflicts of Interest

58. The U.S. Geological Survey says that glyphosate, the active ingredient in Roundup that has been listed as a carcinogen by the World Health Organization, is present in 59 percent of our country's surface water. Recently unsealed court documents in a suit against Monsanto indicate that a senior EPA official colluded with Monsanto to suppress research into glyphosate's toxicity.

    You represented Monsanto on multiple occasions during your time at Toxicology Excellence for Risk Assessment. If confirmed, how will you prevent inappropriate undue influence from regulated industries on EPA employees?

    If confirmed, I will work with the Office of General Counsel to ensure that outside parties, including regulated industries do not unduly influence OCSPP.

59. There are over 86,000 unregulated and largely untested chemicals currently in use in the United States. Thousands of these chemicals are being linked to negative health impacts – including birth defects, cancer, and other problems. Given the massive funding cuts that President Trump has proposed for OCSPP, how do you plan to implement and enforce the recently updated Toxic Substances Control Act (TSCA) and expand the list of banned chemicals?

    I am unfamiliar with the proposed budget.

60. As founder of the chemical consulting firm Toxicology Excellence for Risk Assessment, you represented Monsanto, DuPont Chemical, the Dow Chemical Company, the American Chemistry Council, American Cleaning Institute, and American Petroleum Institute. If confirmed, you will be in charge of making sure that companies like these comply with chemical safety regulations and conduct waste clean-ups.

    As Assistant Administrator of OCSPP, would you have any active conflicts of interests with these companies? If so, will you commit to recuse yourself for the full course of any matter in which any of your former clients is a party? If not, why not?

    If confirmed, I would work with the Office of General Counsel to ensure that I am avoiding any conflicts of interest. I will recuse myself based on their direction and advice.

61. How does your work history of representing the chemical industry qualify you to lead an Agency tasked with ensuring the health and safety of working people, their families, and the communities in which they live?

    My work history, which includes over 10 years at EPA, has consistently focused on provided objective, transparent, and high quality evaluations of scientific evidence to inform public health. I believe this approach is fully consistent with conducting good science at the EPA.

62. Vermont has recently experienced unsafe levels of Perfluorooctanoic acid (PFOA) in ground water. In 2000, the state of West Virginia hired you on DuPont Chemical's recommendation to determine a safe level of PFOA in drinking water. Despite clear science showing that the chemical's negative impacts on residents of West Virginia, you recommended safety standards 150 times less stringent than the maximum safety level that DuPont Chemical itself determined and thousands of times less stringent than the level set by the EPA in 2016.

    How and why did you come to such a radically lower standard than DuPont and the EPA regarding acceptable PFOA safety standards?

    The DuPont standard was understood by me at the time to be a placeholder until a consensus group reviewed all of the science. I was one of 10 scientists on this consensus group, of which 5 were from government (3 of them from EPA). The 150 ppb represented a consensus judgment of these 10 scientists based on the best available information at that time.

    The PFOA safety standard you recommended turned out to be wildly inaccurate. These kinds of mistakes negatively impact the health of millions of people throughout the country. Given these kinds of mistakes and scientific inaccuracies, how will you ensure that standards are based on the best available science? If confirmed, will you commit to adhering to the science, and not necessarily the best interests of your former clients?

    If confirmed, I will ensure that EPA continues to use a systematic review approach that includes seeking all available scientific information, including the newest research, to inform objective decisions to protect public health. The scientific data should be the foundation of decision making in OCSPP.

Science

63. At the EPA, science provides the foundation for Agency policies, actions, and decisions made on behalf of the American people. What should the role of science be in the development of the EPA policies, rules, and regulations?

    Science should be the backbone and foundation of EPA policies, rules, and regulations.

Most Pressing Challenges

64. In your opinion, what are the most pressing chemical safety challenges that deserve the attention of the EPA? If confirmed, what will you do at the EPA to address these challenges?

    The most pressing challenges within OCSPP involve 1) ensuring that EPA has sufficient expertise to fully implement the Lautenberg amendments to TSCA in the timelines required by the statute and 2) ensuring that the pesticides program also has the expertise to meet all the pesticide registration and re-registration deadlines as required by PRIA.

65. Last year's revisions to TSCA banned states from issuing their own toxic substance regulations if they are more stringent than the EPA's regulations. How will you ensure states' rights are preserved when states like Vermont may want to protect the health of people in their states in a more stringent manner than the federal standards?

If confirmed, I will seek to better understand the Lautenberg amendments to TSCA and will work with states to help ensure public health protection in all 50 states in a manner that is consistent with the law.

Environmental Justice

66. If confirmed, how will you address growing environmental and economic justice issues associated with chemical safety and pollution prevention?

I will work with staff to make this determination if confirmed.

67. Over 160 environmental and health groups, including the American Academy of Pediatrics, Breast Cancer Action, the Center for Biological Diversity, Clean Water Action, Food and Water Watch, Friends of the Earth, the Institute of Neurotoxicology and Neurological Disorders, and Utility Workers Union of America, have raised serious concerns with your nomination on the grounds that you are not suited to protect individuals, families, and the environment from potential risks from pesticides and toxic chemicals.

    If confirmed, will you commit to working with these environmental groups and Americans who are threatened by toxic chemical pollution to ensure that OCSPP works to achieve environmental and human health?

    Yes.

Senator Whitehouse:

68. Do you agree that the tobacco industry manipulated and obfuscated scientific research into the dangers of smoking for decades. Why or why not?

I do not have firsthand knowledge to comment.

69. Your name comes up over 460 times in the tobacco industry documents made public as part of the Tobacco Master Settlement Agreement. Some of your emails are there – corresponding with Phillip Morris over work they hired you to do. Even your business card and Articles of Incorporation for your organization TERA are there, in the files of RJ Reynolds with a handwritten note next to your bio that the document should be filed under "Consultants/Dourson."

    a. Did you provide RJ Reynolds your business card and TERA's Articles of Incorporation?

    No. As I recall, and as stated in public records, our total RJ Reynolds work was ~$85 to copy some studies from work we were doing for EPA. Phillip Morris work was $550.

    b. Please provide, for the record, a full accounting of the work, including the amount of money accepted, from whom, and the scope of work, that you did for tobacco companies and the role you played in the campaign to hide the truth about the dangers of smoking.

    TERA was not part of any campaign. Our work is a matter of public record, specifically a 2015 hearing of the U.S. House Committee on Science, Space, and Technology. Our total income from these sources is approximately $13,000.

70. In the late 90s, TERA, the organization you founded, received funding from the Center for Indoor Air Research (CIAR) to study the effects of secondhand smoke. TERA's name pops up throughout the tobacco database.

    a. Do you believe CIAR was a front group for the tobacco industry? Why or why not?

    I am not aware of this.

    b. How much money did you receive from CIAR and for what purposes?

    Approximately $6000 to study the absorption of nicotine and measure its breakdown products in urine.

c. When you undertook work for CIAR, were you aware that secondhand smoke was considered dangerous to your health?

At high enough concentrations any chemical is dangerous to our health. Cigarette smoke is particularly worrisome.

d. When you undertook work for CIAR, were you aware that in a December 9, 1999 email to his colleagues, Philip Morris toxicologist Robert Elves wrote that TERA "may provide an alternative source for third-party verification of product stewardship programs besides the Chemical Manufacturers Association" (now known as the American Chemistry Council)?

No.

e. Have you done any pro bono work you've done for the tobacco industry? If so, please describe it.

No.

71. You are the co-author of a paper "Distribution of Exposure Concentrations and Doses for Constituents of Environmental Tobacco Smoke" that used data from the 16 Cities study to minimize the effects of workplace secondhand smoke.

a. Are you aware that a 1992 EPA report identified secondhand smoke as a human carcinogen and the 16 Cities study was specifically conceived and designed to challenge this finding?

No.

b. When you used the data from the 16 Cities study, were you aware that its experiments and laboratory analyses were designed and carried out by R.J. Reynolds Tobacco Company scientists and that this level of involvement was not properly disclosed when the work was published?

Not that I recall.

c. The methodology used in the 16 Cities study has been criticized for inappropriately combining exposure data collected from workplaces that allowed smoking anywhere and those that allowed it only in designated areas to skew the results. Do you stand by the 16 Cities study methodology and data? Why or why not?

I would have to review these criticisms before taking a stand. However, I stand by the work we did as part of this paper.

d. Your paper minimizes the impact of workplace secondhand smoke based on the 16 Cities data. Do you stand by the findings of your report? Why or why not?

My interpretation of this study, or at least our part of this study, is different than your question.

e. Do you acknowledge that the 16 Cities study used data from workplaces where few cigarettes were observed, while characterizing these environments as "smoking," with the goal of diluting their estimates of workplace secondhand smoke?

I do not know.

f. Are you aware that recent research using 16 Cities data comes to a conclusion that directly contradicts the findings of both the 16 Cities study and your own?

No.

72. According to an analysis by Environmental Defense Fund, the journal *Regulatory Toxicology and Pharmacology* has published 37 of the 66 studies you have co-authored since 1995, including many for which you or TERA received financial support from corporations and trade groups, including Procter & Gamble, Dow AgroSciences, and the American Chemistry Council. Additionally, you sit on the journal's editorial board. *Regulatory Toxicology and Pharmacology* has been widely criticized for its record of publishing industry-funded studies that were favorable to Big Tobacco. The journal editor, Gio Gori, has extensive ties to Big Tobacco.

a. Please provide the date range(s) during which you served as the president of TERA, all financial contributions received by TERA during that time, and resulting publications.

I served as TERA president from February of 1995 to August 2015. A yearly summary of remuneration can be found in TERA's submitted 990s. Many of the publications and reports resulting from this work can be found at www.tera.org, and related websites linked to this website.

b. Please provide a list of all studies you've published in *Regulatory Toxicology and Pharmacology* and who financed those studies.

Please see attachment 2.

c. Please provide the date range(s) for which you've been a member of *Regulatory Toxicology and Pharmacology's* editorial board, a list of all studies you've reviewed, and a list of all the funding for each of those studies.

I joined the board in the 1995. I generally review 4 manuscripts a year for this journal on a probono basis. I do not keep records of my reviews.

d. How many studies published in *Regulatory Toxicology and Pharmacology* have been financed by the tobacco industry?

I do not know.

e. Do you stand by the papers published in *Regulatory Toxicology and Pharmacology* with regards to risks associated with tobacco?

I am not aware of such papers, other than the one I coauthored.

73. In 2002, more than 40 health experts from government, academia, and environmental groups wrote to the *Regulatory Toxicology and Pharmacology's* editors to express concern over the clear conflicts of interest and lack of editorial independence. Do you believe *Regulatory Toxicology and Pharmacology* is free of conflicts of interest? If not, please describe the conflicts of interest of which you are aware.

Yes. As shown in Attachment 2, a large part of my papers were supported by governments, TERA, or the University of Cincinnati, College of Medicine. My most cited papers were published as an employee of EPA. However, most government work is not published in peer review literature. Rather, it forms the basis of government reports.

74. The Texas Commission on Environmental Quality (TCEQ) is the primary enforcer of the Clean Air Act in Texas. The TCEQ gave your organization, TERA, a four-year, $600,000 contract to help review the agency's chemical evaluations. Two-thirds of these TCEQ analysis have made the guidelines less protective than they used to be. Specifically, TERA endorsed TCEQ values for the known carcinogens arsenic and hexavalent chromium that were much looser than those used in California or by the EPA. Please provide, for the record, a full accounting of the work you did for the TCEQ including the financial sponsors of this work?

Generally, the work I conducted was based on more recent science or a larger set of data The work we did for TCEQ is a matter of public record. We had no other financial sponsors for the TCEQ work.

75. Michael Honeycutt sits on the steering committee for the Alliance for Risk Assessment, which is an affiliate of TERA. Mr. Honeycutt also heads the toxicology division at the Texas Commission on Environmental Quality (TCEQ). Although you have claimed that the Alliance is an independent entity, you have remained on its steering committee since its inception in 2007.

The Alliance is sponsored by TCEQ, Georgia Pacific, and the American Petroleum Institute, to name a few. Yet, TERA's nonprofit tax filings don't include anything on the Alliance.

a. How can you explain the significant conflict of interest presented by Mr. Honeycutt routing taxpayer dollars toward a firm whose decisions Honeycutt influences?

Dr. Honeycutt's participation on the Alliance for Risk Assessment (*ARA*) Steering Committee consists of review and endorsement of non-TCEQ projects. He recuses himself on TCEQ projects. The suggested Conflict of Interest (COI) in this question does not exist.

b. Can you provide a full accounting of the work conducted by the Alliance for Risk Assessment and its financial sponsorships?

The *ARA* work and its sponsors are, and have been, publicly available.

76. In implementing TSCA, do you believe risk management costs should be considered when assessing whether a chemical poses an unreasonable risk?

The Lautenberg amendments to TSCA do not allow for the consideration of non-risk factors when making a finding of unreasonable risk. As such, risk management costs should not be considered.

77. In implementing TSCA, EPA, consistent with congressional intent, issued a notice making it clear that substantiation of all non-exempt confidential business information (CBI) claims is required upfront. Do you commit to ensuring the EPA follows and upholds that requirement?

Yes

78. Pursuant to the overhauled TSCA, EPA recently published its first inventory of mercury supply, use, and trade in the U.S., which have very little information because it did not benefit from the new reporting requirements. TSCA requires that EPA promulgate a mercury and mercury compound reporting rule by June 22, 2018 to assist in preparation of the inventory, the next one of which is required to be published by April 1, 2020.
    a. Do you commit to completing the mercury and mercury compounds reporting rule by the June 22, 2018 deadline?

I do not know the status of this rulemaking within the Agency. However, if confirmed I will work to make sure that the TSCA deadline for this rule can be met.

    b. Do you commit to identifying any manufacturing processes or products that intentionally add mercury or mercury compounds and recommend actions to achieve further reductions in such mercury use in the next inventory and publish that inventory by the April 1, 2020 deadline?

As noted above, I do not know the status of these activities within the Agency. If confirmed, I will work to understand their status and to ensure that EPA is meeting the deadlines required by the Lautenberg amendments to TSCA.

79. Mercury was on the 2012 Workplan Chemical List, but was removed from the list in 2014 because EPA already knew how highly toxic mercury is, and the Agency indicated it would be undertaking activities to implement the Minamata Convention on Mercury anyway. Significantly, this action was taken well before the revised TSCA was enacted. Under the revised law, to facilitate meeting its Convention obligations to reduce mercury use in the production of switches and switches, the phase down of mercury use in polyurethane production, and to regulate mercury use in new products and processes, it may be necessary for EPA to identify mercury among the next round of chemicals prioritized for action under TSCA. Will you include mercury among the next round of chemicals prioritized for action under TSCA as needed to further reduce mercury use in products and processes, and meet our obligations under the Minamata Convention?

I am not familiar with why mercury was removed from the 2014 workplan list. If confirmed, I will look into this and seek to ensure that EPA is taking necessary steps to further reduce mercury use in products and processes.

80. Administrator Pruitt has been criticized for spending a disproportionate amount of his time meeting with industry and virtually no time with public-interest groups. If confirmed, will you commit to meet with and listen to all parties in a balanced fashion?

Yes.

81. How should the EPA consider the synergistic effects of chemicals when considering approval of these chemicals under FIFRA?

I am not familiar with how synergistic effects are evaluated currently in the pesticides program. If confirmed, I will seek to understand this to ensure that EPA's approach is appropriate.

82. The Fish and Wildlife Service recently listed the rusty patched bumble bee as endangered, the first wild bee in the lower 48 states to receive this distinction. Pesticides were listed as part of the blame for the bee's current status. Other bumble bee species are also at risk due to increased pesticide use and other environmental challenges. How can the EPA assist in bettering the understanding of pesticides' role in declining bee and other pollinator species?

If confirmed, I will make sure that the impact of pesticides on bee populations is appropriately evaluated. I would work to ensure that the current testing requirements are adequate to ensure appropriate safety.

83. Under your leadership, what role will EPA play in the management and control of vector borne illnesses like Zika?

If confirmed, under my leadership, I will work to ensure that the Office of Pesticides Programs is actively engaged in reviewing the registrations of new pesticide products that can help decrease the spread and existence of Zika.

84. If confirmed, do you commit to notifying the Committee of all of the email addresses you plan to use upon confirmation and within seven days of using a new email address, including any aliases or pseudonyms? Do you commit do conducting all business using official email addresses and other means and to refrain from any mediums that are outside the Freedom of Information Act's reach?

Yes.

85. Do you a believe that climate change is real?

Yes.

86. EPA Administrator Pruitt recently told CNBC that "I would not agree that [carbon dioxide's] a primary contributor to the global warming that we see." Based on the scientific findings from experts such as NOAA and statements on EPA's website, including "Carbon dioxide is the primary greenhouse gas that is contributing to recent climate change," Politifact determined that statement to be false. Do you agree with Administrator Pruitt or scientific experts regarding whether carbon dioxide is the primary greenhouse gas that is contributing to climate change?

Climate science is outside my area of expertise and I would need further information before responding to this question.

87. In 2009, as mandated by the Supreme Court and backed by a robust scientific and technical review, the Environmental Protection Agency produced the Endangerment and Cause or Contribute Findings for Greenhouse Gases (GHGs) under Section 202(a) of the Clean Air Act. It found six greenhouse gases - carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride - "taken in combination endanger both the public health and the public welfare of current and future generations." Do you agree with the EPA's endangerment finding? Why or why not?

I am not familiar with the details of EPA's endangerment finding and would need to do more research on the topic before answering this question.

88. Do you believe hydrofluorocarbons are greenhouse gases? What is the global warming potential of methane, and from what source does that number come?

I am not sufficiently familiar with the definition of greenhouse gases and do not have the expertise to answer these questions.

89. Do you support the amendment to the Montreal Protocol to phase down HFCs?

I am not familiar with this aspect of the Montreal Protocol and thus cannot answer this question.

90. Do you believe the U.S. should remain a party to the United Nations Framework Convention on Climate Change?

Climate science is outside my area of expertise and I would need further information before responding to this question.

91. Do you believe the U.S. should remain a party to the Paris Agreement?

Climate science is outside my area of expertise and I would need further information before responding to this question.

92. If confirmed, do you commit to providing complete and accurate responses to inquiries from EPW members in a timely fashion?

Yes.

University of Cincinnati, College of Medicine--**Dourson Attachment 1**

1,4-Dioxane [1]

a. 2013 to 2016
b. PPG industries, Hamp and Associates, Waste Management, Toxicology Excellence for Risk Assessment (TERA), University of Cincinnati, College of Medicine, US National Toxicology Program
c. Two publications

- Dioxane occurs in foods (up to 15 ppb in dairy products).
- Dioxane causes cancer at high doses, but EPA's IRIS peer review panel thought that a nonlinear assessment might be appropriate.
- The State of Kentucky requested that the Alliance for Risk Assessment petition the government of Japan for relevant data. Four other states joined in this petition. Other collaborators included several consulting groups. Scientists from Health Canada observed.
- This TERA/RSC work was done after EPA's IRIS document and supports the IRIS peer review panel's suggestion that the cancer findings are due to a nonlinear Mode of Action (MOA).
- All of this information has been publicly available.
- Health Canada is using TERA's collaborative work in their evaluation of 1,4-dioxane.

1-Bromopropane [2]

a. 2004
b. Albemarle Corporation and Ameribrom, Inc
c. A report was generated and made publicly available.

- In 2004, occupation limits for 1-bromopropane differed by 16-fold.
- TERA critically evaluated the underlying information and recommended an OEL of 20 ppm based on effects in newborns.
- TERA's value was lower (i.e., safer) than EPA's.

---

[1] Source:

- Nishimura et al., 2004. Study of 1,4-dioxane intake in the total diet using the market-basket method. Journal of Health Science 50:101-107.
- Dourson, M; Reichard, J; Nance, P; Burleigh-Flayer, H; Parker, A; Vincent, M; McConnell, EE; (2014). Mode of Action Analysis for Liver Tumors from Oral 1,4-Dioxane Exposures and Evidence-Based Dose Response Assessment. Reg. Toxicol. Pharmacol. Volume 68, Issue 3, April 2014, Pages 387–401
- Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard. 2017. Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane. Regulatory Toxicology and Pharmacology 88:45-55.
- Website is currently in transfer mode. For current version see: http://med.uc.edu/eh/centers/rsc/risk-resources/ara.

[2] http://www.tera.org/Publications/TERA%20Analysis%20of%20OELs%20for%201-Bromopropane.pdf.

- An NTP study was published after the TERA assessment showing cancer findings.
- New evaluations based on the cancer suggested lower limits.

PFOA-Dupont [3]

a. 2002
b. State of West Virginia
c. A report was generated and place on the website of the State of West Virginia.

- In 2002, 4 governments and one industry recommended TERA as the independent and neutral party to assist in a PFOA evaluation. A West Virginia judge agreed.
- Dr. Deanne Statts of West Virginia DEP chaired a 10-member scientific panel.
- Five panelists were government employees; 3 were from EPA.
- The panel made a unanimous determination of a safe water level of 150 ppb.
- All of this information has been publicly available.
- The science of PFOA has progressed since 2002.

Trichloroethylene (TCE) [4]

a. 2012 to 2016
b. American Chemistry Council, Toxicology Excellence for Risk Assessment (TERA) and University of Cincinnati, College of Medicine
c. The collaboration team had 6 conference calls, including scientists from Australia, 3 webinars, one of which included over 400 folks, and 1 independent peer consultation. The team gave 8 presentations, and published 1 paper.

- In 2012, the Alliance for Risk Assessment (*ARA*) was petitioned by the Alliance for Site Closures to review noncancer toxicity of TCE. The Steering Committee of the *ARA*, composed primarily of government officials, asked the collaboration to focus instead on building range in risk values.
- The team has had one training session with US states.
- All of this information has been publicly available.

Perchlorate [5]

a. 1995 to 2007

---

[3] Source: FINAL CATT REPORT WITH ATTACHMENTS, AUGUST 2002

[4] Source:

- Michael Dourson, Bernard Gadagbui, Rod Thompson, Edward Pfau, and John Lowe. 2016. Managing Risks of Noncancer Health Effects at Hazardous Waste Sites: A Case Study Using the Reference Concentration (RfC) of Trichloroethylene (TCE). Regulatory Toxicology and Pharmacology 80:125-133.
- http://med.uc.edu/eh/centers/rsc/risk-resources/ara

[5] Source: Strawson, J., Q. Zhao and M. Dourson. 2004. Reference dose for perchlorate based on thyroid hormone change in pregnant women as the critical effect. Reg. Tox. Pharm. 39: 44-65.

b. The Perchlorate Study Group (PPG)
c. TERA developed a report for peer review, monitored toxicology studies and offered comments in peer review meetings of EPA Reference Dose (RfD).

- Afterwards EPA and the DOD disagreed on the safe dose.
- TERA independently made its safe dose 500-fold more protective than PPG's original RfD and published it.
- The NAS also developed a safe dose, which was 25 times higher than EPA's, 12-fold lower than DoD's, but within 3 fold of TERA's value.

Chlorpyrifos [6]

a. 2004 to 2006
b. Dow AgroSciences
c. Two publications

- The science for chlorpyrifos has progressed since the time of these publications.
- One epidemiology study shows associations of neurological effects at exposures lower than the current RfD; other studies do not show this association.
- Based on how chlorpyrifos works this association is not expected.
- The raw data from this epidemiology study are not available for review.

Alachlor and Acetochlor [7]

a. 2009-2010
b. Dow AgroSciences and Monsanto
c. A public peer review meeting and one publication

- Michael Dourson talked with senior US EPA leaders to determine their interest. EPA stated that they had developed RfDs for the parent chemicals and did not consider the degradates to be more toxic.
- Dow AgroSciences and Monsanto petitioned the Alliance for Risk Assessment (*ARA*) for their review. The *ARA* Steering Committee endorsed a collaborative approach.
- TERA formed a team of risk assessment scientists from 3 states and the EPA to develop these RfDs. The resulting values were based on a unanimous consensus.

---

[6] Source:

- Zhao, Q., B. Gadagbui and M. Dourson. 2005. Lower birth weight as a critical effect of Chlorpyrifos: A comparison of human and animal data. Reg. Toxicol. Pharmacol. 42:55-63.
- Zhao, Q., M. Dourson and B. Gadagbui. 2006. A Review of the Reference Dose (RfD) for Chlorpyrifos. Reg. Toxicol. Pharmacol. 44:111-124.

[7] Source:

- http://www.tera.org/ART/Degradates/index.html;
- Gadagbui, B; Maier, *M; Dourson*, M; Parker, A; Willis, A; Christopher, JP; Hicks, L; Ramasany, S; Roberts, SM. 2010. Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation. Regulatory Toxicology and Pharmacology 57:220-234.

Diacetyl [8]

a. 2009-2010
b. Food Producers Association
c. One report that was made available to the public

- At the time of TERA's work no standards existed for worker protection.
- TERA's standard published in 2010 (i.e., range from 70 to 200 ppb) was based on the best science at the time, through careful consideration of toxicology, epidemiology, and background exposures.
- Subsequent analyses published by various organizations, including NIOSH, developed standards of 5 to 20 ppb based on different emphasis on toxicology and epidemiology data.
- TERA is continuing its ongoing relationship with NIOSH since 2010 through an Interagency Personnel Agreement Fellowship.

Acrylamide [9]

a. 2007-1009
b. Burger King Corporation, Frito-Lay, Inc., H.J. Heinz Company, KFC Corporation, McDonald's Corporation, The Proctor & Gamble Manufacturing Company, The Proctor & Gamble Distributing Company, and Wendy's International, Inc.
c. Litigation support under proposition 65 of California, and several publications

- TERA determined that the MOA for the most sensitive endpoint, thyroid tumors, was bimodal, with linear at the low dose and an acceleration of thyroid tumors above a threshold for hormonal action.
- TERA's first publication was supported by industry.
- TERA's next two publications were in large part self-supported.

---

[8] Maier, AM; Kohrman-Vincent, M; Parker, A; Haber, LT. (2010) Evaluation of concentration-response options for diacetyl in support of occupational risk assessment. Reg. Toxicol. and Pharmacol. 58(2): 285-296.

[9] Source:

- Dourson, M., Hertzberg, R., Allen, B., Haber, L., Parker, A., Kroner, O., Maier, A. and Kohrman, M. 2008. Evidence-Based Dose Response Assessment for Thyroid Tumorigenesis from Acrylamide. Regulatory Toxicology and Pharmacology 52 (2008) 264–289.
- Haber, LT; Maier, A; Kroner, OL; Kohrman, MJ. (2009) Assessment of Human Relevance and Mode of Action for Tunica Vaginalis Mesotheliomas Resulting from Oral Exposure to Acrylamide. Regul. Toxicol. Pharmacol. 53(2): 134-149.
- Maier, A., Kohrman-Vincent, M., Hertzberg, R., *Dourson, M.*, Haber, L.T and Allen, B. 2012. Critical review of dose-response options for F344 rat mammary tumors for acrylamide – Additional insights based on mode of action. Food Chem. Toxicol. 50:5, 1763-1775.

- All of these publications include more findings than EPA's older IRIS document.

Dourson Attachment 2

PUBLICATIONS in Regulatory Toxicology and Pharmacology [funding group in brackets and refers to only funding to TERA or the RSC and not to contributing authors]

1. Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard. 2017. Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane. Regulatory Toxicology and Pharmacology 88:45-55. [Hamp and Associates, Waste management, and University of Cincinnati, College of Medicine]

2. Richard A. Becker, Vicki Dellarco, Jennifer Seed, Joel M. Kronenberg, Bette Meek, Jennifer Foreman, Christine Palermo, Chris Kirman, Igor Linkov, Rita Schoeny, Michael Dourson, Lynn H. Pottenger, and Mary K. Manibusan. 2017. Quantitative weight of evidence to assess confidence in potential modes of action. Regulatory Toxicology and Pharmacology, 86:205–220. [American Chemistry Council]

3. Michael Dourson and Raymond G York. 2016. Advances in Assessing Ingredient Safety. Regulatory Toxicology and Pharmacology. 79:S112-S118. [University of Cincinnati, College of Medicine]

4. Michael Dourson, Bernard Gadagbui, Rod Thompson, Edward Pfau, and John Lowe. 2016. Managing Risks of Noncancer Health Effects at Hazardous Waste Sites: A Case Study Using the Reference Concentration (RfC) of Trichloroethylene (TCE). Regulatory Toxicology and Pharmacology 80:125-133. [American Chemistry Council]

5. Ted W. Simon, Yiliang Zhu, Michael L. Dourson, Nancy B. Beck. 2016. Bayesian methods for uncertainty factor application for derivation of reference values. Regulatory Toxicology and Pharmacology 80:9-24. [American Chemistry Council]

6. Dourson, M., Reichard, J., Nance, P., Burleigh-Flayer, H., Parker, A., Vincent, M., McConnell, E.E. 2014. Mode of action analysis for liver tumors from oral 1,4-dioxane exposures and evidence-based dose response assessment. Regul.Toxicol. Pharm. 68(3): 387-401. [PPG Industries]

7. Patterson J., Maier A, Kohrman-Vincent M, and ML Dourson. 2013. Peer consultation on relationship between PAC profile and toxicity of petroleum substances. Reg. Tox and Pharm, Volume 67: S86–S93. [American Petroleum Institute]

8. Dourson, M., Gadagbui, B., Griffin, S., Garabrant, D.H., Haws, L.C., Kirman, C. and Tohyama, C. 2013. The importance of problem formulations in risk assessment: A case study involving dioxin-contaminated soil. Reg. Toxicol.Pharmcol. 66(2): 208-216. [DOW Chemical]

9. Hasegawa R, Hirata-Koizumi M, Dourson ML, Parker A, Ono A, Hirose A. 2013. Safety assessment of boron by application of new uncertainty factors and their subdivision. Regul. Toxicol. Pharmacol. 65:1, 108-114. [Toxicology Excellence for Risk Assessment]

10. Meek, M.E., Bolger, M., Bus, J.S., Christopher, J., Conolly, R.B., Lewis, R.J., Paoli, G., Schoeny, R., Haber, L.T., Rosenstein A.B., Dourson, M.L. 2013. A Framework for Fit-for-Purpose Dose Response Assessment. Regul. Toxicol. Pharmacol. 66(2): 234-40 (doi: 10.1016/j.yrtph 2013.03.012. [Toxicology Excellence for Risk Assessment]

11. Nance P, Patterson J, Willis A, Foronda N, Dourson M. 2012. Human Health Risks from Mercury Exposure from Broken Compact Fluorescent Lamps. Reg. Tox. Pharm: 62(3): 542–552. [New Zealand Ministry of Health]

12. Dourson, M.L., M.J. Kohrman-Vincent, B.C. Allen and W.S. Cain. 2010. Dose Response Assessment from Effects of Acute Exposure to Methyl Isothiocyanate (MITC). Reg. Toxicol. Pharmacol: 58(2): 181-188. Available on line. [Amvac Chemical Corporation and Taminco and Tessenderlo-Kerley]

13. Cain, W., M. L. Dourson, M.J. Kohrman-Vincent and B.C. Allen. 2010. Human Chemosensory Perception of Methyl Isothiocyanage: Odor and Chemesthesi. Reg. Toxicol. And Pharmacol: 58(2): 173-180. Available online. [Amvac Chemical Corporation and Taminco and Tessenderlo-Kerley]

14. Gadagbui, B; Maier, M; Dourson, M; Parker, A; Willis, A; Christopher, JP; Hicks, L; Ramasany, S; Roberts, SM. 2010. Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation. Regulatory Toxicology and Pharmacology 57:220-234. [Dow Agro Sciences]

15. Hasegawa R, HK Mutsuko, ML Dourson, A Parker, LM Sweeney, A Nishikawa, M Yoshida, A Ono, A Hirose. 2010. Proposal of new uncertainty factor application to derive tolerable daily intake. Regul. Toxicol. Pharmacol. 58(2): 237-242. [Toxicology Excellence for Risk Assessment]

16. Dourson, M., Hertzberg, R., Allen, B., Haber, L., Parker, A., Kroner, O., Maier, A. and Kohrman, M. 2008. Evidence-Based Dose Response Assessment for Thyroid Tumorigenesis from Acrylamide. Regulatory Toxicology and Pharmacology 52 (2008) 264–289. [Burger King Corporation, Frito-Lay, Inc., H.J. Heinz Company, KFC Corporation, McDonald's Corporation, The Proctor &

Gamble Manufacturing Company, The Proctor & Gamble Distributing Company, and Wendy's International, Inc.]

17. Hays, SM; Aylward, LL; LaKind, JS; Bartels, MJ; Barton, HA; Boogaard, PJ; Brunk, C; DiZio, S; Dourson, M; Goldstein, DA; Lipscomb, J; Kilpatrick, ME; Krewski, D; Krishnan, K; Nordberg, M; Okino, M; Tan, YM; Viau, C; Yager, JW. 2008. Guidelines for the derivation of Biomonitoring Equivalents: report from the Biomonitoring Equivalents Expert Workshop. Regul Toxicol Pharmacol. 51(3 Suppl):S4-15. [Toxicology Excellence for Risk Assessment]

18. Hasegawa R, Hirata-Koizumi M, Dourson M, Parker A, Hirose A, Nakai S, Kamata E, Ema M. 2007. Pediatric susceptibility to 18 industrial chemicals: A comparative analysis of newborn with young animals. Regul Toxicol Pharmacol. 47(3):296-307. (Risk assessment paper of the year, Society of Toxicology, Risk Assessment Specialty Section) [Toxicology Excellence for Risk Assessment]

19. Zhao, Qiyu , M. Dourson and B. Gadagbui. 2006. A Review of the Reference Dose (RfD) for Chlorpyrifos. Reg. Toxicol. Pharmacol. 44:111-124. [Dow AgroSciences]

20. Dolan, D., B. Naumann, E. Sargent, A. Maier, M. Dourson. 2005. Application of the threshold of toxicological concern concept to pharmaceutical manufacturing operations. Reg. Toxicol. Pharmacol. 43:1-9. [Toxicology Excellence for Risk Assessment]

21. Fields, C., M.L. Dourson, And J. Borak. 2005. Iodine-deficient vegetarians: A hypothetical perchlorate-susceptible population? Reg. Tox. Pharmacol. 42(1):37-46. [Toxicology Excellence for Risk Assessment]

22. Zhao, Q., B. Gadagbui and M. Dourson. 2005. Lower birth weight as a critical effect of Chlorpyrifos: A comparison of human and animal data. Reg. Toxicol. Pharmacol. 42:55-63. [Dow AgroSciences]

23. Strawson, J., Q. Zhao and M. Dourson. 2004. Response to Letter to the Editor. "Critical Effect of Perchlorate on Neonates is Iodide Uptake Inhibition". Reg. Tox Pharmacol. 40:378-379. [Toxicology Excellence for Risk Assessment]

24. Strawson, J., Q. Zhao and M. Dourson. 2004. Reference Dose for Perchlorate based on Thyroid Hormone Change in Pregnant Women as the Critical Effect. Reg. Tox. and Pharm. 39:44-65. [Toxicology Excellence for Risk Assessment]

25. Dourson, M.L., G. Charnley and R. Scheuplein. 2002. Differential Sensitivity Of Children And Adults To Chemical Toxicity: II. Risk And

Regulation. Regulatory Toxicology and Pharmacology. 35:448-467. [Crop Life America and the American Chemistry Council]

26. Haber, L.T., A. Maier, P.R. Gentry, H.J. Clewell and M.L. Dourson. 2002. Genetic Polymorphisms In Assessing Interindividual Variability In Delivered Dose. Regulatory Toxicology and Pharmacology. 35:177-197. [American Chemistry Council]

27. Scheuplein, R., G. Charnley and M.L. Dourson. 2002. Differential Sensitivity Of Children and Adults To Chemical Toxicity: I. Biological Basis. Regulatory Toxicology and Pharmacology. 35: 429-447. [Crop Life America and the American Chemistry Council]

28. Dourson, M., M. Andersen, L. Erdreich and J. Macgregor. 2001. Using Human Data to Protect the Public's Health. Reg. Toxicol. Pharmacol. Vol. 33, No. 2, Apr 2001, pp. 234-256. [Toxicology Excellence for Risk Assessment]

29. Haber, L.T., L. Erdreich, G.L. Diamond, A.M. Maier, R. Ratney, Q. Zhao and M.L. Dourson. 2000. Hazard Identification And Dose-Response Of Inhaled Nickel Soluble Salts. Reg. Tox. Pharmacol. 31:210-230. [Metal Finishing Association of Southern California, Inc., U.S. EPA and Health Canada]

30. Haber, L.T., G.L. Diamond, G.L. Q. Zhao, L. Erdreich and M. L. Dourson. 2000. Hazard Identification And Dose-Response Of Ingested Nickel Soluble Salts. Reg. Tox. Pharmacol. 31:231-241. [Metal Finishing Association of Southern California, Inc., U.S. EPA and Health Canada]

31. Teuschler, L.K., M.L. Dourson, W.M. Stiteler, P. Mcclure and H. Tully. 1999. Health risk above the reference dose for multiple chemicals. Reg. Toxicol. And Pharmacol. 30:S19-S26. [Toxicology Excellence for Risk Assessment]

32. Dourson, M.L., L.K. Teuschler, P.R. Durkin, and W.M. Stiteler. 1997. Categorical Regression of Toxicity Data: A Case Study using Aldicarb. Reg. Toxicol. Pharmacol. 25:121-129. [Toxicology Excellence for Risk Assessment]

33. Felter, S.P. and M.L. Dourson. 1997. Hexavalent Chromium Contaminated Soils: Options for Risk Assessment and Risk Management. Reg. Tox. Pharmacol. 25:43-59. [Maxus Corporation]

34. Dourson, M.L., S.P. Felter, and D. Robinson. 1996. Evolution of science-based uncertainty factors in noncancer risk assessment. Regulatory Toxicol. Pharmacol. 24:108-120. [International Life Science Institute]

35. Dourson, M.L. 1996. Editorial: Uncertainty Factors in Noncancer Risk Assessment. Reg. Tox. and Pharmacol. 24, Article No. 0115. p. 107. [Toxicology Excellence for Risk Assessment]

36. Dourson, M.L. and J.M. Clark, 1990. Fish consumption advisories: Towards a Unified, Scientifically-credible Approach. Regulatory Toxicology and Pharmacology. 12:161-178. [U.S. Environmental Protection Agency]

37. Barnes, D.G., and M.L. Dourson. 1988. Reference Dose (RfD): Description and use in health risk assessments. Regulatory Toxicology and Pharmacology. 8:471-486. [U.S. Environmental Protection Agency]

38. Dourson, M. L. and J. F. Stara. 1983. Regulatory History and Experimental Support of Uncertainty Safety) Factors. Regulatory Toxicology and Pharmacology. 3:224-238. [U.S. Environmental Protection Agency]

Senator BARRASSO. Thank you very much, Mr. Dourson.

Mr. Leopold. And if you would like to introduce your family, please go ahead, and then proceed with your testimony.

STATEMENT OF MATTHEW LEOPOLD, COUNSEL, CARLTON FIELDS JORDAN BURT, P.A.

Mr. LEOPOLD. Thank you, Mr. Chairman. With me I have today my wife, Kim, my daughter, Ava, my son, Zane, and my son, Luke. And at home with her grandparents is our 2-year-old daughter, Abby. And not able to be with us here today is my father, Zane, who couldn't make the trip from Florida.

Chairman Barrasso, Ranking Member Carper, distinguished members of the Committee, I am thankful for the privilege of being here before you today as the nominee for the position of General Counsel of the Environmental Protection Agency. I am honored that President Trump, Administrator Pruitt, and the members of this Committee are considering me for this position.

The role of EPA's General Counsel, overseeing the implementation of laws entrusted to the Agency, is a public trust. If I am fortunate enough to be confirmed, I would pledge to execute those duties with the utmost diligence and care.

The EPA is quickly approaching its 50th birthday, and over those years it has already tackled some of the nation's most pressing problems. When President Nixon and the Congress created the Agency in 1970, there were environmental issues that abounded—from the choking smog in Los Angeles, to toxic dumping in our oceans, to an infamous burning river in Ohio. The environmental laws passed by the Congress in the decades that followed EPA's creation have been essential to securing the promise of environmental and human health protections, while at the same time allowing for economic growth and prosperity.

There is no question that EPA has made great strides, significantly improving the quality of the air we breathe and the water we depend on. EPA must always continue to ensure that we don't backslide from those important protections.

To accomplish this important mission, the Federal environmental laws harness the strength not only of the Federal Government, but the resources of the States in a unique partnership known as cooperative federalism. Having served in the Florida Department of Environmental Protection, as well as the Environment and Natural Resources Division of the Department of Justice, I saw firsthand how that cooperation could yield incredible results on issues big and small.

For example, the Federal-State partnership to restore America's Everglades is the largest ecosystem restoration project in the world and has significantly improved water quality and delivery in a vast and rare environment, benefiting State, tribal, and Federal lands. On a smaller scale, I observed the State issue permits, inspect facilities, and collect air and water quality data which enabled EPA to better understand, manage, and ultimately prevent pollution. Leveraging the assets of State and Federal environmental agencies continues to be a key strategy for protecting and improving the environment.

On enforcement of our environmental laws, I have also seen how the Federal Government and States came together to address what has been called the greatest environmental disaster of our time, the Deepwater Horizon oil spill of 2010. I am proud to say that I played a small part in securing funding for restoration by participating in the United States civil enforcement case.

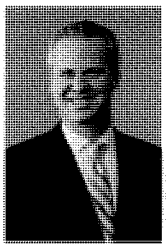
This massive effort, led by the Department of Justice, resulted in a $20 billion settlement that has already begun flowing to Federal, State, and local government entities around the Gulf of Mexico. These funds are going largely to restore and enhance the environment, creating a once in a generation opportunity to address damages to natural resources and conserve sensitive lands in the Gulf.

I have been engaged in environmental law and policy issues for my entire legal career, and for most of those years I have been in public service. Through that experience, I developed great respect for my fellow career civil servants who carry out the day to day work of the Federal agencies. And I think it is important for political appointees in any administration to listen to, understand, and collaborate with the career staff. I plan to do nothing less, should I have the opportunity to lead the Office of General Counsel.

Having been in private practice, I would also emphasize to EPA employees the importance of listening to the regulated community who understand, oftentimes better than government, what it takes to comply with environmental regulation in the real world.

In closing, Mr. Chairman, I again thank the President and this Committee for the opportunity to be here today. I would be humbled to join Administrator Pruitt to carry out EPA's important mission. I respectfully request your support, and I look forward to any questions you or your colleagues may have.

[The prepared statement of Mr. Leopold follows:]



Matthew Leopold
Of Counsel
Carlton Fields

Matthew Z. Leopold is a lawyer in Tallahassee, Florida with the law firm of Carlton Fields. He is the former General Counsel of the Florida Department of Environment Protection and a former attorney at the U.S. Department of Justice, Environment and Natural Resources Division. He has 10 years of combined federal and state government experience. Mr. Leopold's practice focuses exclusively on environment law, policy, and litigation. He has represented the state and federal governments on complex environmental litigation, including *Florida v. Georgia*, an original action in the U.S. Supreme Court, and *United States v. BP Exploration and Production, Inc.*, to address the 2010 Deepwater Horizon oil spill in the Gulf of Mexico. He also represented Florida in the long-running Everglades case working together with policy makers to help move forward comprehensive restoration. Mr. Leopold previously served as an environmental policy advisor in the Washington, DC office of Governor Jeb Bush.

Statement of Matthew Zane Leopold
Nominated to be Assistant Administrator, General Counsel
U.S. Environmental Protection Agency
Before the Senate Environment and Public Works Committee
September 20th, 2017

Chairman Barrasso, Ranking Member Carper, distinguished members of the Committee, I am thankful for the privilege of being before you today as the nominee for the position of General Counsel of the Environmental Protection Agency. I am honored that President Trump, Administrator Pruitt, and this Committee are considering me for this position.

I would like to begin by thanking my family who is with me here today for their tireless support in all my personal and professional endeavors. Behind me is my wife Kim, my daughter Ava, my son Zane, and my son Luke. I would also like to say hello to my two-year-old daughter Abby who is back in Florida with her grandparents. Finally, I'd like to recognize my father Zane Leopold who traveled from Florida to be here today. Thank you Dad for your many years of guidance and support.

The role of EPA's General Counsel, overseeing the implementation of the laws entrusted to the agency, is a public trust. If I'm fortunate enough to be confirmed, I would pledge to execute those duties with the utmost diligence and care. The EPA is quickly approaching its 50th birthday, and over those years it has already tackled some of the nation's most pressing problems. When President Nixon and the Congress created the agency in 1970, there were environmental issues that abounded from the choking smog in Los Angeles to toxic dumping in our oceans to an infamous burning river in Ohio. The environmental laws passed by Congress in

the decades that followed EPA's creation have been essential to securing the promise of environmental and human health protections while at the same time allowing for economic growth and prosperity. There is no question that EPA has made great strides, significantly improving the quality of the air we breathe and the waters we depend on. EPA must always continue to ensure that we don't backslide from those important protections.

To accomplish this important mission, the federal environmental laws harness the strength not only of the federal government, but the resources of the states in a unique partnership known as "cooperative federalism." Having served in the Florida Department of Environmental Protection as well as the Environment and Natural Resources Division of the Department of Justice, I saw firsthand how that cooperation could yield incredible results on issues big and small. For example, the federal-state partnership to restore America's Everglades is the largest ecosystem restoration project in the world and has significantly improved water quality, timing, and delivery in a vast and rare environment, benefiting state, tribal, and federal lands. On a smaller scale, I observed the State issue permits, inspect facilities, and collect air and water quality data, which enabled EPA to better understand, manage, and ultimately prevent pollution. Leveraging the assets of state and federal environmental agencies continues to be a key strategy for protecting and improving the environment.

On enforcement of our environmental laws, I've also seen how the federal government and the states came together to address what has been called the greatest environmental disaster of our time, the Deepwater Horizon oil spill in 2010. I'm proud to say that I played a small part in securing that funding by participating in the United States' civil enforcement case. This massive

effort, led by the Department of Justice, resulted in a $20-billion-dollar settlement that has already begun flowing to federal, state, and local government entities around the Gulf of Mexico. These funds are going largely to restore and enhance the environment, creating a once in a generation opportunity to address damages to natural resources and conserve sensitive lands along the Gulf Coast.

I have been engaged in environmental law and policy issues for my entire legal career, and for most of those years I have been in public service. Through that experience, I developed great respect for my fellow career civil servants who carry out the day to day work of the federal agencies. And I think it's important for political appointees in any administration to listen to, understand, and collaborate with the career staff. I plan to do nothing less should I have the opportunity to lead the Office of General Counsel. Having been in private practice, I also would emphasize to EPA employees the importance of listening to the regulated community who understand – often times better than government – what it takes to comply with environmental regulation in the real world.

In closing Mr. Chairman, I again thank the President and this Committee for the opportunity to be here today. I would be humbled to join Administrator Pruitt to carry out EPA's important mission. I respectfully request your support, and I look forward to any questions you or your colleagues may have.

Senate Committee on Environment & Public Works
Hearing entitled, *"Hearing on the Nominations of Michael Dourson, Matthew Leopold, David Ross, and William Wehrum to be Assistant Administrators of the Environmental Protection Agency, and Jeffery Baran to be a Member of the Nuclear Regulatory Commission."*
October 4, 2017
Questions for the Record for Mr. Matthew Leopold

Ranking Member Carper:

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.

    a. Do you agree that it is essential that in making decisions, EPA's Office of General Counsel (OGC) must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    b. Will you commit to restricting communications between OGC and the White House staff regarding specific matters under the authority of OGC?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    c. Will you commit to ensuring the staff of OGC is familiar with those restrictions?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OGC staff, including you, occur?

If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

2. Recently, EPA conducted "anti-leaking" training for its employees[1]. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.
5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

    a. If you are confirmed, will you commit to protect the rights of all career employees in OGC to make lawful disclosures, including their right to speak with Congress?

    If confirmed, I commit to protecting the rights of all EPA employees and will follow the law.

    b. Will you commit to communicate employees' whistleblower rights via email to all OGC employees within a week of being sworn in?

[1] https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

If confirmed, I commit to protecting the rights of all EPA employees and will follow the law.

3. In the wake of Hurricane Irma, at least 11 deaths and numerous injuries have been reported in Florida due to accidental carbon monoxide poisoning from gasoline-powered portable generators.[2] One additional death has also been reported in North Carolina, along with other injuries throughout the Southeastern United States.[3] Many of these deaths and injuries could have been prevented had stronger safety standards been in place for portable gasoline generators. In November 2016, the U.S. Consumer Product Safety Commission (CPSC), following years of work on the issue, voted to issue a Notice of Proposed Rulemaking (NPRM) to implement a mandatory safety standard for portable generators.[4] Since then, Administrator Pruitt and Acting CPSC Chairman Buerkle have separately said that section 213 of the Clean Air Act precludes CPSC action.

    a. Section 213 of the Clean Air Act is intended to regulate emissions from non-road engines or vehicles when the EPA determines that such emissions "are significant contributors to ozone or carbon monoxide concentrations in more than 1 area which has failed to attain the national ambient air quality standards for ozone or carbon monoxide." In your opinion, would the occasional indoor use of portable generators following a power outage be likely to be a significant contributor to ambient carbon monoxide concentrations in more than 1 area that has failed to attain the national ambient air quality standards for carbon monoxide? Why or why not?

    It would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel.

    b. There are currently no areas in the United States that have failed to attain the national ambient air quality standards for carbon monoxide, and this has been the case since 2010[5]. As a matter of law, could section 213 of the Clean Air Act be used to regulate carbon monoxide emissions due to the indoor use of portable generators if there are no areas in the United States that fail to attain the national ambient air quality standards for carbon monoxide? Why or why not?

    It would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel.

4. You spent more time – 6 years – as an attorney in the Environment and Natural Resources Division of the Department of Justice than in any other position. Based on your experience, to what extent do you believe that the work of the Environment and

[2] http://www.miamiherald.com/news/weather/hurricane/article174097351.html http://www.sun-sentinel.com/news/weather/hurricane/sfl-carbon-monoxide-deaths-20170914-story.html
[3] http://www.charlotteobserver.com/news/article173612361.html
[4] https://www.federalregister.gov/documents/2016/11/21/2016-26962/safety-standard-for-portable-generators
[5] https://www.epa.gov/green-book/green-book-carbon-monoxide-1971-area-information

Natural Resources Division makes an important contribution to the protection of public health and the environment? Please explain and describe your views of the contributions the work of the Division makes.

The Environment and Natural Resources Division (ENRD) is the nation's environmental law firm handling work arising from approximately 150 federal civil and criminal statutes, including the Clean Air Act, Clean Water Act, CERCLA, and Safe Drinking Water Act. It serves as counsel to EPA, the Department of the Interior, and other federal agencies that have environmental or natural resource issues. ENRD is important to protecting human health and the environment as it enforces the federal pollution-control laws EPA oversees.

5. Earlier this year, the fiscal year 2018 budget proposal[6] submitted to Congress sought to eliminate the $20 million in funding the EPA provides for the Justice Department's Environment and Natural Resources Division. EPA has historically provided about 27 percent of that office's budget. Based on your experience as an attorney in the Environment and Natural Resources Division, please describe the potential impact on the work of the Division of such a reduction in funding. Do you support such a reduction in funding? Please provide your reasoning and any information you have supporting your answer. Since 2005, how much funding has been provided to ENRD by EPA? How much money has DOJ secured through fines, penalties, and commitments to remediate contamination and pollution during this same time period?

I support the important work done by ENRD. It would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel. If confirmed, I would manage OGC's functions, including its reliance on ENRD as outside counsel, within the authority and budget provided by Congress.

6. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:

    i) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
    ii) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert

[6] https://www.documentcloud.org/documents/4061910-EPA-Superfund-reimbursements-to-DOJ-documents.html#document/p7/a378119

"annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and c) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.

iii) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did[7].

a) If the events above occurred as described to my staff, do you agree that EPA's failure to even attempt to undertake a credible cost-benefit analysis of its proposal to repeal the Clean Water Rule would be vulnerable to assertions that the agency ran afoul of both the Clean Water Act and the Administrative Procedure Act? Why or why not?

I am not able to speculate about what may or may not have occurred in this instance. If confirmed, I would work to ensure that the legal requirements for analyzing the cost-benefit of EPA rules are adhered to.

b) The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OGC will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

I support the appropriate use of both written and oral guidance and would endeavor to use each in appropriate circumstances.

8. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?

Yes.

9. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily[8]. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

---

[7] https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf See Table 1

[8] https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView

If confirmed, I will make my calendar available on a timely basis.

Senator Cardin:

10. The people of Baltimore must be able to rest assured that the facilities covered by Risk Management Plans under CAA §112(r) will have to evaluate implementing safer measures protections, and that first responders will have the information they need to respond to chemical disasters. In your capacity as General Counsel for EPA, while facing a law suit from various state Attorneys General, including Attorney General Frosh of Maryland, how will you counsel Administrator Pruitt on the question of implementing the original January 2017 Environmental Protection Agency Amendments to the Accidental Release Prevention Requirements for Risk Management Programs under the Clean Air Act without further delay?

    CAA §112(r)(3) provides EPA the authority to amend the List of Regulated Substances. Would you counsel Administrator Pruitt to add chlorosulfonic acid to the List of Regulated Substances?

    Risk Management Plans under CAA §112(r) are an important tool provided by Congress for facilities using substances "known to cause or may reasonably be anticipated to cause death, injury, or serious adverse effects to human health or the environment." The plans include information on the potential effects of an accidental release, the steps a facility is taking to prevent such a release, and directions for those that respond if a release occurs. I am unfamiliar with the specific legal issues raised in the litigation referenced. Also, it would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel. If confirmed, I would request a briefing by EPA staff on the issues and EPA legal authorities.

11. Attorney General Jeff Sessions issued a memo on June 7, 2017, prohibiting all Department of Justice components and United States Attorney's Offices from entering into any settlement agreement that directs or provides for a settlement payment to non-governmental, third parties that were not directly harmed by the conduct. As you know, this is commonplace practice in cases where the environmental harm is irreparable—like the BP oil spill or the Volkswagen diesel emissions case. Please provide your understanding of the legal basis, if any, for prohibiting payments to third parties that will mitigate environmental harms?

    The Department of Justice has certain legal authority to conduct and settle litigation matters. In litigation matters where the Department of Justice is counsel to EPA, I would respect the legal authority of the Department as appropriate.

Senator Markey:

12. In the past, you stated that the EPA was regulating beyond its authority in terms of the Clean Power Plan, however you also said that it's "settled law EPA can regulate

greenhouse gases." Given this and the intentions of the EPA to repeal the CPP, what suggestions would you make to Administrator Pruitt in terms of the Plan's replacement?

It would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel. If confirmed, I would request a briefing by EPA staff on the issues and EPA legal authorities, and I would commit to offer counsel supporting the rule of law in this or any other EPA action.

Senator Sanders:

Climate Change

13. President Trump has suggested in the past that climate change is a hoax. Is the President correct? Is climate change a hoax?

I believe that climate change is real and human activity contributes to climate change.

14. Do you agree with the vast majority of scientists that climate change is real, it is caused by human activity, and that we must aggressively transition away from fossil fuels and toward energy efficiency and sustainable energy like wind, solar, and geothermal?

I believe that climate change is real and human activity contributes to climate change.

Science

15. At the EPA, science provides the foundation for Agency policies, actions, and decisions made on behalf of the American people. What should the role of science be in the interpretation and implementation of EPA policies, rules, and regulations?

High quality science is an essential predicate to many of the decisions that EPA makes. The role of science is critical to EPA's essential mission of protecting human health and the environment.

16. Do you support relying on independent scientists with relevant expertise to evaluate and review the data that the EPA uses when making decisions related to the implementation of environmental regulations?

I support the roles of scientists in helping EPA in its mission of protecting human health and the environment.

Congressional Relations

17. If confirmed, do you commit to assuring staff in the Office of the General Counsel will respond to all relevant inquiries from all Members of Congress, regardless of party or position?

Yes.

Most Pressing Challenges

18. The EPA's FY18 budget lists the following as priorities: clean water and drinking water, infrastructure, work at Brownfields and Superfund projects, improving and protecting air quality, and ensuring the safety of chemicals. If confirmed, would these also be the most pressing challenges that deserve your and OGC's attention? If confirmed, how will you ensure OGC better addresses these challenges?

    If confirmed, I would manage OGC's functions within the authority and budget provided by Congress. I would request a full briefing by OGC staff on the ongoing work of the office and after understanding the scope of its current commitments set priorities based on legal requirements, the needs of the client program offices, and the priorities of the Administrator.

Primary Environmental Enforcement by the States

19. When giving advice to the EPA's staff, how will you balance the EPA's obligation to enforce the nation's environmental laws and regulations where the state and federal governments share authority?

    If confirmed, I would advise EPA staff that it is essential for the federal government and state governments to work together to provide the environmental protection that our laws demand and that the American people deserve. Many federal environmental statutes are designed with states as a primary implementer. EPA and the states should respect the design of cooperative federalism inherent in the law and leverage the assets of each other to achieve greater outcomes.

Environmental Regulations

20. As you may know, the EPA proposed to repeal the Obama Administration's Clean Power plan regulations to address atmospheric carbon pollution. If you are confirmed, will you commit to ensuring that in whatever replacement the Trump Administration makes to the Clean Power Plan, the EPA continues to fulfill its obligations under *Massachusetts v. EPA*?

    It would be inappropriate for me to prejudge the outcome of a matter that may come before me if confirmed as General Counsel. If confirmed, I would commit to offer counsel supporting the rule of law in this or any other EPA action, including advising the Agency on Supreme Court precedent, such as *Massachusetts v. EPA*.

Senator Whitehouse:

21. Administrator Pruitt has been criticized for spending a disproportionate amount of his time meeting with industry and virtually no time with public-interest groups. If confirmed, will you commit to meet with and listen to all parties in a balanced fashion?

It is important for EPA to be accessible to the public and the regulated community. While the primary role of the General Counsel is to advise EPA policy-makers, if confirmed, I would attempt to meet with entities affected by the Office of General Counsel, while abiding by all legal and ethical limitations.

22. The President's budget proposes to cut EPA's budget by 30%. The Office of General Counsel oversees ethics and FOIA. Based on what I've seen, EPA's Office of General Counsel is struggling to keep its head above water with current resources. For example, I've sent ethics-related inquiries to EPA, including one in May about an appointee with extensive conflicts of interest, that EPA has either not responded to or provided slow and incomplete responses. I've seen one inadequate recusal for former Baker Hostetler attorney Justin Schwab that took six months to fix. In the update recusal statement we learned that one of Mr. Schwab's clients was the State of Oklahoma. As of September 29, 2017, EPA had over 2,100 open FOIA requests and outside groups, including the California Attorney General have filed suit over long-languishing requests.

    a. Do you believe these response times to Congress and the public are acceptable?

    I am not familiar with the specific details of these requests. If confirmed, I would request a briefing by EPA staff on OGC's history in responding to Congressional and FOIA requests.

    b. Do you believe the President's budget, if enacted, would provide enough money for your office to fulfill its ethics requirements and respond to Congress and FOIA requests from the public?

    If confirmed, I will manage OGC's functions within the authorities and budget provided by Congress.

    c. What specific steps will you take as General Counsel to ensure that responses to congressional inquiries and FOIA requests are made in the most expeditious manner possible?

    If confirmed, I would request a full briefing by OGC staff on the ongoing work of the office and after understanding the scope of its current commitments set priorities as appropriate for responses to requests for information. I would work with members of Congress to provide requested information, while respecting legal privileges and the role of the Executive branch.

23. If confirmed, do you commit to notifying the Committee of all of the email addresses you plan to use upon confirmation and within seven days of using a new email address, including any aliases or pseudonyms? Do you commit do conducting all business using official email addresses and other means and to refrain from any mediums that are outside the Freedom of Information Act's reach?

If confirmed, I commit to notifying the Committee of the e-mail address I use for official business. If confirmed, I commit to following EPA's Records Policy and the Federal Records Act.

24. Have you heard anything to suggest that EPA may close or consolidate any Regional Offices?
    a. What is your opinion of such a proposal?

I am not aware of any such plans.

25. Do you a believe that climate change is real?

Yes.

26. EPA Administrator Pruitt recently told CNBC that "I would not agree that [carbon dioxide's] a primary contributor to the global warming that we see." Based on the scientific findings from experts such as NOAA and statements on EPA's website, including "Carbon dioxide is the primary greenhouse gas that is contributing to recent climate change," Politifact determined that statement to be false. Do you agree with Administrator Pruitt or scientific experts regarding whether carbon dioxide is the primary greenhouse gas that is contributing to climate change?

I believe that carbon dioxide contributes to climate change.

27. In 2009, as mandated by the Supreme Court and backed by a robust scientific and technical review, the Environmental Protection Agency produced the Endangerment and Cause or Contribute Findings for Greenhouse Gases (GHGs) under Section 202(a) of the Clean Air Act. It found six greenhouse gases - carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride - "taken in combination endanger both the public health and the public welfare of current and future generations." Do you agree with the EPA's endangerment finding? Why or why not?

If confirmed, I would commit to advising the Agency on Supreme court precedent, such as *Massachusetts v. EPA* and the Agency's Endangerment Finding on Greenhouse Gases respective to the relative statutory framework established by Congress.

28. Do you believe the U.S. should remain a party to the United Nations Framework Convention on Climate Change?

The United Nations Framework Convention on Climate Change is an international agreement. The US Department of State has primary responsibility for such matters. I defer to the State Department on this issue.

29. Do you believe the U.S. should remain a party to the Paris Agreement?

The Paris Agreement is an international agreement. The US Department of State has primary responsibility for such matters. I defer to the State Department on this issue.

30. Do you support the amendment to the Montreal Protocol to phase down HFCs?

The Montreal Protocol is an international agreement. The US Department of State has primary responsibility for such matters. I defer to the State Department on this issue.

31. If confirmed, do you commit to providing complete and accurate responses to inquiries from EPW members in a timely fashion?

Yes.

Senator BARRASSO. Thank you very much, Mr. Leopold, and congratulations.

Mr. Ross.

STATEMENT OF DAVID ROSS, ASSISTANT ATTORNEY GENERAL, STATE OF WISCONSIN, AND DIRECTOR, WISCONSIN DEPARTMENT OF JUSTICE ENVIRONMENTAL PROTECTION UNIT

Mr. ROSS. Chairman, I would like to first introduce my family. With me are my wife, Tiffany, and my girls, Payton and Kennedy, who are sitting behind me. The girls are here on special assignment from their social study classes back in Waunakee, Wisconsin.

[Laughter.]

Mr. ROSS. My brother, Admiral Eric Ross, is also here. Eric is taking time out of his busy schedule to attend today. Eric had the honor of being confirmed by the U.S. Senate as a Rear Admiral in the U.S. Navy earlier this year, and I thank the Senate for that family honor.

My mother, Sue, and my sister, Debbie, are back home, hopefully participating, watching right now.

Chairman Barrasso, Senator Carper, and distinguished members of this Committee, I am honored to be here today, and I want to thank President Trump and Administrator Pruitt for placing their trust in me and for providing me with this amazing opportunity to serve the public as the Assistant Administrator for EPA's Office of Water.

I also want to thank my wife, Tiffany, my amazing girls, Payton and Kennedy, and the rest of my family for their support as I continue my career in public service.

And Chairman Barrasso, I want to thank you for the introduction and for your support during my time working for the great State of Wyoming.

I have worked on water quality and resource management issues my entire career. My experience ranges from serving as a consultant on wastewater reclamation and reuse projects, to advising members of the regulated community on Clean Water Act compliance and related matters, to serving as the lead water quality attorney for the State of Wyoming and currently as the lead environmental prosecutor for the State of Wisconsin. I, therefore, understand water resource issues from multiple perspectives, and I have a deep appreciation for the complexity inherent in managing those waters.

Our waterways help transform the nation into an economic power, and they continue to support economic activity that sustains our position in the world. They move commerce, supply power, provide drinking water, sustain wildlife, grow crops, and serve as playgrounds for outdoor enthusiasts. These competing uses highlight the critical importance of our nation's water resources, but they result in divergent views on how best to manage those resources.

The Office of Water must consider those diverse perspectives while pursuing common objectives, including protecting and enhancing the quality of our water, ensuring that our citizens have access to safe and reliable drinking water, and promoting regulatory certainty.

I will pursue those objectives based on a few core principles. First, we must manage our nation's waters within the statutory framework established by Congress, while respecting the constitutional limitations imposed by our founding fathers. If I have a bias as a lawyer, it is a profound respect for the rule of law.

Second, I will respect the role of States, tribes, and local governments as key partners in managing our nation's water resources. I have been fortunate to observe firsthand the expertise and professionalism of State environmental officials and their dedication to the protection of the resources that they know best. I have also witnessed the frustration those environmental experts experience when the Federal Government fails to engage with them on matters of critical importance to the States. Should I be confirmed, I will embrace cooperative federalism as envisioned by Congress when it enacted many of the statutes that govern the work of EPA.

Third, and finally, I will manage with an open mind, I will seek the input and expertise of the dedicated career professionals at EPA, I will listen to the advice and recommendations of the regulated community and the rest of the American public, I will engage with the States, tribes, and local governments, and I will pursue the objectives of my management with dedication, while always striving to give them my best counsel.

The nation has made great progress improving the quality of our waters over the past 50 years. There is certainly more work to do, but I am confident that we can continue to make progress while pursuing the twin goals of environmental protection and economic prosperity for the nation. Indeed, to be successful, I think those goals are—and must be—interdependent.

Thank you for your time today and the opportunity to appear. I look forward to answering any questions that you may have, and more importantly, to working collaboratively with all members of this Committee and your colleagues in both chambers, should I have the honor of being confirmed.

[The prepared statement of Mr. Ross follows:]



David Ross
Director of the Environmental Protection Unit
Wisconsin Department of Justice

Mr. Ross currently serves as the Director of the Environmental Protection Unit for the Wisconsin Department of Justice. He previously served as a senior assistant attorney general in the Wyoming Attorney General's Office, where he represented the Environmental Quality on water quality matters. Mr. Ross also represented the State of Wyoming on the Assumable Waters Subcommittee of the National Advisory Council for Environmental Policy and Technology. Prior to entering public service, Mr. Ross practiced environmental law in Washington DC and worked as an environmental consultant in California.

Mr. Ross attended the University of Wisconsin-Madison for undergraduate studies, and grew up in Appleton, Wisconsin. He earned his law degree and a Master of Studies in Environmental Law from Vermont Law School. While in law school, Mr. Ross served as Editor-in-Chief of the Vermont Law Review.

Statement of David Patrick Ross
Nominated to be Assistant Administrator for the Office of Water
United States Environmental Protection Agency
Before the Senate Environment and Public Works Committee
September 20th, 2017

Chairman Barrasso, Senator Carper and distinguished members of the Committee, I am honored to appear before you today as the nominee to serve as the Assistant Administrator for the Office of Water within the U.S. Environmental Protection Agency. I want to thank President Trump and Administrator Pruitt for placing their trust in me and for providing me with this amazing opportunity to serve the public in such a critical role. I also want to thank my family for their incredible support and encouragement as I continue my career in public service.

I have worked on water quality and resource management issues my entire career. I pursued a career in environmental law and policy after growing up paddling the Boundary Waters and other lakes and streams with my father and friends, and have stayed that course my entire professional career. My experience ranges from serving as a consultant on wastewater reclamation and reuse projects, to advising members of the regulated community on Clean Water Act and related matters, to serving as the lead water quality attorney for the State of Wyoming and as the lead environmental prosecutor for the State of Wisconsin. I therefore understand water resource issues from multiple perspectives, and have a deep appreciation for the complexity inherent in managing our nation's waters.

Our waterways helped transform the nation into an economic power, and continue to support economic activity that sustains our position in the world. They move commerce, supply power, provide drinking water, sustain wildlife, grow crops, and welcome recreational uses of all kinds. These competing uses highlight the critical importance of our

nation's water resources, but result in divergent views on how best to manage those resources. The Office of Water must consider and balance those diverse perspectives while pursuing important common objectives: protecting and enhancing the quality of our waters; ensuring that our citizens have access to safe and reliable drinking water; and promoting regulatory certainty for the regulated community.

I will pursue those objectives based on a few core principles. First, we must manage our nation's waters within the statutory framework established by Congress while respecting the constitutional limitations imposed by our founding fathers. If I have a bias as a lawyer, it is a profound respect for the rule of law.

Second, I will respect the role of states, tribes and local governments as key partners in managing our nation's waters. I have been fortunate to observe firsthand the expertise and professionalism of state environmental officials and their dedication to the protection of the natural resources they know best. I have also witnessed the frustration those experts experience when the federal government fails to engage with them on matters of critical importance to the states. Should I be confirmed, I will embrace cooperative federalism as envisioned by Congress when enacting many of the statutes that govern the work of EPA.

Third, I will manage with an open mind. I will seek the input and expertise of the dedicated career professionals at EPA, I will listen to the advice and recommendations of the regulated community and other members of the public, I will engage with the states, tribes and local governments, and I will pursue the objectives of my management with dedication while always striving to give them my best counsel.

The nation has made great progress improving the quality of our waters over the past 50 years. There is certainly more work to do, but I am confident that we can continue to

make progress while pursuing the twin goals of environmental protection and economic prosperity for the nation. Indeed, to be successful, I believe those goals are and must be interdependent.

Thank you for your time today and the opportunity to appear. I look forward to answering any questions you may have, and to working collaboratively with members of this Committee and your colleagues in both chambers should I have the honor of being confirmed.

Senate Committee on Environment & Public Works
Hearing entitled, *"Hearing on the Nominations of Michael Dourson, Matthew Leopold, David Ross, and William Wehrum to be Assistant Administrators of the Environmental Protection Agency, and Jeffery Baran to be a Member of the Nuclear Regulatory Commission."*
October 4, 2017
Questions for the Record for Mr. David Ross

Ranking Member Carper:

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.

    a. Do you agree that it is essential that in making decisions, EPA's OW must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    b. Will you commit to restricting communications between OW and the White House staff regarding specific matters under the authority of OW?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    c. Will you commit to ensuring the staff of OW is familiar with those restrictions?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OW staff, including you, occur?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

2. Recently, EPA conducted "anti-leaking" training for its employees[1]. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

   5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences - (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation...." In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

   a. If you are confirmed, will you commit to protect the rights of all career employees in OW to make lawful disclosures, including their right to speak with Congress?

      If confirmed, I commit to ensuring that the Office of Water and its employees comply with and recognize all applicable legal and ethical requirements and protections.

   b. Will you commit to communicate employees' whistleblower rights via email to all OW employees within a week of being sworn in?

      If confirmed, I commit to protecting the rights of all EPA employees and will follow the law.

[1] https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

3. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:

    i) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.
    ii) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and c) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.
    iii) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did[2].

    a. If the events above occurred as described to my staff, do you agree that EPA's failure to even attempt to undertake a credible cost-benefit analysis of its proposal to repeal the Clean Water Rule would be vulnerable to assertions that the agency ran afoul of both the Clean Water Act and the Administrative Procedure Act? Why or why not?

    Should I be confirmed, I look forward to engaging in the rulemaking process, including working with the Office of General Counsel to ensure the development of a robust administrative record that is grounded in the law.

[2] https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf See Table 1

b. The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OW will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

I support the appropriate use of both written and oral guidance and would endeavor to use each in appropriate circumstances.

4. As someone with substantial experience with states' perspectives on the role of states in a federalist regulatory framework, would you agree that environmentally protective strategies developed by states individually and jointly should be given strong deference by federal regulatory agencies like EPA?

Yes, as long as the states comply with baseline federal requirements.

a. Given that respect for state responsibilities and initiative, would you bring the full force of your authority at EPA to ensure that the Chesapeake Bay states live up to their commitments to reduce pollution loadings under the Chesapeake Bay TMDL?

Should I be confirmed, I will implement the Office of Water program authority to work collaboratively with the states in the Chesapeake Bay region to achieve the targeted water quality improvements in the Bay.

5. Given your substantial experience working with state water programs and as a member of the Assumable Waters Subcommittee of the National Advisory Council for Environmental Policy and Technology, do you support state assumption of Clean Water Act responsibilities and programs?

Yes.

a. Assuming you support active state engagement in implementing and enforcing Clean Water Act responsibilities, how do you feel about substantially reducing federal funding to state partners to handle these federal obligations?

I support strong federal partnership and collaboration with the states, both financially and logistically, to achieve success in implementing the delegated state programs.

b. Do you agree with the philosophy that if states assume primary responsibility for keeping their water clean that the federal government should not provide any funding to support their efforts? Why or why not?

I believe in shared financial responsibility and collaborative partnerships with the states in order to realize the promise of cooperative federalism envisioned by the Clean Water Act.

c. Do you believe from your experience in Wyoming and Wisconsin and familiarity with the financial, technical and legal capacities of other states that they can take care of the nation's water quality on their own?

I believe we can achieve greater success in managing the nation's waters through leveraged relationships, including providing financial and technical support to the states.

d. How important is EPA's oversight of states' compliance with their Clean Water Act responsibilities?

EPA's oversight and technical support is important in helping the states effectively implement the many Clean Water Act programs.

e. What can EPA do better to ensure that states are doing their jobs, for example to prevent future water crises as we saw with lead in drinking water in Flint, Michigan?

I believe that EPA can focus on building relationships to establish trust in the collaborative partnership, with smarter, more focused oversight that emphasizes core program areas and responsibilities and deemphasizes box-checking exercises. Effective oversight depends on effective prioritization and shared ownership in establishing those priorities.

6. Do you feel that the Clean Water Act overly limits the ability of developers and agricultural producers to conduct their business and support themselves and the nation's economy?

If implemented correctly and within the legal guideposts established by Congress, no.

a. Would you advocate rolling back clean water regulation beyond the Clean Water Rule that require developers and agriculture producers to reduce the adverse impacts of their operations on water quality? If so, which ones and why?

I support the development of a predictable and clear regulatory scheme that stays within the legal framework established by Congress while respecting the Constitutional limitations placed on both Congress and the Executive Branch agencies. This basic principle should apply to all EPA regulations, including the development of a regulatory definition for the term "waters of the United States."

b. Are there other sectors of the economy you feel are over-regulated by Clean Water Act programs? If so, which ones, and what do you advocate EPA should/could/would do to alleviate the burden?

I do not enter federal service with any pre-determined views on this topic.

7. The Farm Bureau has come out strongly against the Clean Water Rule (CWR). But the CWA section 404(f), which was enacted in 1977, specifically exempts normal farming activities including the construction of roads, ditches, and farm ponds. The CWR does not impinge on section 404(f) at all. Which specific farm activities does the CWR affect that are currently exempted under the 2008 guidance that is now in place?

If confirmed, I look forward to learning more about how the agency has implemented 404(f) to ensure the agency has provided the exemptions Congress intended.

8. Did EPA formulate a new, updated legal rationale for embracing the current waters of the United States definition through its proposed repeal and replacement of the Clean Water Rule? If so, please describe your understanding of the rationale.

I am not familiar with the legal analysis EPA performed as part of its ongoing effort to implement President Trump's February 28, 2017 Executive Order.

9. Coal-fired power plants are by far the largest discharger of toxic water pollution in the US. In 2015, an effluent limitations guidelines (ELG) rule was finalized that would require power plants to eliminate the vast majority of this pollution using readily available, affordable wastewater treatment technology. In the last few months, however, EPA has postponed the compliance dates for two waste streams in the rule and begun a new rulemaking to reconsider the standards for these waste streams. EPA has argued that the 2015 rule was too cost-prohibitive to industry, yet the vast majority of power plants will incur zero costs to comply with the 2015 ELG rule. EPA had previously estimated that complying with this rule would prevent 1.4 billion pounds of toxic pollutants, including known carcinogens like arsenic and known neurotoxins like lead and mercury, from being discharged into waterways each year.

a. How will you ensure that any revised Steam ELG standards and/or limits do not negatively impact drinking water systems?

The development of effluent limitation guidelines are governed by regulatory procedures that take into account applicable legal, technical, economic and other important considerations. If confirmed, I will work to ensure that Office of Water personnel follow those procedures to develop an appropriate and protective standard.

b. In its proposed revisions to the 2015 power plant ELG, should EPA consider technology options for treating flue gas desulfurization waste that would limit bromide discharges from power plants? Why or why not?

Should I be confirmed, I look forward to evaluating the status of the regulatory effort at that time, including potential options for that particular waste stream.

10. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?

Yes.

11. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily[3]. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

If confirmed, I will make my calendar available on a timely basis.

12. You are currently the Wisconsin Department of Justices' Environmental Protection Unit Director. It is your responsibility to manage environmental litigation and prosecute violations of state environmental law.

a. Under the cooperative federalism structure of many of our environmental statutes, do you believe the federal government, and EPA in particular, is an important partner to state environmental work?

Yes.

b. The Trump Administration has proposed reducing funding for the Office of Enforcement and Compliance Assurance by 24 percent. In your opinion, how would a funding cut of this size affect the partnership between Wisconsin and EPA?

I am not familiar with the details of the FY18 budget but if confirmed I will work collaboratively with the Office of Enforcement and Compliance Assurance to uphold the mission of the EPA.

[3] https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView

c. If the Wisconsin Department of Justice's Environmental Protection Unit was cut by 24 percent, how would that affect the ability of your unit to perform its statutory responsibilities?

I am not in a position to comment on hypotheticals, and the issue is entirely dependent on a variety of factors.

13. The Trump Administration has proposed eliminating the Great Lakes Restoration Initiative. This would cut $300 million dollars in funding to states like Wisconsin for environmental restoration activities designed to improve the health of the Great Lakes. You have been nominated to head the Office of Water. Do you support the proposed elimination of EPA's Geographic Programs funding? What impact will this have on the Great Lakes? If this program is eliminated, how would you, if confirmed, accomplish your statutorily required objective to improve the health of the nation's waters, including the Great Lakes? In particular, how would the elimination of this program affect multistate and binational commitments and initiatives to deal with non-point source pollution issues and resulting algal blooms, as described in an October 3, 2017 New York Times article[4]? Do you support designation of the Western portions of Lake Erie as impaired and development of a TMDL to identify and reduce the loadings of nutrients, especially phosphorus, that contribute to the problem?

If confirmed, I will work with Office of Water and regional staff to implement the budget Congress provides for the Great Lakes program as effectively and efficiently as possible. Should I be confirmed, I look forward to working with our state partners to holistically address the ongoing challenge of nutrient loading in Lake Erie.

[4] https://www.nytimes.com/interactive/2017/10/03/science/earth/lake-erie.html?smid=tw-share&_r=0

Senator Booker:

14. Our nation's water infrastructure is in desperate need of repair. Ongoing water contamination in Flint, Michigan and the challenges presented by natural disasters like Hurricanes Irma and Maria, which left Puerto Rico without access to clean, safe drinking water underscore the importance of having a skilled water workforce, including pipe fitters, electricians, carpenters, treatment operators. Water access also drives economic growth. For every day of water service disruption, the average U.S. business loses $230 in sales per employee.

    a. Seeing the potential impact on public health, safety, and the environment, several municipalities have already launched innovative and successful efforts to drive workforce development. For example, the City of Camden in my home state of New Jersey has partnered with local secondary schools to introduce students to utility work and develop skills. To replicate these efforts across the country, would you urge the Administrator to support a federal water workforce grant program that leverages local funds and drives water workforce recruitment?

    If confirmed, one of my top priorities is to identify innovative state and local projects and provide a platform for replicating their success nationally. I look forward to learning more about the City of Camden project and others like it so that I can formulate legal, policy and funding recommendations to the Administrator while at the same time working to encourage and facilitate ongoing innovation at the local level.

    b. Over the next 40 years, the federal government will need to invest approximately $1.7 trillion to update pipes that provide clean drinking water to Americans (according to the American Water Works Association). Would you look for ways to improve and incorporate water workforce as part of any infrastructure package?

    Yes. I think workforce development helps drive innovation and is key to implementing innovation when realized.

Senator Cardin:

15. The District Court for the Middle District of Pennsylvania, where you represented the plaintiffs challenging the TMDL, upheld the TMDL as a valid exercise of EPA's powers under the Clean Water Act. In upholding the TMDL, the District Court provided welcome certainty as the states carry out the complex task of developing their own plans for meeting the cleanup goals set forth in the Bay TMDL. Key to the District Court's decision, which was affirmed by the Court of Appeals for the Third Circuit, was the TMDL's demonstrated commitment to cooperative federalism. The Bay states asked EPA to set pollution levels for the entire watershed in 2007 and, as the court emphasized, "no state has filed suit challenging the TMDL."

    a. Regarding the Chesapeake Bay Agreement, will you commit to allowing the will of the states to stand?

    Should I be confirmed, the Office of Water will remain committed to working with the Chesapeake Bay Watershed states to implement the principles outlined in the 2014 Agreement.

    b. If so, how do you plan to support them to achieve their goals?

    I believe we can help them achieve their goals by continuing to facilitate the principles of cooperative federalism and supporting the states as they implement the Bay TMDL and the other objectives of the 2014 Agreement.

16. President Trump's proposed budget would eliminate federal funding for the cleanup of the Chesapeake Bay, just as the effort reaches its halfway point. Through the Chesapeake Bay Program, the EPA awards millions in grants each year to the six states in the bay watershed—Virginia, Maryland, West Virginia, Pennsylvania, New York and Delaware and the District of Columbia—for restoration.

    a. Will you uphold EPA's commitments as a signatory of the 2014 Chesapeake Bay Watershed agreement, including allocation of funds appropriated by Congress?

    If confirmed, I will work to ensure that the Office of Water implements the budget Congress provides for the Chesapeake Bay program as effectively and efficiently as possible. The Office of Water will remain committed to working with the Chesapeake Bay Watershed states to restore the ecological health of the Bay.

17. The Clean Water Rule was found to be economically beneficial—$572 million dollars per year—to the American people. As you know, having cleaner water going into our taps makes treating and filtering it cheaper, or altogether unnecessary, for when it comes out of our taps to drink. Yet, EPA is now on a path to replace this very favorable Clean Water Rule with another rule.

    a. Do you commit to use the best available peer-reviewed science in developing any new rule?

    Should I be confirmed, I will work to ensure that sound, peer-reviewed science supports, where applicable, the legal and policy decisions inherent in defining the statutory and regulatory term "waters of the United States."

    b. In such rulemaking, do you commit to include the best available peer-reviewed science in the valuation of the benefits provided by wetlands and the other Waters of the United States?

    As stated above, I will work to ensure that relevant, peer-reviewed sound science supports the legal and policy determinations implicit in any determination regarding the meaning of the term "waters of the United States," including applicable wetland valuation methodologies.

Senator Ernst:

18. Administrator Pruitt has made engagement with rural America a priority and he has expressed particular concern over how EPA regulations, such as the Waters of the United States (WOTUS) rule, impact these local communities. In cases like WOTUS, the previous EPA did not fully analyze the costs associated with the regulation, particularly for rural communities. At the same time, the benefits of this rule, and others, were often overstated. How will you work to assure transparency when documenting the costs and benefits associated with EPA actions under your office?

In my experience, the Agency can do a much better job of early-stage problem formulation through active engagement with states, tribes and local governments, members of the regulated community, external experts, and other interested stakeholders. All too often, stakeholder engagement and consultation occurs too late in the regulatory process. Cost-benefit analysis is one of many areas where early stage consultation would improve performance, as the analysis frequently accelerates to the valuation stage without clearly articulating the scope of the assessment and the specific data input needs. This problem is frequently compounded by a lack of comprehensive understanding of the regulated activity by those who regulate that activity. Significant enhancements, including trust in the regulatory process, can be achieved through better engagement and transparency earlier in the process.

Senator Markey:

The EPA and the Army Corps of Engineers released a proposal to repeal the 2015 Clean Water Rule a few months ago.

19. Do you feel that the Clean Water Act overly compromises the ability of developers and agricultural producers to conduct their business?

    If fairly and properly implemented within the statutory constraints imposed by Congress, no.

20. Aside from the Clean Water Rule, will you advocate for rolling back other water program requirements that help prevent negative impacts on water quality?

    If confirmed, I will work to assure that the Office of Water objectively implements the laws that Congress has enacted to address the quality of the nation's waters.

21. How will you ensure that credible and vetted scientific research will be used in your decisions as Assistant Administrator for the Office of Water?

    I will assure that the scientific research that is presented to me is credible, balanced, and objective and is targeted at the correct issues and questions. I will also establish a strong preference for peer-reviewed science wherever feasible.

Senator Sanders:

Climate Change

22. President Trump has suggested in the past that climate change is a hoax. Is the President correct? Is climate change a hoax?

    I believe that climate change is real and human activity contributes in some manner.

23. Do you agree with the vast majority of scientists that climate change is real, is caused by human activity, and that we must aggressively transition away from fossil fuels and toward energy efficiency and sustainable energy like wind, solar, and geothermal?

    I believe that climate change is real and human activity contributes in some manner.

24. Changes in weather patterns, such as heavier precipitation events that increase run-off and flooding, are affecting lakes, rivers, and reservoirs nationwide. Water quality, quantity, and the integrity of our water infrastructure are at risk. Recent studies in the Northeast have found that degraded water quality on lakes can cost lakeside communities millions of dollars in losses from both tourism and taxable income due to reduced property values. If confirmed, how will you support water resource management programs to address these issues?

    I will support water resource management programs to address these issues by implementing the core statutory programs as effectively as possible, prioritizing government's limited resources to focus on the most critical issues that return the greatest value for our tax payer and human capital investments, working with the states, tribes and local governments to leverage or shared resources and expertise, and streamlining our decision-making processes.

Background

25. In your past career, you have brought suit against the EPA for its enforcement of the Clean Water Act. Can you explain why federal courts should be in the position of determining safe levels of pollution to protect the health and welfare of Vermonters, as opposed to the federal Agency whose mission it is to protect human and environmental health?

    If EPA complies with the laws that Congress enacts and bases its decisions on balanced, objective science, accurate technological and economic analyses, and reasoned policy choices, federal courts should not be placed in such a position. The litigation process is a poor substitute for effective government decision-making.

26. Do you support the current stated goal of the Office of Water to "protect human health, support economic and recreational activities, and provide healthy habitat for fish, plants, and wildlife"?

Yes.

Science

27. At the EPA, science provides the foundation for Agency policies, actions, and decisions made on behalf of the American people. What should the role of science be in the development of EPA policies, rules, and regulations?

Sound, balanced, objective science is a key component of the EPA decision-making process, and works in tandem with the proper application of and respect for the rule of law to help guide the Agency's core missions.

Most Pressing Challenges

28. In your opinion, what are the most pressing water quality challenges that deserve the attention of the EPA? What will you do at the EPA to address these challenges?

The nation's aging water and wastewater infrastructure in both urban and rural America is, in my opinion, our most pressing short- and long-term concern. I am pleased that both President Trump and Administrator Pruitt share that view. From a drinking water perspective, lead is a high priority water quality concern while nutrients remain our most difficult surface water quality challenge.

Environmental Regulations

29. How do you intend to work collaboratively with states in the event that a state violates the federal Clean Water Act or the Safe Drinking Water Act, or a state requests technical assistance from the EPA?

Should I be confirmed, one of the first directives I will establish for the Office of Water program staff is to be fully and immediately responsive to state requests for technical assistance and to work hard to establish the relationships necessary to enable the free flow of those technical requests without concern for reflexive enhanced oversight or elevation into program authority review or enforcement. Should a state violation be discovered through self-reporting, oversight or other mechanisms, the focus should be on performing a root cause analysis to better assess and support planning to make sure the problem does not continue or reoccur. Collaborative enhancement is more timely and effective than coercive enforcement, particularly in the cooperative federalism model.

30. Then-candidate Trump stated that the lead poisoning in Flint, Michigan "would never have happened if I were president." Today, nearly 3,000 communities have lead poisoning levels higher than those found in Flint, Michigan. And, even Flint does not yet have clean drinking water.

    If confirmed, what actions will you take to ensure that every community has clean water to drink?

    Ensuring effective implementation of the Safe Drinking Water Act through strong partnerships with state, tribal and local governments, targeted oversight, and robust enforcement when necessary.

    What changes, if any, in environmental laws, policies and regulations will you need to ensure that a Flint-like situation never happens again?

    Modernization of the Lead and Copper Rule is a first step, but to fully answer this question I will need to perform a deep dive into the root cause of the Flint, Michigan crisis to be personally satisfied that the core issues in that crisis have been addressed and that state and local governments are getting the resources and attention they need to successfully address the problem. That analysis will then help inform my evaluation of the existing regulatory structure and its ability to prevent future Flints.

31. Oil and natural gas extraction by way of hydraulic fracturing, or "fracking," has expanded rapidly in the United States. The EPA conducted a study of the drinking water impacts and released a final report in December 2016. The Agency found "hydraulic fracturing activities can impact drinking water resources under some circumstances." Do you concur with the conclusions of the EPA's final report on fracking and drinking water?

    I have not studied the report in detail, but I am familiar with the general conclusion quoted above. Under certain circumstances, hydraulic fracturing activities can have negative consequences if adequate precautions are not implemented.

    What further studies—if any—do you believe would be appropriate for the EPA to conduct on the effects of fracking on water quality?

    Another general conclusion of the report indicated that the existing data could support certain qualitative assessments, but not quantitative assessments. Future research might address that significant shortcoming in the available literature.

    If confirmed, would you support implementing a requirement to provide full, well-specific public disclosure of all information related to oil and gas development involving hydraulic fracturing that informs understanding groundwater, surface water, public health and safety, and habitat potential impacts?

If confirmed, I would need to spend more time analyzing the available research and related information before developing an opinion or recommendation on the matter.

Environmental Justice

32. If confirmed, will you commit to addressing issues of environmental justice in Native American communities and offer a voice to those most affected by the environmental consequences of industrialization, especially in regard to resources protected by treaties, such as water rights?

If confirmed, I look forward to working to ensure that the nation's environmental laws are implemented effectively for all Americans, including those most at risk or most impacted from the effects of degraded resources.

Vermont

33. Lake Champlain is one of Vermont's most treasured natural resources. Tourism and property values are tied to the health of the lake—and keeping its waters swimmable, fishable and drinkable is important to Vermonters. Run-off—including from farmlands, lawns, and paved roads and point source pollution contributes to high levels of phosphorus that spur algae growth. The algae turns the lake green and can be toxic. In 2016, the EPA released new phosphorus limits for the lake by establishing a TMDL. As assistant administrator, will you continue the Agency's support for the clean-up of Lake Champlain through this new TMDL and federal funding?

If confirmed, I will work with Vermont and New York to continue to make progress on addressing the ongoing water quality issues in Lake Champlain through implementation of the TMDL and other mechanisms.

Specifically, should Vermont fail to make satisfactory progress toward meeting the TMDL, would you support increased funding and support from the EPA to crack down on pollution? If not, how will you ensure Clean Water Act obligations are satisfied?

I understand that Vermont continues to make progress in implementing its shared commitments under the Lake Champlain TMDL, including pursuing the necessary funding for state program activities. Should I be confirmed, the Office of Water will continue to work with Vermont to provide the requisite support that is necessary to achieve lasting improvements in the Lake.

Do you as Assistant Secretary of Water commit to the EPA's partnership with the states in developing plans for, and responding to, the case of an oil spill that affects waters under its jurisdiction, such as Lake Champlain?

EPA, together with its federal, state and local partners, performs an integral role in oil spill response planning for inland waters under existing authorities. Should I be confirmed, I would be happy to look into the status of planning efforts for Lake Champlain.

Senator Whitehouse:

34. Given your professional history challenging the Clean Water Rule, how can I be assured that you will be impartial in future rulemakings to revoke, revise, or replace the rule?

I fundamentally believe that a lawyer's most important skill is objectivity. Without that baseline skill, a lawyer cannot properly advise clients on the full scope of problems or see, let along recommend, holistic solutions. As the lead environmental prosecutor for Wisconsin, the public relies on our team to uphold the law with integrity and accuracy while ensuring the fair and impartial treatment of the regulated community. Those same skills will continue to inform and guide my decision-making should I be confirmed to lead the Office of Water.

35. Your current boss, Wisconsin Attorney General Brad Schimel, recently co-led a comment letter from twenty-five state Attorneys General to EPA and the Army Corps on the Clean Water Rule revision effort. What role did you have in drafting this letter?

None.

36. What interactions did you have with representatives of the Republican Attorneys General Association in drafting this letter?

None.

37. Have you attended any Republican Attorneys General Association events, or supported in any capacity Wisconsin Attorney General Brad Schimel in his attendance or participation at these events?

No.

38. To your knowledge was EPA Administrator Scott Pruitt or any member of his staff involved in the drafting of the comment letter, either directly or indirectly through early drafts, attendance at meetings or other discussions where the letter was discussed, or any other familiarity with the letter before it was submitted as a formal comment to the agencies?

I have no knowledge of the development process for the letter.

39. Last year, the National Estuary Program (NEP) was reauthorized through 2021 at $26.5 million per year. Just a few months after Congress reaffirmed its support of this program through the reauthorization, the President proposed terminating funding for the program through his FY2018 proposed EPA budget. Do you agree with the President's request to defund the NEP?

Should I be confirmed, I will work to implement the budget Congress provides for the Office of Water as efficiently and effectively as possible.

40. Do you believe wetlands provide economic benefits? Please explain what research and data you rely upon to come to that conclusion.

Based on personal experience, I believe that wetlands have the potential to provide economic benefits aesthetically, ecologically and hydrologically.

41. Rhode Island Department of Environmental Management completed a study earlier this year that identified seven of the nineteen major wastewater treatment plants in the state as likely to be predominately inundated by increased flooding risk due to climate change. All but one of these plants is along the coast where sea level rise and increased storm surge risks threaten the treatment facilities.

    a. Do you believe that climate change is real?

    I do believe that the climate is changing.

    b. EPA Administrator Pruitt recently told CNBC that "I would not agree that [carbon dioxide's] a primary contributor to the global warming that we see." Based on the scientific findings from experts such as NOAA and statements on EPA's website, including "Carbon dioxide is the primary greenhouse gas that is contributing to recent climate change," Politifact determined that statement to be false. Do you agree with Administrator Pruitt or scientific experts regarding whether carbon dioxide is the primary greenhouse gas that is contributing to climate change?

    I believe there are several greenhouse gases that have the potential to contribute to climate change, including carbon dioxide.

    c. In 2009, as mandated by the Supreme Court and backed by a robust scientific and technical review, the Environmental Protection Agency produced the Endangerment and Cause or Contribute Findings for Greenhouse Gases (GHGs) under Section 202(a) of the Clean Air Act. It found six greenhouse gases - carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride - "taken in combination endanger both the public health and the public welfare of current and future generations." Do you agree with the EPA's endangerment finding? Why or why not?

    I have not studied the legal or technical basis for the endangerment finding.

    d. Do you believe that sea levels are rising?

    I think there is sufficient data to indicate that sea levels may be rising.

e. Do you believe that higher sea levels increase the risk to coastal communities from storm surges?

If not properly managed through infrastructure and other means, higher sea levels have the potential to increase risk to coastal communities in storm surge events.

f. Do you believe that increasing levels of carbon dioxide in the atmosphere contributes to sea level rise?

Increasing levels of greenhouse gases in the atmosphere have the potential to contribute to sea level rise.

g. Do you believe that anthropomorphic activities are at least in part responsible for increasing levels of carbon dioxide in the atmosphere?

Yes.

42. Do you believe that sea level rise can put drinking water and wastewater systems at risk?

If not properly managed over the long term, yes.

43. Would you support efforts to direct funding and technical assistance from the EPA towards readying coastal infrastructure for the effects of climate change?

If EPA is appropriated such funds by Congress, yes, with a particular emphasis on aging water and wastewater infrastructure.

44. Do you accept the basic science of ocean acidification, and that the rate of acidification is faster now than in the past 50 million years?

I understand the basic science of ocean acidification, but have not studied those rates as compared to historic trends. Should I be confirmed, I look forward to studying the issue in greater detail.

45. Do you believe the U.S. should remain a party to the United Nations Framework Convention on Climate Change?

The role of the United States in the Framework Convention on Climate Change is an international agreement. The US Department of State has primary responsibility for such matters. I defer to the State Department on this issue.

46. Do you believe the U.S. should remain a party to the Paris Agreement?

The Paris Agreement is an international agreement. The US Department of State

has primary responsibility for such matters. I defer to the State Department on this issue.

47. A 2016 Associated Press study of EPA data identified Providence, RI as "one of the largest [drinking water systems] in the country to exceed a federal lead standard since 2013." Almost 20 percent of all retail customers' homes were found to be serviced by utility-owned lead lines. EPA's lead limit before corrective action is required is currently 15 parts per billion. The city's water supply was found to be over this limit six times since 2010. Providence's water hit 30 parts per billion in tests in 2009 and 2013. Providence has shown marked improvement since those peaks, but there is still millions of dollars of investment needed in the city's drinking water infrastructure to reduce the risk of lead. What role do you believe EPA should play supporting these investments?

Improving the nation's water infrastructure is and must be a shared responsibility of local, state, federal and private partnerships. EPA should continue to implement the state revolving fund and other grant appropriations as strategically as possible at whatever levels Congress provides, while continuing to pursue innovations in water and wastewater infrastructure financing mechanisms.

48. What have you done in your career to demonstrate lead contamination of drinking water will be a priority if you are confirmed as EPA Administrator? Please cite specific examples.

I spent the first four years of my career performing and supporting research on the efficacy of various forms of water and wastewater treatment systems as part of the City of San Diego's Total Resource Recovery Project and Aqua 2000 Research Center. Part of that research involved heavy metals testing and evaluating potential corrosivity concerns in potable water delivery systems.

49. In an interview with the Providence Journal last April, Rhode Island's chief of the Center for Drinking Water Quality at the RI Department of Health stated that "[i]n the last monitoring period, we had six small water systems exceed the lead action level. Five were school systems." These systems were brought back into compliance, but the concern remains. How will you prioritize lead abatement in schools and among the most vulnerable populations?

By making sure that the WIIN Act, Safe Drinking Water Act and other authorities are implemented as effectively as possible in close coordination with our state and local partners. EPA must also continue to make progress on modernizing the Lead and Copper Rule.

50. EPA's regulations on lead in drinking water, otherwise known as the Lead and Copper Rule, were last revised in 2007. In its October 2016 white paper on revising the rule, the EPA recognized "[t]here is a compelling need to modernize and strengthen implementation of the rule—to strengthen its public health protections and to clarify its implementation requirements to make it more effective and more readily enforceable." Do you agree the Rule is in need of updating to reflect the latest science? Will you prioritize reviewing and updating the Lead and Copper Rule?

Yes, and yes.

51. Do you believe all covered water systems should follow EPA's drinking water analytical methods when testing drinking water for contamination? If so, what efforts will you undertake to ensure all water systems are brought into compliance?

All covered water systems must comply with established standards for testing drinking water quality. Should I be confirmed, the Office of Water will continue to work with our local, state and regional partners to ensure that the requirements of the Safe Drinking Water Act are fully implemented.

52. In a November 2016 interview with the New York Times, President-elect Trump specifically called out "crystal clear water" as a priority. Do you agree "crystal clear water" should be a priority of the EPA? If so, please list the specific steps you would take as Administrator to make the President-elect's vision a reality.

I'm not familiar with the context or content of the interview, but I share the President's enthusiasm for what I assume from the quote is prioritizing safe and reliable drinking water for all Americans.

53. Over 40,000 water bodies in the United States are considered "impaired" under Section 303(d) of the Clean Water Act, meaning they do not meet water quality and health standards. What, if any, specifics steps have you taken to improve the water quality in these impaired waters in states in which you have worked on clean water issues?

I provided legal advice to the Water Quality Administrator for the Wyoming Department of Environmental Quality and his TMDL development team while serving as the lead water quality attorney for the State of Wyoming, and in Wisconsin I facilitated the settlement of litigation brought by a tribe and local lake association seeking the development of a site-specific water quality criteria for phosphorus for an impaired lake in northern Wisconsin. The result of the settlement accelerated the work of the Wisconsin Department of Natural Resources in developing the requested water quality criterion. I also recently prosecuted a dairy farm in Kewaunee County, Wisconsin for manure management violations, and required as part of the settlement implementation of at least 100 acres of seasonal cover crop on highly erodible soils and the development and maintenance of approximately nine acres of vegetated filter strips along and near the Kewaunee River, portions of which are impaired by phosphorus.

54. What clean water initiatives undertaken by the EPA in the last five years do you support?

I support EPA's efforts on integrated planning, enhancements in green infrastructure and storm water management planning for municipalities, innovative financing developments for water infrastructure projects, the nutrient recycling challenge, and better recognition of state partnerships as key to solving the nutrient loading challenges in the Mississippi River Basin, to name a few.

55. Factory farming of animals is known to cause multiple forms of pollution, such as contaminating local groundwater with nitrates, contributing to hypoxia and "dead zones" in rivers and coastal waters, and releasing the potent greenhouse gas methane. Do you commit to enforcing the Clean Water Act to the fullest extent of the law to protect the public from pollution from animal feeding operations?

I commit to fully and fairly implementing the Clean Water Act for all sectors of the economy, and to working with the Office of Enforcement and Compliance Assurance to fully and fairly enforce the law against all sectors, including agriculture.

56. Each year, around 8 million metric tons of plastic waste enters the oceans from land. Proper waste management, including stormwater management, is an essential part of preventing marine debris. Under your leadership, how would you promote the use of EPA's authorities under the Clean Water Act to improve the use of TMDLs, NPDES permits, and other authorities to encourage states and municipalities to manage wastewater and stormwater for debris and litter?

EPA has made significant progress in working with municipalities in particular to improve stormwater management systems. There is certainly more work to do, particularly in our urban centers, and tools like integrated and long-term planning together with targeted grant funding will help facilitate continued improvements.

57. How will you address EPA's National Pollutant Discharge Elimination System permitting backlog without undermining any environmental protections or subverting the goals of the Clean Water Act?

By making sure bureaucracy does not get in the way of progress. We need to strategize, prioritize, plan and implement, and not let isolated goals of perfection become the enemy of incremental improvement in the aggregate.

58. More than fifty percent of the plastic waste that enters the ocean comes from just five rapidly developing economies in Asia. Do you see a role for the EPA in providing technical assistance and other recommendations to these and other priority countries that are contributing the most plastic waste into the oceans?

I think EPA should share its technical expertise and problem-solving skills with our global partners, within our statutory and budgetary authorities to do so.

59. Administrator Pruitt has been criticized for spending a disproportionate amount of his time meeting with industry and virtually no time with public-interest groups. If confirmed, will you commit to meet with and listen to all parties in a balanced fashion?

If confirmed, I intend to consult with and listen to interested stakeholders with multiple perspectives.

60. If confirmed, do you commit to notifying the Committee of all of the email addresses you plan to use upon confirmation and within seven days of using a new email address, including any aliases or pseudonyms? Do you commit do conducting all business using official email addresses and other means and to refrain from any mediums that are outside the Freedom of Information Act's reach?

If confirmed, I commit to notifying the Committee of the e-mail address I use for official business. If confirmed, I also commit to following EPA's Records Policy and the Federal Records Act.

61. Factory farming of animals is known contaminate local groundwater with nitrates, contributing to harmful algal blooms, hypoxia, and "dead zones" in rivers and coastal waters. Harmful algal blooms in particular can contain various toxins that can affect the liver, skin, or nervous system, causing a range of health effects, from mild rashes to severe illness. To address these health concerns, the EPA co-chairs with NOAA the Interagency Working Group on the Harmful Algal Bloom and Hypoxia Research and Control Act.

    a. Under your direction, will the EPA to maintain a leadership role on the committee?

    Yes.

    b. How will you continue EPA's coordinated work with NOAA and other agencies to address HAB and hypoxia events and develop action plans and assessments of these situations?

    Should I be confirmed, I look forward to evaluating the existing practices and procedures of the working group, which will then inform any recommendations I may have.

62. If confirmed, do you commit to providing complete and accurate responses to inquiries from EPW members in a timely fashion?

Yes.

Senator BARRASSO. Well, thank you very much, Mr. Ross, and congratulations.

Mr. Wehrum, welcome to the Committee. We look forward to your testimony.

STATEMENT OF WILLIAM WEHRUM,
PARTNER, HUNTON & WILLIAMS LLP

Mr. WEHRUM. Thank you, Mr. Chairman.

I would first like to introduce my family who are here with me today. My wife, Cindy, is sitting immediately behind me; my mother, Mary Ann, and my sisters, Lisa and Laura, who, believe it or not, are twins, fraternal, of course.

Senator Carper, my wife came down on 111 this morning and will be on 188 tonight, so if you happen to be on the train, please be sure to say hello to her.

Chairman Barrasso, Ranking Member Carper, and members of the Committee, thank you for the opportunity to appear before you today as the nominee for the position of Assistant Administrator for the Office of Air and Radiation at U.S. EPA. I am honored that President Trump nominated me for this position.

I would also like to thank, in particular, Senator Inhofe, for your very kind introduction. Under your leadership, previously in 2005, my nomination was voted out of this Committee, and I very much appreciate that. That meant a whole lot to me.

President Trump and Administrator Pruitt have set a clear agenda that I intend to implement if confirmed to this position. The President has issued executive orders that will eliminate needless and burdensome regulations, simplify and streamline compliance obligations, and strike a better balance between the twin goals of protecting human health and the environment and promoting the economic vitality of the nation.

Administrator Pruitt emphasized three key objectives in his remarks to this Committee during his confirmation hearing. First, we are a nation of laws. He explained that EPA's role is to administer those laws faithfully and that the Agency should avoid the temptation to bootstrap its own powers and tools through rulemaking.

Second, Administrator Pruitt committed that the Agency would acknowledge, respect, and promote the critical role of States in implementing Federal environmental laws and in protecting human health and the environment. Cooperative federalism is one of the cornerstones of the Clean Air Act. In fact, in the very first section of the Act, Congress declares that air pollution control at its source is the primary responsibility of States and local governments. Administrator Pruitt's commitment to State involvement carries out Congress's stated intent.

Third, Administrator Pruitt emphasized the important role that the public plays in the regulatory process. He said, "It is critical to me that EPA also truly listen to the diverse views of the American people and learn from them." He rightly stated that "we simultaneously pursue the mutual goals of environmental protection and economic growth," but cautioned that that can only happen if EPA listens, listens to the views of all interested stakeholders.

These are goals and objectives that have been established by our leadership. I concur in them, and if confirmed, will do all I can to achieve them.

Mr. Chairman and members of the Committee, thank you again for the opportunity to be here, and I would be happy to answer any questions you may have today.

[The prepared statement of Mr. Wehrum follows:]



William Wehrum
Partner
Hunton & Williams LLP

Bill Wehrum is a partner and the head of the Administrative Law Group at Hunton & Williams LLP. Bill's practice focuses on air quality issues including regulatory development and related litigation; compliance counseling and enforcement defense; legislative advice; and permitting. Prior to joining Hunton & Williams, Bill served for two years as Acting Assistant Administrator for Air and Radiation at the U.S. Environmental Protection Agency. He has a BS in Chemical Engineering from Purdue University and a JD from Widener University. Bill is a member of the District of Columbia bar.

Statement of William L. Wehrum
Nominated to Be Assistant Administrator, Office of Air and Radiation
U.S. Environmental Protection Agency

Chairman Barrasso, Ranking Member Carper, and members of the Committee, thank you for the opportunity to appear before you today as the nominee for the position of Assistant Administrator for the Office of Air and Radiation at the U.S. Environmental Protection Agency. I am honored that President Trump nominated me for this position.

As you may know, I previously was nominated in 2005 by President Bush for this position. Under Senator Inhofe's leadership, this Committee approved of my nomination at that time. I appreciate the opportunity to appear before you again.

President Trump and Administrator Pruitt have set a clear agenda that I intend to implement if confirmed to this position. The President has issued Executive Orders that will eliminate needless and burdensome regulations, simplify and streamline compliance obligations, and strike a better balance between the twin goals of protecting human health and the environment and promoting the economic vitality of the Nation.

Administrator Pruitt emphasized three key objectives in his remarks to this Committee during his confirmation hearing. First, we are a Nation of laws. He explained that "EPA's role is to administer those laws faithfully" and that the Agency should avoid the temptation to "bootstrap its own powers and tools through rulemaking."

Second, Administrator Pruitt committed that the Agency would acknowledge, respect, and promote the critical role of the states in implementing Federal environmental laws and in protecting human health and the environment. "Cooperative federalism" is one of the cornerstones of the Clean Air Act. In the very first section of the Act, Congress declares that "air

pollution control at its source is the primary responsibility of States and local governments." Administrator Pruitt's commitment to state involvement carries out Congress's stated intent.

Third, Administrator Pruitt emphasized the important role that the public plays in the regulatory process. He said that "it is critical to me that EPA also truly listen to the diverse views of the American people, and learn from them." He rightly stated that "[w]e can simultaneously pursue the mutual goals of environmental protection and economic growth," but cautioned that "that can only happen if EPA listens – listens to the views of all interested stakeholders."

These are the goals and objectives that have been established by our leadership. I concur in them and, if confirmed, will do all I can to achieve them.

Mr. Chairman and members of the Committee, thank you again for the opportunity to appear before you. I am happy to answer any questions that you may have.

Senate Committee on Environment & Public Works
Hearing entitled, *"Hearing on the Nominations of Michael Dourson, Matthew Leopold, David Ross, and William Wehrum to be Assistant Administrators of the Environmental Protection Agency, and Jeffery Baran to be a Member of the Nuclear Regulatory Commission."*
October 4, 2017
Questions for the Record for Mr. William Wehrum

Ranking Member Carper:

1. For decades, both Republican and Democratic administrations alike have had written policies limiting White House contacts with agencies that have investigatory and enforcement responsibilities. These policies have recognized that even a simple phone call from the White House to an agency inquiring about or flagging a specific matter can upset the evenhanded application of the law. I recently learned that Devon Energy, a strong political supporter of Administrator Pruitt's, informed the EPA just 5 days after Mr. Pruitt was sworn in as Administrator that it was no longer willing to install air pollution technology or pay a high penalty to EPA for its illegal air emissions of cancer-causing benzene and other chemicals. We also know that Trump family casinos, hotels and golf courses have been the subject of EPA enforcement actions for violations of the Clean Air Act and Clean Water Act.

    a. Do you agree that it is essential that in making decisions, EPA's OAR must be shielded from political influence and spared even the appearance of being subject to political influence or considerations?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    b. Will you commit to restricting communications between OAR and the White House staff regarding specific matters under the authority of OAR?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

    c. Will you commit to ensuring the staff of OAR is familiar with those restrictions?

    If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

d. Will you commit to advising this Committee within one week if any inappropriate communications from White House staff to OAR staff, including you, occur?

If confirmed, I commit to work with Administrator Pruitt and his team to ensure strict compliance with all legal and ethical obligations.

2. Recently, EPA conducted "anti-leaking" training for its employees[1]. According to EPA sources, the briefing stated that "Prohibitions we will discuss do not refer to "Whistleblowing". Agency employees have the right to make lawful disclosures to anyone, including, for example, management officials, the Inspector General, and/or the Office of Special Counsel. Employees may make disclosures to the EPA Office of the Inspector General through the EPA OIG Hotline at 888-546-8740." This presentation evidently failed to note the rights of federal employees have to make disclosures to Congress.

5 U.S.C. § 7211, provides that: The right of employees, individually or collectively, to petition Congress or a Member of Congress or to furnish information to either House of Congress, or to a committee or Member thereof, may not be interfered with or denied. Pursuant to 5 U.S.C. § 2302(b)(8), it is a violation of federal law to retaliate against whistleblowers. That law states: Any employee who has authority to take, direct others to take, recommend, or approve any personnel action, shall not, with respect to such authority ... take or fail to take, or threaten to take or fail to take, a personnel action with respect to any employee or applicant for employment because of. ... (A) any disclosure of information by an employee or applicant which the employee or applicant reasonably believes evidences- (i) a violation of any law, rule, or regulation, or (ii) gross mismanagement, a gross waste of funds, an abuse of authority, or a substantial and specific danger to public health or safety, any disclosure to the Special Counsel, or to the Inspector General of an agency or another employee designated by the head of the agency to receive such disclosures, of information which the employee or applicant reasonably believes evidences a violation of any law, rule, or regulation... " In addition, pursuant to 18 U.S.C. § 1505, it is against federal law to interfere with a Congressional inquiry: Whoever corruptly, or by threats or force, or by any threatening letter or communication influences, obstructs, or impedes or endeavors to influence, obstruct, or impede the due and proper administration of the law under which any pending proceeding is being had before any department or agency of the United States, or the due and proper exercise of the power of inquiry under which any inquiry or investigation is being had by either House, or any committee of either House or any joint committee of the Congress.

a. If you are confirmed, will you commit to protect the rights of all career employees in OAR to make lawful disclosures, including their right to speak with Congress?

b. Will you commit to communicate employees' whistleblower rights via email to all OAR employees within a week of being sworn in?

If confirmed, I will work closely with EPA Office of Administration and

[1] https://www.washingtonpost.com/politics/whitehouse/federal-employees-are-ordered-to-attend-anti-leaking-classes/2017/09/21/032b40d6-9edd-11e7-b2a7-bc70b6f98089_story.html?utm_term=.e2bfc5e54d95

Resources Management to ensure all OAR employees continue to apprised of their rights as federal employees.

3. In the wake of Hurricane Irma, at least 11 deaths and numerous injuries have been reported in Florida due to accidental carbon monoxide poisoning from gasoline-powered portable generators.[2] One additional death has also been reported in North Carolina, along with other injuries throughout the Southeastern United States.[3] Many of these deaths and injuries could have been prevented had stronger safety standards been in place for portable gasoline generators. In November 2016, the U.S. Consumer Product Safety Commission (CPSC), following years of work on the issue, voted to issue a Notice of Proposed Rulemaking (NPRM) to implement a mandatory safety standard for portable generators.[4] Since then, Administrator Pruitt and Acting CPSC Chairman Buerkle have separately opined that section 213 of the Clean Air Act precludes CPSC action.

    a. Section 213 of the Clean Air Act is intended to regulate emissions from non-road engines or vehicles when the EPA determines that such emissions "are significant contributors to ozone or carbon monoxide concentrations in more than 1 area which has failed to attain the national ambient air quality standards for ozone or carbon monoxide." In your opinion, would the occasional indoor use of portable generators following a power outage be likely to be a significant contributor to ambient carbon monoxide concentrations in more than 1 area that has failed to attain the national ambient air quality standards for carbon monoxide? Why or why not?

    b. There are currently no areas in the United States that have failed to attain the national ambient air quality standards for carbon monoxide, and this has been the case since 2010[5]. As a matter of law, could section 213 of the Clean Air Act be used to regulate carbon monoxide emissions due to the indoor use of portable generators if there are no areas in the United States that fail to attain the national ambient air quality standards for carbon monoxide? Why or why not?

    I do not have experience with interpreting or applying CAA § 213 to these circumstances. If confirmed, I will work with Administrator Pruitt as needed to properly implement this section of the Act.

4. Your public financial disclosure material lists, among others, several clients such as the American Petroleum Institute and others that are trade or other associations that consist of individual member companies. For each such association or organization listed on your financial disclosure form, please provide a complete list of the individual companies and other entities that comprise its members.

---

[2] http://www.miamiherald.com/news/weather/hurricane/article174097351.html http://www.sun-sentinel.com/news/weather/hurricane/sfl-carbon-monoxide-deaths-20170914-story.html

[3] http://www.charlotteobserver.com/news/article173612361.html

[4] https://www.federalregister.gov/documents/2016/11/21/2016-26962/safety-standard-for-portable-generators

[5] https://www.epa.gov/green-book/green-book-carbon-monoxide-1971-area-information

The trade associations listed in my financial disclosure are my clients and not their individual members. As such, I do not have current member lists for my trade association clients.

5. In addition to employees or representatives of the trade associations or organizations listed as your clients, have you met or otherwise communicated with employees or representatives of the companies that are members of the associations or organizations as part of your work for the client itself? If so, which ones?

   The trade associations listed in my financial disclosure are my clients and not their individual members. I routinely meet with member companies, but do not keep comprehensive records of such contacts.

6. Your ethics agreement states that you "will not participate personally and substantially in any particular matter involving specific parties in which I know a former client of mine is a party or represents a party for a period of one year after I last provided service to that client, unless I am first authorized to participate, pursuant to 5 C.F.R. 2635.502(d)."

   a. Please provide a list of all such particular matters involving specific parties that you will either need to recuse yourself from or seek authorization to participate in. For each such particular matter, please also indicate whether you plan to seek authorization to participate.

   b. If that list does not include particular matters involving the list of individual companies and other entities described in question 4, why not?

   c. 5 C.F.R 2635.502(a) states that
      "where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the employee determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and received authorization from the agency designee in accordance with paragraph (d) of this section."

      Do you agree that your representation of numerous industry clients in litigation to repeal or weaken EPA regulations would cause a reasonable person with knowledge of the relevant facts to question your impartiality if you are confirmed and continue to participate either in the litigation or in an administrative action designed to accomplish the identical outcome – repeal or weakening of an EPA regulation – that the litigation sought to accomplish? Why or why not?

      Attachment A is a list of particular matters involving specific parties to

which I believe my ethics agreement will apply. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

7. Do you intend to participate in non-public meetings with your former clients or their member companies (as applicable) if you are confirmed, even if the meetings are about the repeal or weakening of the very same EPA regulations you sought, on behalf of those clients, to repeal or weaken through litigation? If so, please explain why this would not cause a reasonable person with knowledge of the relevant facts to question your impartiality in the matter at hand.

   If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

8. Your Ethics Agreement also states that you will either recuse yourself from or seek authorization to participate in "any particular matter involving specific parties in which I know the law firm [Hunton & Williams] is a party or represents a party." Please provide a list of all the EPA-related particular matters involving specific parties in which Hunton & Williams is a party or represents a party, and indicate whether you plan to seek authorization to participate in each such matter.

   I do not have a list of all particular matters involving specific parties in which Hunton & Williams is a party or represents a party. If confirmed, I intend to ascertain Hunton's involvement on a case-by-case basis before becoming involved in any particular matter involving specific parties.

9. On February 28, 2017, President Trump directed EPA and the Army Corps to review and possibly rescind or repeal the Clean Water Rule in Executive Order 13776. EPA recently ended the public comment process on the first step of a two-step process to repeal the rule and replace it with a rule that will protect far fewer sources of drinking water. Individuals with first-hand knowledge of the process EPA utilized to prepare its have informed my staff that:

   a) When EPA first submitted the proposed repeal rule to OMB, the draft stated that the agency would undertake a new cost-benefit analysis as part of the second step of its process.

   b) OMB interpreted EPA's first proposal to mean that the rule's repeal would not avoid any costs to industry or have any economic impact at all. EPA's political staff then directed the career staff to undertake a new economic analysis. In response to this direction from OMB, EPA career staff reportedly changed the table included in the 2015 rule to a) reflect 2016 dollars instead of 2014 dollars, b) convert "annual costs incurred" under the Clean Water Rule to "annual costs avoided" due to its repeal and c) convert "annual benefits gained" under the Clean Water Rule to "annual benefits forgone" due to its repeal. This new table was sent to OMB on June 8, 2017.

c) OMB correctly concluded from EPA's June 8 submittal that repealing the rule would cost more in lost benefits than it would save industry in compliance costs. On June 13, 2017, presumably to avoid such an admission on the part of EPA, EPA career staff were verbally directed by political staff to solve this 'problem' by simply deleting the majority of the benefits of the rule from the table and re-submitting it to OMB, which they did[6].

The direction that was reportedly provided to the EPA career staff to make the various revisions to what was submitted to OMB was verbal, not written. If you are confirmed, do you commit to ensure that career staff in OAR will receive appropriately documented, rather than verbal, direction from political officials before they take action? If not, why not?

If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

10. As Attorney General of Oklahoma, Administrator Pruitt copied and pasted materials sent to him by industry onto his own letterhead and sent them to EPA. Similarly, when you last served in EPA's air office, language drafted by your old law firm found its way into an EPA mercury regulation that you helped write. You also repeatedly prevented EPA employees from verifying the public health benefits of reducing mercury exposure.

    a. If confirmed, do you commit that you will not allow industry to exert an undue influence on any of the regulatory and policy efforts you will be charged with leading? If not, why not?

    b. Do you commit not to censor or exclude the dedicated and knowledgeable career EPA staff? If not, why not?

    If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

11. Do you agree to provide complete, accurate and timely responses to requests for information submitted to you by any Member of the Environment and Public Works Committee? If not, why not?

    Administrator Pruitt has made responsiveness to Congress an important priority. The 2800 pages of EPA responses provided to Members of the Environment and Public Works Committee on display at the nomination hearing is a testament to this commitment. Accordingly, I will continue to be a part of EPA's transparent and responsive culture.

[6] https://www.epa.gov/sites/production/files/2017-06/documents/economic_analysis_proposed_step1_rule.pdf See Table 1

12. Recently, EPA announced that Administrator Pruitt would be publishing brief summaries of his calendars biweekly, after dozens of Freedom of Information Act requests for this information as well as a March request by me and my colleagues that he do so. During the Obama Administration, the Administrator, regional Administrators and all those serving in confirmed roles published their calendars daily[7]. If you are confirmed, will you commit to publishing your calendars daily? If not, why not?

    If confirmed, I will make my calendar available on a timely basis.

13. In 2006, when you were last nominated to lead the Office of Air and Radiation (OAR), the then-Bush Administration requested for FY 2007 $1.33 billion (adjusting to 2017 dollars) for State and Tribal Assistance Grants, of which $250 million (in 2017 dollars) was for Air and Radiation programs. Earlier this year, the Trump Administration requested for FY 2018 $597 million, of which $168 million was for Air and Radiation programs. This is more than 50% less for the STAG program in general, and almost 1/3 less for Categorical Grants for OAR programs.

    a. Did you support the request for FY 2007, and do you support the request for FY 2018? Why, or why not?

    b. If you support both the requested levels in FY 2007 and FY 2018, why do you believe that a 1/3 cut to the funding levels in FY 2018 from FY 2017 levels is appropriate?

    If confirmed, I will manage OAR's programs within the authorities and budget provided by Congress, including STAG grants.

14. How many legal cases have you filed, or joined others in filing against the EPA, since leaving the agency? Please provide a full list with the outcome of each case, including those cases in which the court disagreed with your argument, agreed with your argument, and those in which the court refused to hear the matter.

    I believe that I have been involved in five cases against EPA that have been decided: (1) a challenge to EPA's E15 waiver (dismissed on standing); (2) a challenge to EPA's misfueling mitigation rule (dismissed on standing); (3) a challenge to EPA's most recent PM2.5 NAAQS (petition denied); (4) a challenge to the Wise Co., TX nonattainment area designation for the 2008 ozone NAAQS (petition denied); and (5) a challenge to CSAPR (mixed result). I continue to search my files and will update this answer if I find more cases. In addition, Attachment 1 is a table listing all of my pending cases against EPA.

15. You've represented industry in at least thirty-one cases against the EPA since you left the agency. Can you name one Clean Air Act regulation that was promulgated by the Obama Administration – not a voluntary or grant program – that you do support and why? If you support more than one, please name these as well.

[7] https://yosemite.epa.gov/opa/admpress.nsf/Calendars?OpenView

I represent clients in private practice. It is my legal ethical duty to zealously represent their interests.

16. Delaware is already seeing the adverse effects of climate change with sea level rise, ocean acidification, and stronger storms. While all states will be harmed by climate change, the adverse effects will varyby state and region. Would you comment on why it is imperative that we have national standards to reduce carbon pollution? If you do not believe it is imperative, why not?

If confirmed, my primary responsibility will be to faithfully implement the Clean Air Act, including authorities and restrictions applicable to greenhouse gases.

17. In a *per curiam* opinion, the U.S. Circuit Court of Appeals for the District of Columbia affirmed the Endangerment Finding and thc U.S. Supreme Court declined to issue a writ of certiorari on the D.C. Circuit's decision. The Endangerment Finding set in motion EPA's legal obligations to set greenhouse gas emissions standards for mobile and stationary sources, including those established by the Clean Power Plan in August 2015.[8] During an exchange with Senator Gillibrand during Administrator Pruitt's confirmation hearing before thc Environment and Public Works Committee, he stated, "I believe that thc EPA, because of the Mass v. EPA case and the endangerment finding, has obligations to address the CO2 [carbon dioxide] issue."

    a. Do you agree with Administrator Pruitt's statement?

    b. If the Clean Power Plan is withdrawn, and if confirmed, how will you lead the agency to fulfill its legal obligations to address climate change?

    I agree with Administrator Pruitt. If confirmed, my primary responsibility will be to faithfully implcment the Clean Air Act, including authorities and restrictions applicable to greenhouse gases.

18. EPA policy prohibits the use of non-EPA e-mail accounts and instructs employees to: "not use any outside e-mail system to conduct official Agency business. If, during an emergency, you use a non-EPA e-mail system, you are responsible for ensuring that any e-mail records and attachments are saved in your office's recordkeeping system." When last at the EPA, did you ever use personal email to conduct official EPA business? Did you ever use an email alias to conduct official EPA business when you last served at the agency? Do you commit that if confirmed, you will not use an email alias or use personal email addresses to conduct EPA business?

I do not recall using personal e-mail to conduct official business when last at EPA. I did not use an e-mail alias to conduct official business when last at EPA. If

[8] https://www.epa.gov/climatechange/us-court-appeals-dc-circuit-upholds-epas-action-reduce-greenhouse-gases-under-clean

confirmed, I intend to use my EPA e-mail account to conduct official business.

19. Clean car standards save consumers money at the pump and help reduce oil imports. Automakers are complying with vehicle standards ahead of schedule. If confirmed, will you commit to support, defend and enforce EPA's current programs to address greenhouse gas emissions from vehicles?

If confirmed, my primary responsibility will be to faithfully implement the Clean Air Act, including authorities and restrictions applicable to greenhouse gases.

20. For the most part, patients and their families only participate in scientific trials and studies once they know their privacy - and any resulting health-related information - will remain confidential and secure. If confirmed, do you commit to respecting confidentiality agreements that exist between researchers and their subjects? Will you protect the health information of the thousands of people that have participated in health studies in the past?

If confirmed, I will comply with appropriate standards to continue the protection of sensitive or confidential information.

21. In December 2007, President Bush's EPA proposed to declare greenhouse gases as a danger to public welfare through a draft Endangerment Finding, stating,
"The Administrator proposes to find that the air pollution of elevated levels of greenhouse gas (GHG) concentrations may reasonably be anticipated to endanger public welfare…Carbon dioxide is the most important GHG (greenhouse gas) directly emitted by human activities, and is the most significant driver of climate change." [9]

    a. Do you agree with these statements, if not, why not?

    b. Did you participate in drafting the proposed Bush Endangerment Finding document in any way? If so, how?

    I believe that the climate is changing and that anthropogenic emissions contribute to the change. I did not participate in drafting the proposed Bush Endangerment Finding document.

22. When you last served in the EPA OAR office, did the EPA ever propose to disapprove state mercury emissions control programs that were stronger than the Clean Air Mercury? If so, please provide how many times this happened and what your role was in these actions. Please also provide how this fits in Administrator Pruitt's views of "cooperative federalism."

I do not recall that EPA proposed to disapprove any state program proposed

[9] https://insideclimatenews.org/sites/default/files/2007_Draft_Proposed_Endangerment_Finding.pdf

pursuant to the Clean Air Mercury Rule.

23. The Rule of Law Defense Fund is an affiliate of the Republican Attorneys General Association. Have you ever contributed any money or time to the Rule of Law Defense Fund?

No.

24. Have you ever contributed any money or time to two election fundraising groups, Oklahoma Strong PAC and Liberty 2.0 PAC?

No.

25. How many legal cases have you filed, or joined others in filing, that involved the Renewable Fuel Standard, biofuels or biodiesel since leaving the EPA? Please provide a summary of your argument and the outcome of each case, including those cases in which the court disagreed with your argument.

I was counsel of record on three cases related to the RFS (principal clients are included in parentheses): (1) a challenge to EPA's E15 waiver (API and the Grocery Manufacturers Association); (2) a challenge to EPA's misfueling mitigation rule (API); and (3) a challenge to Minnesota's B10 mandate (API, the Auto Alliance, the American Fuel and Petrochemical Manufacturers).

26. Have you ever argued in court, or been part of a legal argument, that the Renewable Fuel Standard, as being implemented by the EPA, will lead to an increase in the overall demand for corn, which will lead to an increase in the price of corn? If so, please cite the case and the data used for the argument.

I am not authorized by my clients to discuss relevant cases.

27. In your 2005 EPW confirmation hearing, you answered a question, with the following, "I was barred for 1 year starting September 29, 2001, from participating in the particular matters listed in Attachment A of the memorandum and from taking official action on any particular matter in which my former clients, listed in Attachment B, were or represented a party to the matter. The ethics memorandum also addressed the general rulemakings on which I had represented various clients…With respect to the ethylene MACT rule and the semiconductor MACT rule, he [Kenneth J. Wernick, EPA's then Alternate Agency Ethics Official] concluded that it would be prudent for me not to handle these matters during my first year at EPA. Subsequent to that time, there was no bar to my participating as an EPA official in these rulemakings... In accordance with the ethics memorandum referenced above, I refrained for 1 year starting September 29, 2001, from participating in the particular matters identified by the memorandum and from taking official action with respect to any particular matter involving the entities listed in the memorandum. I also did not participate in the

ethylene and semiconductor MACT rules in my first year at EPA."[10]

[10] https://www.gpo.gov/fdsys/pkg/CHRG-109shrg42275/pdf/CHRG-109shrg42275.pdf

a. Please provide a full list of the cases you filed, joined others in filing, or participated in some way related to the ethylene and semiconductor MACT rules prior to you joining the EPA in 2001. Please include any other work that you may have done while employed at Latham and Watkins – or any other organization – prior to coming to the EPA in 2001 that was related to the ethylene and semiconductor MACT rules.

b. What led Kenneth J. Wernick, EPA's then Alternate Agency Ethics Official to conclude it wouldn't "be prudent" for you to handle the ethylene MACT rule and the semiconductor MACT rule during your first year at EPA?

c. In 2001, what other issues and rulemakings did you have to recuse yourself for one year to meet the ethical standards set by the EPA?

Prior to and upon joining EPA in 2001, I sought, obtained, and strictly followed advice from EPA's ethics officials as to my ethical obligations related to my prior work in private practice. My prior ethics agreement is a matter of public record.

28. How many legal cases have you filed, or joined others in filing, since leaving the EPA that challenged rules the Obama EPA had to re-write because the courts said the original rules written by the Bush Administration were illegal?

To my knowledge, I have been involved in three cases challenging rules that EPA issued on remand from court decisions on Bush Administration air rules.

29. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee, "Clear Skies would also reduce mercury emissions from power plants. EPA is required to regulate mercury because EPA determined that mercury emissions from power plants pose an otherwise unaddressed significant risk to health and the environment, and because control options to reduce this risk are available."[11] At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.

a. Did you agree at the time with Mr. Holmstead's determination, if so why? If not, why not?

b. Did you ever provide legal counsel to Mr. Holmstead, or others within the EPA, that helped provided the legal basis for these remarks?

c. Do you agree with Mr. Holmstead's remarks today?

I believe Mr. Holmstead was referring to Administrator Browner's 1999

[11] https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

"appropriate and necessary" determination, which was still in effect at the time. That determination, as amended in the Mercury and Air Toxics Rule, was determined to be illegal by the US Supreme Court.

30. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee: "Mercury, a potent toxin, can cause permanent damage to the brain and nervous system, particularly in developing fetuses when ingested in sufficient quantities. People are exposed to mercury mainly through eating fish contaminated with methylmercury... EPA estimates that 60% of the mercury falling on the U.S. is coming from current man-made sources. Power generation remains the largest man-made source of mercury emissions in the United States...Mercury that ends up in fish may originate as emissions to the air. Mercury emissions are later converted into methylmercury by bacteria. Methylmercury accumulates through the food chain: fish that eat other fish can accumulate high levels of methylmercury".[12] At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.

    a. Did you have any involvement in the drafting of these remarks? If so, what was your involvement?

    b. Did you agree at the time with Mr. Holmstead's remarks, if so why? If not, why not?

    c. Do you still agree with Mr. Holmstead's remarks today? If not, why not?

    I do not recall being involved in drafting Mr. Holmstead's remarks. I believe that, for the most part, mercury emissions from power plants are dispersed widely in the global atmosphere. I believe that global mercury emissions inventories have significantly changed since my prior time at EPA. Therefore, I cannot speak to his comments related to domestic and global emissions inventories. I believe his comments about the movement and transformation of mercury in the environment are correct.

31. In the *White Stallion Energy Center v. EPA, February 2012,* industry argued, "the record does not support EPA's findings that mercury, non-mercury HAP metals, and acid gas HAPs [hazardous air pollutants] pose public health hazards."[13] Do you agree with this statement? Did you have any involvement with this case, if so, please explain.

    I believe that comments were submitted to the record in this rulemaking demonstrating significant flaws in EPA's exposure and risk assessment. I was not counsel of record in this case.

[12] https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

[13] https://www.cadc.uscourts.gov/internet/opinions.nsf/284AC47088C07D0985257CB8004E0795/%24file/12-1100-1488346.pdf

32. On April 17, 2012, Dr. Jerome Paulson, Chair, Council on Environmental Health, American Academy of Pediatrics, testified before the EPW Committee, stating, "Methyl mercury causes localized death of nerve cells and destruction of other cells in the developing brain of an infant or fetus. It interferes with the movement of brain cells and the eventual organization of the brain…The damage it [methylmercury] causes to an individual's health and development is permanent and irreversible. …There is no evidence demonstrating a "safe" level of mercury exposure, or a blood mercury concentration below which adverse effects on cognition are not seen. Minimizing mercury exposure is essential to optimal child health."[14]

    a. Do you agree with the American Academy of Pediatrics' finding on the importance of minimizing mercury exposures for child health? If not, please cite the scientific studies that support your disagreement.

    b. Do you agree the record supports EPA's findings that mercury, non-mercury hazardous air pollutant metals, and acid gas hazardous air pollutants emitted from uncontrolled power plants pose public health hazards? If not, why not?

    I am not familiar with Dr. Paulson's testimony. I believe that comments were submitted to the record in this rulemaking demonstrating significant flaws in EPA's exposure and risk assessment.

33. On July 8, 2003, Jeff Holmstead, then-EPA Assistant Administrator for Air and Radiation provided the following remarks in his written testimony to the House Energy and Air Quality Subcommittee of the Energy and Commerce Committee, "We have not developed methodologies for quantifying or monetizing all the expected benefits of Clear Skies…These estimates [for Clear Skies] do not include the many additional benefits that cannot currently be monetized but are likely to be significant, such as human health benefits from reduced risk of mercury emissions, and ecological benefits from improvements in the health of our forests, lakes, and coastal waters."[15] At the time Mr. Holmstead provided these remarks, you were serving as his chief counselor within the EPA OAR office.

    a. Did you have any involvement in the drafting of these remarks? If so, what was your involvement?

    b. Did you agree at the time with Mr. Holmstead's remarks, if so why? If not, why not?

    c. Do you agree with Mr. Holmstead's remarks today that it is currently difficult, or impossible, to monetize the reduced risk of human health and ecological benefits from reducing mercury emissions from power plants? If so, please explain. If not, why not?

---

[14] https://www.epw.senate.gov/public/_cache/files/4/3/4324fd62-dc89-4820-bd93-ff3714fcbe30/01AED79733D77F24A71FEF9DAFCCB056.41712hearingwitnesstestimonypaulson.pdf

[15] https://archive.epa.gov/ocir/hearings/testimony/108_2003_2004/web/pdf/2003_0708_jh.pdf

I do not recall being involved in drafting Mr. Holmstead's testimony. I believe that EPA was not able in 2003 to monetize all benefits associated with reducing mercury emissions. I do not know the current state of EPA's knowledge.

34. In 2005 GAO report that reviewed EPA's cost-benefit analysis for the Clean Air Mercury Rule, which you have testified you were heavily involved in writing, GAO identified, "four major shortcomings in the economic analysis underlying EPA's proposed mercury control options that limit its usefulness for informing decision makers about the economic trade-offs of the different policy options."[16]

    a. Can you explain the cost-benefit analysis used for the proposed Clean Air Mercury Rule and why it was used?

    b. Can you explain why the GAO found short-comings with this approach?

    c. Do you agree that co-benefit pollution reductions should be considered when EPA is quantifying the benefits and costs of regulations? If not, why not?

    d. While you were at EPA, did the agency ever use co-benefits to justify a clean air rule and has this approach ever been used in the past?

    I do not recall being involved in preparing the cost-benefit analysis for the Clean Air Mercury Rule. If confirmed, I intend to address the question of how co-benefits should be considered in cost-benefit analyses. I cannot prejudge the outcome because any such analysis would be an integral part of informal legislative rulemaking.

35. You were substantially involved in EPA's proposal and adoption of the Clean Air Mercury Rule and accompanying Delisting Rule. In 2005, for your EPW confirmation hearing you were asked the following question for the record: "With regard to trading of mercury, in your view, would it have been legally acceptable for EPA, taking into account the requirements of the Clean Air Act, to propose and adopt a facility specific mercury MACT that did not allow trading?" You answered, "After considering the utility unit emissions that would remain following imposition of the requirements of the Act, EPA determined that it was neither appropriate nor necessary to regulate utility units under section 112 of the Clean Air Act. Once EPA made that determination, it would not have been legally appropriate for EPA to issue a MACT standard." Three years later, the D.C. Circuit vacated the EPA's decision to delist power plants as a source under Section 112. Six years later under the Obama Administration, the EPA issued the Mercury and Air Toxics Rule to address mercury and air toxic emissions from power plants under the Section 112 of the Clean Air Act.

[16] http://www.gao.gov/products/GAO-05-252

a. Did you disagree with the court's ruling and legal reasoning against the EPA's actions while you were at the agency on mercury and air toxic power plant emissions? Do you continue to disagree today?

b. Do you still hold the position that it is not "appropriate nor necessary" for the EPA to regulate utility units under Section 112 of the Clean Air Act and therefore, still agree it is not legally appropriate for EPA to issue a MACT standard, as the EPA did through the Mercury and Air Toxics Standard? If so, please explain.

c. If you do not agree that EPA has met the "necessary and appropriate" criteria found in Section 112(n), what is your understanding of what that would mean for the Mercury and Air Toxics Rule?

I respect the court's decision with regard to the Clean Air Mercury Rule. I also respect the US Supreme Court's determination that the "appropriate and necessary" finding relied upon in the Mercury and Air Toxics Rule was illegal.

36. The US Supreme Court has expressly declined to consider whether EPA should have chosen some other mechanism "under section 112" in regulating power plant mercury and all the other HAPs emitted by the industry. What is your position on that precedent?

The Supreme Court chooses which areas they should consider providing judgement on when issuing decisions and which areas they decline to consider. I cannot infer the intent of the court from their decision not to consider this one specific issue.

37. Do you agree that the EPA's recent consideration of the costs of the Mercury and Air Toxics Rule shows that the agency has met the "necessary and appropriate" criteria Congress provided under 112(n) to direct the EPA to regulate power plant mercury (and other air toxic) emissions under Section 112, and more specifically under Section 112(d)? If not, why not?

If confirmed, I likely will be involved in assessing this question. I cannot prejudge the outcome.

38. The Edison Electric Institute (EEI), the association that represents all U.S. investor-owned electric companies, has told my staff that, to their knowledge, about five facilities received an approval from the EPA to operate for up to an additional year, which was through April 2017. According to EEI, to their knowledge all of their member companies have fully implemented the Mercury and Air Toxics Standard Rule. EPA staff has reported to my staff something similar. The Mercury and Air Toxics Rule protects our children from harmful mercury and air toxics pollution; and by industry accounts is already being met with technology that is already bought, paid for and running on almost all our power plants.

a. Do dispute reports that nearly all covered facilities are already in compliance with the Mercury and Air Toxics Standard? If so, please explain.

b. According to a recent report by Bloomberg New Energy Finance Report and the Business Council for Sustainable Energy, "consumers now pay 3% less per kilowatt-hour for electricity than in 2007."[17] This means the near universal compliance of the Mercury and Air Toxics Rule has been achieved without significant impacts to electricity reliability or affordability, in fact electricity prices have gone down. Do you agree? If not, why not?

c. Even though industry has achieved near universal compliance with the Mercury and Air Toxics Standards and electricity prices have gone down, not up, Administrator Pruitt is currently reviewing whether it is "appropriate and necessary" to issue the standards in the first place. Do you agree that the EPA should be conducting this review, if so, why?

d. If the EPA determines the agency has not met the "necessary and appropriate" criteria found in Section 112(n), and revokes the Mercury and Air Toxics Rule, what does that mean for all the pollution control technology that has been bought, paid for and running on our power plants helping the industry be in full compliance of the rule?

e. When you were last at the EPA, or after, do you know of any instances when a power plant bought and installed air control technology and decided not to run the technology? If so, please explain the instance. Please include in your explanation if there were any impacts to downwind states or to air pollution levels.

If confirmed, I likely will be involved in assessing the question of how to appropriately respond to the US Supreme Court's remand of the MATS "appropriate and necessary" determination. I cannot prejudge the outcome of that assessment. I will note that MATS imposed substantial costs on electric power generators. The fact that power prices have declined in recent years does not necessarily mean that MATS did not impose substantial incremental costs.

39. In a 2016 Law 360 article, you are quoted as saying, "The reason this [the Mercury and Air Toxics Standards Rule] was such a big issue for us is because by EPA's own analysis, if you look at the benefits generated by the hazardous air pollutant reductions this rule would achieve, the costs vastly outweigh the benefits. So from our perspective, it's a regulation that made no sense and wasn't justified."[18] In April 2017, the EPA asked the D.C. Circuit Court of Appeals to delay oral arguments scheduled the Mercury and Air Toxics Standards (MATS) as it reviews the rule.

[17] http://www.bcse.org/wp-content/uploads/2017-Sustainable-Energy-in-America-Factbook-Executive-Summary.pdf
[18] https://www.law360.com/articles/742955/environmental-group-of-the-year-hunton-williams

a. It is clear from this statement you already have a formed view of the validity of the Mercury and Air Toxics Standard going into the agency. Will you commit to this Committee that you will recuse yourself from the review and any possible rewriting of the Mercury and Air Toxics Rule? If not, why not?

b. Do you continue to believe the Mercury and Air Toxics Standards is a regulation that made no sense and wasn't justified? If so, why?

The quantifiable monetized benefits of the HAP reductions predicted to occur under MATS measured only a few million dollars. I understand that EPA has recalculated the benefits attributable to MATS in response to the Supreme Court remand. I am not familiar with the new estimates. If confirmed, I intend to consider them objectively.

40. Will you commit, that if confirmed, you will not act to weaken the Mercury and Air Toxics Standards, if not, why not?

I cannot prejudge any decision that might be made by EPA if I am confirmed.

41. This year, you represented the American Petroleum Institute as an intervenor in defense of Administrator Pruitt's 90-day stay of oil and gas pollution standards, which the D.C. Circuit found violated the Clean Air Act. In my office, you refused to recuse yourself from participating in this rule, is that still true and how do you justify that, if confirmed, you will come into the EPA as impartial regulator as it relates to this issue? Do you agree with the court's decision, and why not?

Comprehensive rules of ethics govern the transition from private practice to government service. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

42. Section 109 of the Clean Air Act is very clear. It requires EPA to review the NAAQS for six common air pollutants including ground-level ozone, particulate matter, sulfur dioxide, nitrogen dioxide every 5 years. The Clean Air Act requires EPA to set these standards that "are requisite to protect the public health," with "an adequate margin of safety," and secondary standard necessary to protect public welfare.

a. If confirmed, will you continue to hold to the five-year National Ambient Air Quality Standards review time period that the Clean Air Act requires of the EPA?

b. The science was clear that the 2008 ozone standard was not protecting public health, so EPA was required to Act. Is that not your understanding of the Clean Air Act?

c. If confirmed, will you commit to not further delay the implantation of the 2015 ozone NAAQS? If not, why not?

d. Do you agree with Justice Scalia's opinion in Whitman v. American Trucking Associations that it is "fairly clear that [the Clean Air Act] does not permit the EPA to consider costs in setting the standards" and if so, will you commit not to include consider costs when setting the National Ambient Air Quality Standards? If you do not agree, why not?

If confirmed, I will endeavor to meet all statutory deadlines. I am not familiar with the record for the 2015 ozone NAAQS decision, so cannot comment on the decision to change the standard. I respect all US Supreme Court decisions.

43. In 2006, while you served as Acting Assistant Administrator for Air, the EPA proposed to eliminate lead as a criteria pollutant under the Section 109 Clean Air Act National Ambient Air Quality Standard (NAAQS) process. Did you have any involvement in this proposal? If so, please explain.

Yes, I was involved in developing that proposal. CAA § 108(a)(1)(B) states that ambient levels of a criteria pollutant should "result[] from numerous or diverse mobile or stationary sources." Information at the time indicated that there were few industrial sources of lead emissions and that lead emissions from mobile sources had been virtually eliminated. The proposal asked for comment on whether lead continued to meet the § 108(a)(1)(B) criterion.

44. Like you, I am an avid runner. In Delaware during the summer, we often have code orange days warning about the high levels of ozone for that day. Much of Delaware's ozone pollution is coming across the state boundary from upwind states.

a. Can you describe how high levels of ozone could damage my lungs if I were to take a long run during a code orange day?

b. Do you agree that ground-level ozone is a dangerous pollutant that causes respiratory and cardiovascular harm? If not, on what basis do you disagree?

c. If confirmed, how would you direct states to work together to reduce ozone pollution?

Inhaling too much ozone can cause a wide range of adverse cardiovascular effects. CAA §§ 110(a)(2)(D) and 126 are designed to address interstate transport (i.e., emissions from upwind states that significantly contribute to downwind nonattainment).

45. Clean Air Act section 110(a)(2)(D)(i)(I), also known as the "Good Neighbor" provision, requires that state implementation plans to address air pollution "contain adequate provisions prohibiting, consistent with the provisions of this subchapter, any source or other type of emissions activity within the State from emitting any air pollutant in amounts

which will contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any such national primary or secondary ambient air quality standard." Under this provision of the Clean Air Act, "[w]henever the Administrator finds that the applicable implementation plan for any area is substantially inadequate . . . to mitigate adequately [] interstate pollutant transport . . . or to otherwise comply with any requirement of this chapter, the Administrator shall require the State to revise the plan as necessary to correct such inadequacies."

a. Do you support the "Good Neighbor Provision" in the Clean Air Act and agree that this provision does not "encroach upon state sovereignty"? If not, why?

b. If confirmed, do you commit to fully apply and enforce the Good Neighbor provision?

CAA § 110(a)(2)(D) describes one of many elements that must be included in an approval State Implementation Plan. My hope is that more states address this obligation in the first instance so that US EPA does not need to make findings of substantial inadequacy. If confirmed, my goal is to faithfully implement all aspects of the Clean Air Act.

46. Currently, under the Clean Air Act section 110(a)(2)(D)(i)(I), also known as the "Good Neighbor" provision, Delaware has sent four petitions to the EPA that identify facilities in other states that are emitting air pollution that are significantly contributing to Delaware's air quality and impacting Delaware's ability to maintain or be in attainment for the 2008 national ambient air quality standards (NAAQS) for ozone and the 2015 ozone NAAQS. The petitions are for: 1) Brunner Island facility's electric generating units located near York, Pennsylvania; 2) Homer City Generating Station's electric generating units located in Indiana County, Pennsylvania; 3) Harrison Power Station's electric generating units located near Haywood, Harrison County, West Virginia; and 4) Conemaugh Generating Station's electric generating units located in Indiana County, Pennsylvania. In addition, Maryland has filed a petition that requests EPA make a finding that 36 electric generating units located in the states of Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia are emitting air pollutants that significantly contribute to nonattainment or interfere with maintenance of the 2008 and the 2015 ozone NAAQS in Maryland. The EPA has granted itself six months extension on every petition and has done nothing after that. All of the extensions have long since expired.

a. If confirmed, will you commit to promptly act on Good Neighbor petitions so states, like Delaware and Maryland, can protect their citizens from upwind pollution in neighboring and distant states? If not, why not?

b. If confirmed, will you support, defend and enforce EPA's Good Neighbor provisions to address air pollution that crosses state borders? If not, why not?

c. In some of these situations, like the Harrison Power Station near Haywood in West Virginia, the power plant in question has the needed technology on the

facility to help reduce ozone pollution in downwind Delaware and West Virginia ratepayers are already paying for the technology, but the pollution control isn't running. If confirmed, what will you do to ensure pollution control technology already on facilities runs to ensure downwind states have clean air?

d. If confirmed, will you fully implement the Cross State Air Pollution Rules?

e. If the Mercury and Air Toxics Rule is revoked, do you expect there will be an increase in upwind ozone and particulate pollution and have an impact on downwind states? If so, please explain. If not, why?

I think your question relates to CAA § 126 and not to § 110(a)(2)(D). I am not familiar with the specific petitions described in this question. But, I will note that CSAPR and the CSAPR update rule were intended to address interstate transport under § 110(a)(2)(D), such that there should not be a need or justification for § 126 petitions addressing the same plants, pollutants, and standards. If confirmed, I will endeavor to meet all CAA deadlines and my goal will be to faithfully implement all aspects of the CAA.

47. Just last month, you argued against an Obama Administration Occupational Safety and Health Administration indoor air rule that protects construction workers against silica dust, a type of dust that is linked to cancer and lung disease. During your arguments, you are quoted as saying, "People are designed to deal with dust — people are in dusty environments all the time, and it doesn't kill them," [19]The American Industrial Hygiene Association has stated that delaying the full enforcement of this rule will put – and this is their words, quote "2.3 million workers at greater risk to exposure, especially the construction industry — the backbone of our economy"

a. Please provide the scientific studies that provided the basis for your argument in this case.

b. When you stated "people are designed to deal with dust," what did you mean by that statement?

c. When you were last in the EPA, did you ever work on a rule was deemed later to ignore all of the science dealing with particle matter pollution?

d. Do you agree that there is robust science linking small particle pollution to negative health impacts, even death? If so, why is the science here different than for silica pollution?

The silica case dealt with the unique toxicological properties of silica and not with the pollutant "particular matter" that is regulated by EPA. The quote in this question was taken out of the context of a broader argument related to

[19] https://www.eenews.net/greenwire/stories/1060061731/search?keyword=silica

the question of whether there is an exposure threshold for respirable silica below which significant adverse health effects should not be expected to occur. The silica case remains an active matter and I am not authorized by my clients to say more.

48. Do you agree with President Trump's decision to withdraw the United States from the International Paris Climate Accord? If so, please explain.

President Trump is the Nation's Chief Executive. I believe it was within his authority to withdraw. I respect his decision.

49. In part of his justifications for withdrawing from the Paris Climate Agreement, President Trump stated the Paris Accord could, "cost America as much as 2.7 million lost jobs by 2025 according to the National Economic Research Associates (NERA)."[20] This economic statistic and others linked to the NERA study were also distributed in White House materials as reasons the President was deciding to withdraw from the Paris Accord. Soon after the President's speech, NERA stated, "In a set of talking points distributed by the White House in conjunction with its announcement of the US withdrawal from the Paris Agreement, the Trump Administration selectively used results from a NERA Economic Consulting study, "Impacts of Greenhouse Gas Regulations on the Industrial Sector." ... Use of results from this analysis as estimates of the impact of the Paris Agreement alone mischaracterizes the purpose of NERA's analysis, which was to explore the challenges of achieving reductions from US industrial sectors over a longer term. Selective use of results from a single implementation scenario and a single year compounds the mischaracterization."[21]

    a. In light of the NERA statement, do you think the President misspoke when he wrongly cited information from the NERA study in his Paris speech? If not, why not?

    b. If confirmed, will you commit that you will not distort the NERA study – or any other economic study - to justify the U.S. withdrawing from the Paris Climate Accord or to justify the elimination or delay of climate policies?

    c. After the President's Paris Climate Accord speech, MIT's Joint Program on the Science and Policy of Global Change issued a statement stating the President's characterization of their analysis of the Paris Accord to be misleading.[22] If confirmed, will you commit that you will not distort the climate science studies to justify the U.S. withdrawing from the Paris Climate Accord or to justify the elimination or delay of climate policies?

---

[20] https://www.whitehouse.gov/the-press-office/2017/06/01/statement-president-trump-paris-climate-accord

[21] http://www.nera.com/news-events/press-releases/2017/nera-economic-consultings-study-of-us-emissions-reduction-polici.html

[22] http://news.mit.edu/2017/mit-issues-statement-research-paris-agreement-0602

I am not familiar with the NERA study, so I cannot assess NERA's comments. If confirmed, my goal would be not to "distort" anybody's statements.

50. In a Law360 interview, you were asked, "What is the most challenging case you have worked on and what made it challenging?" You responded, "Without a doubt, it would be Massachusetts v. EPA. I was at the EPA at the time, working as counsel to the assistant administrator for air, Jeff Holmstead."[23] Please explain in detail, what your involvement was while in the EPA regarding regulations that led to, and the agency's defense of the Massachusetts v. EPA case.

There were no regulations that led to the Mass v EPA decision. The decision under review was EPA's denial of a citizen petition asking EPA to regulate GHG emissions from motor vehicles. OAR was responsible in the first instance for preparing the proposed and final denial. OAR staff – including myself – provided support to the government litigation team while the case was pending in the DC Circuit and the US Supreme Court.

[23] https://www.law360.com/articles/427231/q-a-with-hunton-williams-bill-wehrum

Senator Cardin

51. On December 15, 2016, EPA extended by six months the deadlines to respond to petitions submitted by the state of Maryland under section 126 of the Clean Air Act. The petition from Maryland requests that EPA make a finding that 36 electric generating units located in the states of Indiana, Kentucky, Ohio, Pennsylvania, and West Virginia are emitting air pollutants that significantly contribute to nonattainment or interfere with maintenance of the 2008 and the 2015 ozone NAAQS in Maryland. On September 27, 2017, the State of Maryland filed a complaint in the United States District Court of the District of Maryland against the EPA because of the lack of response in regard to the 2016 Good Neighbor petition.

    Will you commit to urge the EPA to approve the petition and enforce the air pollution controls already in place in Maryland at upwind out-of-state facilities that directly impede efforts to attain and maintain federal health-based air quality standards in Maryland?

    I cannot commit at this time to take any action for which I might be responsible if confirmed to be AA for OAR. I will note that CSAPR and the CSAPR update rule were intended to address interstate transport under § 110(a)(2)(D), such that there should not be a need or justification for § 126 petitions addressing the same plants, pollutants, and standards. If confirmed, and if the issues have not yet been resolved, I will look closely at the intersection of Maryland's § 126 petition with the CSAPR rules.

Senator Duckworth:

52. The Renewable Fuel Standard (RFS) program passed Congress with broad bipartisan support and was signed into law by President George W. Bush because it strengthens our nation's energy independence and security. The RFS supports rural communities and American farmers, while reducing greenhouse gas emissions. In my home State of Illinois alone, the RFS has helped create 4000 jobs and more than $5 billion in economic impact.

    I am concerned Administrator Pruitt, who reassured Congress that he would execute the program as Congress intended, will break his promise and implement the law in such a way as to limit or cap the growth in renewable fuels – directly violating the RFS program's statutory goals to increase American energy independence and security through increased production of biofuels. As the U.S. Environmental Protection Agency (EPA) has repeatedly affirmed, any policy that decreases or limits growth in biofuels is inconsistent with the statutory goals that Congress enshrined in the law.

    Do you believe that Congress intended the RFS to promote long-term growth in all biofuels fuels, including cellulosic ethanol? If confirmed, will you commit that EPA will issue Renewable Volume Obligations that increase production of renewable fuels across the board?

    The RFS clearly was intended to promote the growth of a wide range of biofuels, including cellulosic ethanol. I cannot commit at this time to take any action for which I might be responsible if confirmed to be AA for OAR. If confirmed, my intention is to faithfully implement all aspects of the CAA, including the RFS.

53. During your nomination hearing you stated that you will seek guidance from EPA ethics officials on whether or not you should recuse yourself from issues for which you have previously been engaged in. However, as a regulator and a public servant, you can and should use your own discretion on recusal to avoid even the appearance of conflict of interest.

    If confirmed, will you commit to recusing yourself on any issue related to biofuels or the renewable fuels standard given your past work on behalf of industry interests? What other steps will you take to guarantee that your financial and political interests do not influence your work on the RFS?

    Comprehensive rules of ethics govern the transition from private practice to government service. These rules address both real conflicts and appearances of impropriety. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

54. Will you submit for the record a full list describing any action you performed in your professional career related to the RFS program and identify the client or clients on whose behalf you were acting for each action?

I was counsel of record on three cases related to the RFS (principal clients are included in parentheses): (1) a challenge to EPA's E15 waiver (API and the Grocery Manufacturers Association); (2) a challenge to EPA's misfueling mitigation rule (API); and (3) a challenge to Minnesota's B10 mandate (API, the Auto Alliance, the American Fuel and Petrochemical Manufacturers). I also was responsible for RFS implementation during my prior tenure at EPA.

55. The Mercury and Air Toxics Rule, or MATS, is an EPA success story about protecting our most vulnerable – our children. After decades of delayed action, EPA implemented the MATS rule to protect our children and our pregnant women from our country's number one source of unregulated mercury and other air toxic pollution: power plants.

    Today, EPA says very few power plants in the country are not meeting the MATS pollution reduction timelines. Dr. Goldman, a world-renowned epidemiologist, pediatrician and Dean of the School of Public Health at George Washington University, testified earlier this year that we are seeing the public health benefits of MATS faster than predicted. Simply put, compliance for industry has been easier than opponents of this rule predicted and children are better protected than doctors expected – a real win-win that would never have occurred had corporate special interests prevailed in killing this critical public health rule.

    Despite these successes, you continue to lead industry lawsuits against the MATS Rule, falsely claiming that EPA has yet to prove it is appropriate and necessary to regulate mercury and air toxic emissions from power plants, a decision made almost two decades ago. You have argued that the price of our children's mental development is worth less than running pollution control technology that is already bought, paid for and running on our power plants.

    How can you assure us you will be impartial – you will choose our children over industry - when it comes to the Mercury and Air Toxics rule? How can you assure the American public that you will do the right thing to protect the children of Illinois and the children of all Americans?

    This question is premised on two factual inaccuracies. First, I do not "lead industry lawsuits against the MATS Rule." I was not counsel of record in the challenges to MATS and am not counsel of record in challenges to EPA's renewed "appropriate and necessary" finding. Second, industry petitioners in the MATS case did not make "false claims" related to the "appropriate and necessary" finding. In fact, the US Supreme Court determined that that finding was unlawful, which supported the petitioners' claims in this regard. Having said that, I have a deep interest in protecting public health and the environment, including children's health.

56. As you know Administrator Pruitt, like Secretary Zinke and former Secretary Price have spent millions of dollars combined flying on private jets across the country. This is a gross waste of taxpayer dollars.

Yes or no, as a taxpayer, do you approve of Administrator Pruitt's travel practices on the public dime, and will you commit to utilizing commercials flights in your position?

I am not familiar with Administrator Pruitt's or Secretary Zinke's travel history, so cannot speak to this aspect of your question. Should I be confirmed, I intend to utilize commercial flights to carry out my official duties.

Senator Ernst:

57. Administrator Pruitt has made engagement with rural America a priority and he has expressed particular concern over how EPA regulations, such as the Waters of the United States (WOTUS) rule, impact these local communities. In cases like WOTUS, the previous EPA did not fully analyze the costs associated with the regulation, particularly for rural communities. At the same time, the benefits of this rule, and others, were often overstated. How will you work to assure transparency when documenting the costs and benefits associated with EPA actions under your office?

    Costs can be considered in setting some, but not all, Clean Air Act rules. But, even when costs cannot be considered, it is important to prepare a comprehensive regulatory impact analysis so that the full costs and benefits of a rule are known. If confirmed, I will work hard to ensure that costs and benefits are accurately assessed and appropriately considered.

58. At multiple times over the course of your career you have represented clients such as API, GMA and others in cases intended to undermine the RFS. The questions you have argued in those cases are relevant to the current RVO rule making for 2018 and 2019, as well as those statutorily required going forward. Additionally, they are relevant to the regulatory decisions related Reid Vapor Pressure waivers, biofuel pathway approval, and topics you will have oversight of, if confirmed. Given this, will you recuse yourself from RFS rulemaking, administering the program or some portions of the program if confirmed, and if you do, who will administer the RFS?

    I was counsel of record in cases challenging EPA's E15 waiver, EPA's misfueling mitigation rule, and Minnesota's B10 mandate. These cases have all been decided and have no direct bearing on RFS implementation going forward. If confirmed, I do not believe it will be necessary or appropriate for me to recuse myself from RFS matters, although I will continue to work with EPA ethics officials to make sure that I fully comply with my obligations, and my intention is to faithfully implement all aspects of the CAA, including the RFS.

59. If you are confirmed, will you commit to have an open door policy for all interest groups, including those representing biofuels, to ensure that their perspectives are taken into consideration by yourself, the Administrator, and the rest of political leadership at EPA?

    If confirmed, I fully intend to have an open door policy on all issues.

60. Do you believe it is fair and appropriate to use only the input of parties regulated by the Clean Air Act when making regulatory decisions?

    No, many parties that are not subject to EPA's rules are affected by the rules and should have the opportunity for input.

Senator Fischer:

61. Mr. Wehrum, during questioning you stated that you did not have an in depth understanding around the Renewable Fuels Standard (RFS). Were you ever counsel for any clients involved in lawsuits around the RFS or ethanol-blended fuels? Can you state what your role was in that case(s) and who you represented?

    I have worked with the RFS in private practice and in my prior tenure at EPA. I was particularly familiar with the first phase RFS rules that implemented the original RFS that was enacted as part of the 2005 energy bill. The first phase rules were put in place while I was at EPA. OAR was primarily responsible for developing them. I am much less familiar with the second phase RFS program, which implemented the RFS amendments enacted as part of the 2007 energy bill. The cases I handled after leaving EPA dealt with very limited aspects of the RFS including challenges to EPA's E15 waiver, EPA's misfueling mitigation rule, and Minnesota's B10 mandate. These cases have all been decided and had essentially nothing to do with the second phase program nor do they have any direct bearing on RFS implementation going forward. Also, there are a number of recent court decisions more pertinent to EPA's most recent RFS-related actions that I am not familiar including recent case law on EPA's RFS waiver authority that I have not analyzed. I also do not know EPA's view of the recent cases and, more broadly, its current view of its waiver authority.

62. As a follow-up, were you serving in the position you are currently nominated to serve in again during the George W. Bush Administration while the RFS1 was implemented?

    As explained in my response to your first question, the RFS1 rules were developed and implemented during my prior tenure at EPA. I was involved in that effort.

63. Do you plan to recuse yourself from any items on the RFS or ethanol-blended fuels that you litigated on while in private practice?

    I was counsel of record in cases challenging EPA's E15 waiver, EPA's misfueling mitigation rule, and Minnesota's B10 mandate. These cases have all been decided and have no direct bearing on RFS implementation going forward. If confirmed, I do not believe it will be necessary or appropriate for me to recuse myself from RFS matters, although I will continue to work with EPA ethics officials to make sure that I fully comply with my obligations, and my intention is to faithfully implement all aspects of the CAA, including the RFS.

Senator Markey:

Mr. Wehrum, because of the Landmark 2007 Supreme Court ruling in Massachusetts v. EPA the EPA made a finding that carbon pollution poses a danger to America, known as the endangerment finding. This ruling made it possible for states like California and Massachusetts to use their Clean Air Act Authority to set higher fuel economy emissions standards for vehicles. State action combined with my 2007 fuel economy law, resulted in an auto industry approved increase of the fuel economy emissions standards to 54.5 miles per gallon by 2025. Those standards will save nearly 2.5 million barrels of oil a day by 2030, are the single largest step any nation has taken to reduce global warming pollution and will save consumers more than $1 trillion. And the auto industry has added 700,000 new jobs since these standards began to take effect.

Administrator Pruitt in his confirmation hearing before this Committee stated that the Endangerment Finding "needs to be enforced and respected." Administrator Pruitt also said earlier this year that "the Clean Air Act focused on mobile sources over the last several years I think has made a substantial difference with respect to GHG and CO2."

64. Mr. Wehrum, yes or no, do you agree with Administrator Pruitt that the endangerment finding needs to be enforced and respected?

    I have not discussed the endangerment finding with Administrator Pruitt, so I do not know his current views on the topic.

65. Mr. Wehrum, yes or no, do you support EPA's continued regulation of greenhouse gases from cars under the Clean Air Act?

    I believe that primary responsibility for regulating fuel economy belongs to the Department of Transportation. I believe that it is important for EPA to harmonize its actions with those of DOT.

Senator Merkley:

66. If you are confirmed as the Assistant Administrator of EPA's Office of Air and Radiation, you will be responsible for implementing the Clean Air Act, which, according to the Supreme Court in *Massachusetts vs EPA,* EPA has the authority to regulate greenhouse gases. Therefore, your understanding of the most basic principles of climate change science will be essential to your role in the regulation of greenhouse gases. In the Intergovernmental Panel on Climate Change's 5th Assessment Report, entitled, "Climate Change 2014 Synthesis Report Summary for Policymakers" (found here: http://www.ipcc.ch/pdf/assessment-report/ar5/syr/AR5_SYR_FINAL_SPM.pdf) the finding under "SPM1" that is labeled "{1}" (note that the labels {x} immediately follow the findings they refer to), states "Human influence on the climate system is clear, and recent anthropogenic emissions of greenhouse gases are the highest in history. Recent climate changes have had widespread impacts on human and natural systems. {1}". Do you agree with that finding?
    a. If you do not agree with this finding, please explain why, and provide at least one peer reviewed study supporting your stated position.

       I believe that the climate is changing and that manmade emissions are contributing to the change. I believe that amount attributable to manmade emission is not currently known with certainty. The IPCC quote is not inconsistent with these views.

67. In that same report, the finding under "SPM 1.1" labeled "{1.1} states "Warming of the climate system is unequivocal, and since the 1950s, many of the observed changes are unprecedented over decades to millennia. The atmosphere and ocean have warmed, the amounts of snow and ice have diminished, and sea level has risen. {1.1}." Do you agree with that finding?

    a. If you do not agree, please explain why, and provide at least one peer reviewed study supporting your stated position.

       I believe that the climate is changing, as is suggested by the quote.

68. In that same report, the finding under "SPM 1.2" labeled "{1.2, 1.3.1}" states "Anthropogenic greenhouse gas emissions have increased since the pre-industrial era, driven largely by economic and population growth, and are now higher than ever. This has led to atmospheric concentrations of carbon dioxide, methane and nitrous oxide that are unprecedented in at least the last 800,000 years. Their effects, together with those of other anthropogenic drivers, have been detected throughout the climate system and are *extremely likely* to have been the dominant cause of the observed warming since the mid-20th century." Do you agree with this finding?

a. If you do not agree with this finding, please explain why, and provide at least one peer reviewed study supporting your stated position.

I believe that the climate is changing and that manmade emissions are contributing to the change. I do not know what is meant by "other anthropogenic drivers." If confirmed and as necessary, I can delve into this question.

69. In that same report, the finding under "SPM 2" labeled "{2}" states "Continued emission of greenhouse gases will cause further warming and long-lasting changes in all components of the climate system, increasing the likelihood of severe, pervasive and irreversible impacts for people and ecosystems. Limiting climate change would require substantial and sustained reductions in greenhouse gas emissions which, together with adaptation, can limit climate change risks. {2}". Do you agree with this finding?

a. If you do not agree with this finding, please explain why, and provide at least one peer reviewed study supporting your stated position.

It is my understanding that domestic reductions in greenhouse gas emissions, such as those accomplished by EPA's current regulatory programs, are projected to have little effect on predicted climate change.

70. In that same report, the finding under "SPM 3" labeled "{3.2, 3.3, 3.4}" states "Adaptation and mitigation are complementary strategies for reducing and managing the risks of climate change. Substantial emissions reductions over the next few decades can reduce climate risks in the 21st century and beyond, increase prospects for effective adaptation, reduce the costs and challenges of mitigation in the longer term and contribute to climate-resilient pathways for sustainable development. {3.2, 3.3., 3.4}". Do you agree with this finding?

a. If you do not agree with this finding, please explain why, and provide at least one peer reviewed study supporting your stated position.

It is my understanding that domestic reductions in greenhouse gas emissions, such as those accomplished by EPA's current regulatory programs, are projected to have little effect on predicted climate change.

71. In that same report, the finding under "SPM 3.2" labeled "{3.2, 3.4} states "Without additional mitigation efforts beyond those in place today, and even with adaptation, warming by the end of the 21st century will lead to high to very high risk of severe,

widespread and irreversible impacts globally (high confidence). Mitigation involves some level of co-benefits and of risks due to adverse side effects, but these risks do not involve the same possibility of severe, widespread and irreversible impacts as risks from climate change, increasing the benefits from near-term mitigation efforts. {3.2, 3.4}". Do you agree with this finding?

a. If you do not agree with this finding, please provide at least one peer reviewed study supporting your stated position.

The Trump Administration has announced its intent to reconsider the so-called "social cost of carbon," which is an estimate of the benefit associated with each ton of GHG emissions reduced. That work is directly related to the topic of this question. If confirmed, I likely will be involved in this effort. It is inappropriate for me to prejudge the outcome of this effort.

72. In that same report, the finding under "SPM 4" labeled "{4} states "Many adaptation and mitigation options can help address climate change, but no single option is sufficient by itself. Effective implementation depends on policies and cooperation at all scales and can be enhanced through integrated responses that link adaptation and mitigation with other societal objectives. {4}". Do you agree with this finding?

a. If you do not agree with this finding, please explain why, and provide at least one peer reviewed study supporting your stated position.

To the degree manmade GHG emissions are contributing to climate change, I believe that emissions worldwide are contributing.

73. What are the annual emissions of greenhouse gases from power plants in the United States?

a. Are power plants one of the largest sources of greenhouse gas emissions?

I do not know the current level of GHG emissions from domestic power plants. Yes, they collectively are one of the largest domestic sources of manmade GHG emissions.

74. Mr. Wehrum, in your testimony, you said that human's contribution to climate change is "an open question". Please name which of these major scientific organizations have stated that human activity is the major driver of climate change.

The American Association for the Advancement of Science (AAAS)
American Chemical Society

American Geophysical Union;
American Institute of Biological Sciences;
American Meteorological Society;
American Public Health Association;
American Society of Agronomy;
American Society of Ichthyologists and Herpetologists;
American Society of Naturalists;
American Society of Plant Biologists;
American Statistical Association;
Association for the Sciences of Limnology and Oceanography;
Association for Tropical Biology and Conservation;
Association of Ecosystem Research Centers;
BioQUEST Curriculum Consortium;
Botanical Society of America;
Consortium for Ocean Leadership;
Crop Science Society of America;
Ecological Society of America;
Entomological Society of America;
Geological Society of America;
National Association of Marine Laboratories;
Natural Science Collections Alliance;
Organization of Biological Field Stations;
Society for Industrial and Applied Mathematics;
Society for Mathematical Biology;
Society for the Study of Amphibians and Reptiles;
Society of Nematologists;
Society of Systematic Biologists;
Soil Science Society of America;
University Corporation for Atmospheric Research.

My statement was not based on the views of these groups.

75. Mr. Wehrum, in your testimony, you declined to comment on the graphs I presented depicting the natural forces on observed temperature, and of greenhouse gases on observed temperature, saying you would need to see the underlying data. This website provides a clear presentation of the data, https://www.bloomberg.com/graphics/2015-whats-warming-the-world/, as well as an explanation of the methodology for these charts, including links to the models and data. Now that you have the time to review the methodology and data, can you please provide your own interpretation of these data sets?

    a. Do you agree with NASA's finding that human activity is the primary driver of climate change as shown by these data sets?

b. If you do not agree with NASA's finding from these data sets that human activity is the primary driver of climate change, please explain, in detail, your critiques of these data sets, and please cite at least one peer reviewed study that informs your critique.

Given the short schedule provided for responding to these questions, and given the substantial number of complex questions, I have not had time to further investigate your graphs or the data used to prepare the graphs.

76. You responded to my question about ocean acidification with the response that you are familiar with the "allegation of ocean acidification." The definition of allegation, according to Merriam-Webster, is "1. The act of alleging something", where "alleging" means "to assert without proof or before proving", and "2. A positive assertion especially of misconduct", and "3. An assertion unsupported and by implication regarded as unsupportable". Given that NOAA has directly measured changes in the pH of the oceans, showing that ocean water has become more acidic over time, do you believe that "ocean acidification" is an assertion "without proof"?

a. If you believe ocean acidification is an allegation, do you doubt scientists' ability to measure the pH of water?

b. If you do not believe that "ocean acidification" is an assertion "without proof", then will you retract your use of the word "allegation" to describe ocean acidification?

c. Scientists from both NOAA and the EPA have published information and data sets on ocean acidification, found here: https://www.epa.gov/ocean-acidification and here: https://pmel.noaa.gov/co2/story/A+primer+on+pH Can you please describe both NOAA and EPA's conclusion on the causes of ocean acidification?

d. In your testimony, you said you would defer to EPA scientists and career staff on matters of science. Will you defer to EPA career staff on the science of climate change and ocean acidification?

e. Please describe your current understanding of ocean acidification in detail, and provide at least one peer reviewed study supporting your stated position.

Given the short schedule provided for responding to these questions, and given the substantial number of complex questions, I have not had time to

review the sources to which you refer in this question. I have high regard for EPA career staff and executives. If confirmed, I will consider their views and advice very carefully on all matters, including climate change and ocean acidification.

77. In a recent public disclosure of Administrator Pruitt's calendar of meetings, less than 3% of his meetings were with public health and environmental advocacy organizations, whereas over 25% of his meetings were with industry representatives. Do you believe this reflects fair and balanced input from public health and environmental advocacy organizations?

I am not familiar with Administrator Pruitt's schedule, so I cannot comment on it.

78. Will you commit to a fair and balanced ratio of input from public health and environmental advocacy organizations?

Many parties that are not subject to EPA's rules are affected by the rules and should have the opportunity for input. I fully intend to have an open door policy on all issues.

Senator Sanders:

Climate Change

79. President Trump has suggested in the past that climate change is a hoax. Is the President correct? Is climate change a hoax?

    I believe that climate change is real and human activity contributes to climate change.

80. Do you agree with the vast majority of scientists that climate change is real, is caused by human activity, and that we must aggressively transition away from fossil fuels and toward energy efficiency and sustainable energy like wind, solar, and geothermal?

    I believe that climate change is real and human activity contributes to climate change.

81. Do you agree with the vast majority of scientists that the combustion of fossil fuels contributes to climate change?

    Yes, the combustion of fossil fuels results in GHG emissions, which contribute to climate change.

82. If confirmed, what will you do to ensure that OAR addresses climate change?

    If confirmed, I will faithfully implement the Clean Air Act, including authorities related to GHGs and climate change.

Background

83. As a lobbyist with Hunton and Williams, you have represented a host of fossil fuel and chemical companies in lawsuits, some of which are still active, against the EPA. If confirmed, you would be in charge of making sure that these industries install necessary pollution control technologies and conduct waste cleanup.

    As Assistant Administrator for the Office of Air and Radiation, would you have any active conflicts of interests with these companies? If so, will you commit to recuse yourself for the full course of any matter in which any of your former clients is a party? If not, why not?

    Comprehensive rules of ethics govern the transition from private practice to government service. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

84. While serving as Assistant Administrator for the Office of Air and Radiation under President Bush, you attempted to roll back environmental protections under the Clean Air Act. These rollback attempts were eventually defeated in the Supreme Court. If confirmed, will you commit to carrying out the Office of Air and Radiation's obligations under the

law, including as decided by the Supreme Court?

If confirmed, I will faithfully implement the Clean Air Act, including as construed by the US Supreme Court.

85. In your past career, you have brought suit against the EPA for its enforcement of the Clean Air Act. Can you explain why federal courts should be in the position of determining safe levels of pollution to protect the health and welfare of Vermonters, as opposed to the federal Agency whose mission it is to protect human and environmental health?

Separation of powers is a core principle embedded in the US Constitution. As applied here, US EPA has been authorized by Congress to implement the national environmental laws. The role of the courts is to determine if EPA has fulfilled its legal obligations.

Science

86. At the EPA, science provides the foundation for Agency policies, actions, and decisions made on behalf of the American people. What should the role of science be in the development of EPA policies, rules, and regulations?

As you say, science provides the foundation for many agency policies, actions, and decisions. EPA's role is to apply science and other relevant information in implementing the law.

Most Pressing Challenges

87. In your opinion, what are the most pressing air quality challenges that deserve the attention of the EPA? What will you do at the EPA to better address these challenges?

Full implementation of the CAA § 112 air toxics program is one of the most pressing and difficult challenges facing OAR. If confirmed, this would be a priority for me and my staff.

Environmental Regulations

88. If confirmed, do you commit to upholding the goal of the Clean Air Act, which according to the EPA website is "to address the public health and welfare risks posed by certain widespread air pollutants"?

Yes.

89. The EPA has adopted many cost-effective safeguards in the past eight years that would significantly reduce the pollution that contributes to asthma in children. If confirmed, will you commit to addressing threats from air pollution to America's children?

Yes, protecting the public health requires consideration of susceptible subpopulations, such as children.

Environmental Justice

90. If confirmed, will you commit to addressing the growing environmental and economic justice issues associated with air quality?

If confirmed, I commit to working with you to promote public health and equal application of the law for all Americans.

91. If confirmed, will you commit to addressing issues of environmental justice in Native American communities and offer a voice to those most affected by the environmental consequences of industrialization, especially in regard to resources protected by treaties?

If confirmed, I commit to working with you to promote public health and equal application of the law for all Americans, including Native Americans.

92. Latino children are twice as likely as non-Latino white children to die from asthma while, from 2012-2014, African American children had a death rate ten times that of non-Latino white children. African American children are three times as likely to suffer an asthma attack.

As Assistant Secretary of Air, will you commit to ensuring that vulnerable low-income communities and communities of color are protected from the harmful impacts of air pollution?

If confirmed, I commit to working with you to promote public health and equal application of the law for all Americans, including low-income communities and communities of color.

Senator Whitehouse:

93. You have been leading the fight against EPA air standards so it's unclear to me how you're capable of serving in this position consistent with the requirements of Executive Order 13770, "Ethics Commitments by Executive Branch Employees," otherwise known as the Trump ethics pledge. The pledge prohibits appointees from "participat[ing] in any particular matter involving specific parties that is directly and substantially related to [their] former employer or former clients" for the first two years after their appointment. Your ethics agreement states you intend to sign the pledge. We are aware of dozens of separate air cases you've worked on for clients regulated by EPA during your time at Hunton & Williams. Further, your law firm has performed millions of dollars worth of lobbying for Exxon Mobil, Koch Companies, Southern Company, and several other companies regulated by EPA.

    a) To ensure compliance with the pledge, please provide for the record all of Hunton & Williams clients, cases, regulatory matters, and issues/legislation on which its lobbied from the past two years, noting all clients with whom you've worked, cases on which you've worked, regulatory work you've done, and any issues/legislation on which you've lobbied.

    b) Your financial disclosure or 278 form does not require disclosure of pro bono work. For the past two years, please provide a list of all Hunton & Williams pro bono work, including the clients, cases, regulatory matters, and lobbying, noting all pro bono clients with whom you've worked, pro bono cases on which you've worked, pro bono regulatory work you've done, and pro bono lobbying you've preformed.

    I do not have a list of all particular matters involving specific parties in which Hunton & Williams is a party or represents a party. If confirmed, I intend to ascertain Hunton's involvement on a case-by-case basis before becoming involved in any particular matter involving specific parties. With regard to pro bono, for the past two years I have done work on state "freedom of information act" laws for a non-profit charitable organization. Please see attachment 1.

94. Your ethics statement suggests to me that you will be seeking waivers to ethics requirements. You may be allowed to seek a waiver, which I find troubling given your extensive history attacking clean air regulations on behalf of companies regulated by EPA.

    a. Please identify all particular matters which you believe at this time may require you to seek a waiver.

    b. For each of these matters, please state why it would be in the public interest to grant you a waiver.

    c. For any matters that you have not identified in response to this question, will you commit to not seeking a waiver from ethics requirements?

I do not have current plans to seek waivers.

95. Through documents produced from Oklahoma Open Records Act requests, we also know that Hunton & Williams staff worked with industry in key states to get other state Attorneys General on a comment letter Pruitt was leading to EPA opposing the carbon pollution standards for new power plants. Hunton & Williams staff also worked with Pruitt's staff to discuss who to approach about signing on, and coached them on how and when to submit the comments. Which client or clients did Hunton and Williams bill for this work?

The client(s) has not authorized me to disclose this information.

96. According to a separate set of documents, some of which are marked "confidential", Hunton & Williams arranged a Summit on Federalism and the Future of Fossil Fuels convened by then-Oklahoma Attorney General Pruitt, sponsored by the George Mason School of Law's Law & Economics Center. Which client or clients did Hunton and Williams bill for this work?

The client(s) has not authorized me to disclose this information.

97. Hunton & Williams, directly contributed to Scott Pruitt's campaign in 2010 and contributed over $200,000 to RAGA and RAGA's predecessor organization, the Republican State Leadership Committee during Scott Pruitt's time as board chair and on the executive committee.

    a. Between November 1, 2011 and February 17, 2017, how much have you or Hunton & Williams contributed to the Rule of Law Defense Fund (RLDF)?

    b. While Scott Pruitt was Attorney General of Oklahoma, what, if any, fundraising events for Scott Pruitt did you attend?

    c. While Attorney General of Oklahoma, did Scott Pruitt ever solicit money from you or Hunton & Williams for his campaign, his Oklahoma Strong or Liberty 2.0 PACs, RAGA, or the RLDF?

    d. If yes, please describe each solicitation and how much you and Hunton & Williams contributed as a result of each solicitation.

    e. Please provide a list of all RAGA or RLDF contributions, calls, meetings, events, or activities of yours or Hunton & Williams since November 1, 2011 and February 17, 2017.

    I have not contributed to or been involved with RLDF, Administrator Pruitt's campaigns or PACs, or to RAGA. Hunton & Williams' political contributions are a matter of public record.

98. Please describe any role you or Hunton & Williams played in the establishment of or financial contributions to America Rising, America Rising Squared, Protecting America Now, and any other organizations that funded efforts to get Scott Pruitt confirmed as EPA Administrator.

I played no role in any of these efforts or organizations. I am not aware that anyone from Hunton was involved.

99. EPA Administrator Pruitt recently told CNBC that "I would not agree that [carbon dioxide's] a primary contributor to the global warming that we see." Based on the scientific findings from experts such as NOAA and statements on EPA's website, including "Carbon dioxide is the primary greenhouse gas that is contributing to recent climate change," Politifact determined that statement to be false. Do you agree with Administrator Pruitt or scientific experts regarding whether carbon dioxide is the primary greenhouse gas that is contributing to climate change?

I believe the degree to which manmade GHG emissions are contributing to climate change has not been conclusively determined.

100. In 2009, as mandated by the Supreme Court and backed by a robust scientific and technical review, the Environmental Protection Agency produced the Endangerment and Cause or Contribute Findings for Greenhouse Gases (GHGs) under Section 202(a) of the Clean Air Act. It found six greenhouse gases - carbon dioxide, methane, nitrous oxide, hydrofluorocarbons, perfluorocarbons, and sulfur hexafluoride - "taken in combination endanger both the public health and the public welfare of current and future generations."

    a. Do you agree with the EPA's endangerment finding? Why or why not?

    b. Do you commit to not take any steps to narrow the scope or otherwise weaken the endangerment finding?

    I have not read the endangerment finding or the record prepared in support of the finding. Therefore, I currently do not have a view. Otherwise, I cannot prejudge any decision that might be made by EPA if I am confirmed.

101. Four Republican former EPA Administrators – Bill Reilly, Bill Ruckelshaus, Lee Thomas, Governor Christine Todd Whitman – testified before EPW that climate change is real and EPA has clear authority under the Clean Air Act to curb carbon dioxide?

    a. Do you agree that climate change is real?

    b. Do you agree that EPA has authority under the Clean Air Act to reduce carbon dioxide?

I agree that climate change is real and that EPA has limited authority under the CAA to regulate carbon dioxide emissions.

102. Industry frequently talks about compliance costs while ignoring the costs to people harmed by the effects of pollution. In Rhode Island these effects cannot be ignored as we see them through bad air days and other problems. Because Rhode Island ozone air quality issues are largely due to transported emissions from upwind states leading to ozone formation that pollutes the air and lungs of people in downwind states like mine. Over the past two years in Rhode Island, the 8-hour standard ozone standard exceeded 0.07 ppm 10 times in 2015 and 6 times in 2016.

    a. With respect to ozone, do you believe EPA should look at only the costs to industry when undertaking its regulatory impact analysis?

    b. Should the costs to families, such as children sent to emergency rooms due to asthma attacks triggered by smog, be included in the analysis?

    c. If so, should those costs be given a different weight than those claimed by industry?

    Costs can be considered in setting some, but not all, Clean Air Act rules. But, even when costs cannot be considered, it is important to prepare a comprehensive regulatory impact analysis so that the full costs and benefits of a rule are known. If confirmed, I will work hard to ensure that costs and benefits are accurately assessed and appropriately considered.

103. Ozone levels in RI are strongly affected by the transport of pollutants emitted in upwind states into RI. Although RI is currently designated as an unclassifiable/attainment area for the ozone NAAQS, monitored ozone levels in the state still exceed the standard on a number of days in the summer months because of out of state pollution.

    a. What, if any steps, have you taken in your career to help reduce the transport of pollution from upwind states into downwind states like Rhode Island?

    b. If confirmed, what steps will you take to address the transport of pollutants emitted in upwind states that contribute to exceedances of the ozone standard in RI and other downwind states?

    The "Clean Air Interstate Rule" was issued during my prior tenure at EPA. It was designed to address "interstate transport" (including into the State of Rhode Island) under the authority of CAA § 110(a)(2)(D). If confirmed, I intend to faithfully implement the Clean Air Act, including the interstate transport provisions.

104. According to EPA, 49% of coal units lack the most advanced NOx controls (Selective Catalytic Reduction systems or SCR). Several units that have SCR or other NOx emission control technology installed are not optimizing their use. For example, these six coal units have SCR installed but are not using it to optimize NOx reductions. In 2015, these facilities' NOx emissions were significantly higher than 2009 because they are not using the systems they have in place to reduce NOx.

Facilities with Increasing NOx

Facility	NOx Emission Increase	NOx Rate Increase
Harrison Power Station, West Virginia	13,139 tons (277%)	0.22 lb/mmBtu (220%)
Keystone, Pennsylvania	10,594 tons (285%)	0.22 lb/mmBtu (296%)
Pleasants Power Station, West Virginia	8,734 tons (341%)	0.24 lb/mmBtu (284%)
Homer City, Pennsylvania	7,522 tons (72%)	0.20 lb/mmBtu (107%)
Montour, Pennsylvania	5,889 tons (109%)	0.24 lb/mmBtu (207%)
St. Johns River Power, Florida	4,262 tons (60%)	0.23 lb/mmBtu (142%)

a. Why would this be the case?

b. Do you think these facilities should be required to keep on their NOx controls on?

I am not familiar with these particular power plants and do not know why they emit at the levels you report.

105. EPA's independent science advisers, leading medical groups like the American Medical Association, American Academy of Pediatrics, American Thoracic Society, American Lung Association, American Heart Association, and leading public-interest groups such as the NAACP called for a 60 ppb standard instead of the 70 ppb standard EPA finalized last year.

a. What do you believe is a health-protective standard for ozone?

b. Do you agree that one of the goals of the Clean Air Act is to set NAAQS standards to address the public health and welfare risks of NAAQS pollutants?

c. When considering setting NAAQS limits, should cost be considered?

I am not familiar with the current science on the health effects of ozone, so I cannot comment on your question as to the appropriate level of the standard. The US Supreme Court has ruled that cost may not be considered in determining the level of a NAAQS and that a primary standard should be set at the level "requisite" to protect public health with an adequate margin of safety. I respect the court's decision.

106. According to the EPA, it has been estimated that the Clean Air Act has a history of reducing air pollution, while creating jobs. Since 1970 aggregate emissions of common air pollutants dropped 72 percent, while the U.S. gross domestic product grew 219 percent. Total private sector jobs increased by 101 percent over the same period. In 2020, EPA

estimates that the standards will create the equivalent of over 104,000 new jobs including 17,000 new jobs building renewable energy facilities and over 78,000 jobs in improving demand-side energy efficiency.

a. Do you agree that regulations under the Clean Air Act since 1970 have helped grow the economy?

b. If not, can you provide your analysis, materials used, and people you solicited to come to this conclusion?

I am not familiar with the EPA analysis that produced these estimates. I believe that some, but not all, CAA-based regulations produce net benefits to the country.

107. How will you separate your history representing polluters in challenging environmental protections to defending EPA's mission of protecting public health and the environment?

Comprehensive rules of ethics govern the transition from private practice to government service. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations.

108. Have you heard anything to suggest that EPA may close or consolidate any Regional Offices? What is your opinion of such a proposal?

I do not know whether this is being considered and do not have an opinion.

109. During previous administrations, senior EPA managers' schedules have been available to the public and Administrator Pruitt recently started releasing his. If confirmed, do you agree to make your schedule available as well?

If confirmed, I will make my calendar available on a timely basis.

110. I found it extremely troubling that when asked about ocean acidification during your confirmation hearing, that you, a chemical engineer, said you were "aware of the allegation." The definition of "allegation" is "a claim or assertion… typically one made without proof." According to the following experts, ocean acidification is real and occurring:

National Academies of Sciences, Engineering and Medicine 2013 Review of the Federal Ocean Acidification Research and Monitoring Plan:
"The world's ocean has already experienced a 30% rise in acidity since the industrial revolution, with acidity expected to rise 100 to 150% over preindustrial levels by the end of this century. Potential consequences to marine life and also to economic activities that depend on a healthy marine ecosystem are difficult to assess and predict, but potentially devastating."

EPA 2016 Report on Climate Change Indicators in the U.S.:
"As the concentration of carbon dioxide in the atmosphere increases, the ocean absorbs more of it. Over the past 250 years, oceans have absorbed about 28% of the carbon dioxide produced by human activities that burn fossil fuels. Rising levels of carbon dioxide dissolved in the ocean negatively affect some marine life, because carbon dioxide reacts with sea water to produce carbonic acid. The increase in acidity changes the balance of minerals in the water and makes it more difficult for corals and plankton to produce the mineral calcium carbonate, which is the primary component of their hard skeletons and shells. Resulting declines in coral and plankton populations can change marine ecosystems and ultimately affect fish populations and the people who depend on them. Signs of damage are already starting to appear in certain areas.

Measurements made over the last few decades have demonstrated that ocean carbon dioxide levels have risen in response to increased carbon dioxide in the atmosphere, leading to an increase in acidity."

NOAA Ocean Acidification Program:
"Ocean acidification is occurring because our ocean is absorbing carbon dioxide from the atmosphere, leading to lower pH and greater acidity. This is causing a fundamental change in the chemistry of the ocean.
Since the industrial revolution, the atmospheric concentration of carbon dioxide has increased from 280 to over 400 parts per million due to the burning of fossil fuels such as coal, gas, and oil, along with land use change. Ocean acidification refers to a change in ocean chemistry in response to the uptake of increasing carbon dioxide (CO_2) in the atmosphere. The world's surface ocean is tightly linked with the atmosphere and absorbs huge amounts of carbon dioxide each year. This exchange, in part, helps to regulate the planet's atmospheric CO_2 concentrations, but comes at a cost for the oceans and life within it; from the smallest, single celled algae to the largest whales. Were it not for ocean uptake of CO_2, atmospheric CO_2 levels would be increasing at an even greater rate than they are now."
NOAA Pacific Marine Environmental Laboratory Carbon Program:

"Since the beginning of the Industrial Revolution, the pH of surface ocean waters has fallen by 0.1 pH units. Since the pH scale, like the Richter scale, is logarithmic, this change represents approximately a 30% increase in acidity. Future predictions indicate that the oceans will continue to absorb carbon dioxide and become even more acidic. Estimates of future carbon dioxide levels, based on business as usual (BAU) emission scenarios, indicate that by the end of this century the surface waters of the ocean could be nearly 150% more acidic, resulting in a pH that the oceans haven't experienced for more than 20 million years."

Do you accept the findings of these experts that:

a. The human-caused increase in atmospheric carbon pollution is directly related to decreases in ocean pH (ocean acidification)?

b. Oceans are currently acidifying at a rate unprecedented in tens of millions of years?

c. Ocean acidification is damaging coral reefs worldwide, important habitats for recreation, tourism, and commercial fishing?

d. Ocean acidification is harmful to marine ecosystems, negatively affecting fish populations and the communities who depend on them?

e. If you do not agree with any of these statements, please identify the evidence, studies, or analyses you are relying upon to justify your position.

Given the short schedule provided for responding to these questions, and given the substantial number of complex questions, I have not had time to review the sources to which you refer in this question.

111. Since 2009, the states participating in the Regional Greenhouse Gas Initiative (RGGI) have seen carbon pollution fall by 18% while their economies grew by 9.2%. Emissions in the other 41 states fell by 4% while their economies grew by 8.8%.

a. Do you agree that RGGI has developed a successful model for growing our states' economies and cutting carbon pollution at the same time?

b. Do you believe funding levels for EPA grant programs that fund state level initiatives to reduce their emissions should remain level, be increased, or be decreased?

The very low allowance prices under RGGI and the similar performance in other states suggest that RGGI is not a driving factor in these statistics. If confirmed, I will manage OAR's programs within the authorities and budget provided by Congress, including STAG grants.

112. EPA operates multiple networks to monitor compliance with the Clean Air Act's National Ambient Air Quality Standards and to track hazardous air pollutants regulated under the act. These networks include, among others, the State and Local Air Quality Monitoring Network, the National Air Monitoring Network (which targets areas of high population density with a variety of air pollution sources), Special Purpose Monitoring Stations (used for short-term studies and other purposes), Photochemical Assessment Monitoring Stations (used to measure pollutants that contribute to ground-level ozone, a harmful air pollutant), and the National Air Toxics Trends Stations.

a. What is your vision for air monitoring?

b. Do you believe funding at EPA for these important monitoring networks should remain level, be increased, or decreased?

c. Under your leadership, will you push for greater inclusion of technology-based tools for compliance monitoring and implementation, including electronic reporting and additional air monitors?

Actual air monitoring data is far preferable to modeling or other forms of estimation. The question of compliance monitoring is primarily the responsibility of the Office of Enforcement and Compliance Assurance, with which I will work closely, if confirmed. With regard to budget, if confirmed, I will manage OAR's programs within the authorities and budget provided by Congress.

113. Section 105 grants provide significant funding to states for implementing the Clean Air Act requirements. EPA is proposing a new formula for how the 105 grants are distributed to each of the regional offices (and subsequently to the states). Region 1, where Rhode Island receives its funding from, will receive a smaller percentage of the total 105 funds under this revised formula. EPA is proposing an implementation approach that would limit regional losses to no more than 2.5% from each region's prior year amount. Region 1 will lose 2.5% for, at least, each of the next five fiscal years and possibly ten years, under this proposed approach. Will you commit to not implementing the new formula until and unless there is sufficient overall funding such that no Region will see reduced funding from the prior year's amount?

If confirmed, I will manage OAR's programs within the authorities and budget provided by Congress, including STAG grants.

114. The Clean Air Act regulates air emissions from stationary and mobile sources, protecting public health and ensuring Americans have safe air to breathe. Concentrated animal feeding operations (CAFOs) may emit air pollutants in high enough quantities to subject them to CAA and other statutory requirements.

a. Do you believe CAFOs pollute the air?

b. Do you believe it is important for EPA, state and local agencies, and the public to know what air quality and health risks are posed by animal feeding operations?

c. Will you commit to ensuring that the law is enforced with regards to CAFOs.

CAFOs emit a number of CAA-regulated air pollutants. CAFOs also are different than most other stationary sources regulated under the CAA. These differences must be carefully considered in crafting any CAA-based regulatory requirements.

115. On September 19, 2017, the EPA Office of Inspector General (OIG) released a report on EPA's attempts to develop reliable emission estimation methods (EEMs) to determine

whether animal feeding operation are subject to or comply with Clean Air Act permit requirements or emission reporting requirements under CERCLA or EPCRA (Report No. 17-P-0396). On June 23, 2017, the Office of Air and Radiation agreed with OIG's recommendations and OIG has accepted its planned corrective actions. If confirmed, do you commit to ensuring EPA fulfills its commitment to implement the actions laid out in OAR's June 23, 2017 letter to OIG?

I am not familiar with the OIG report or OAR's response. If confirmed, I will take time to familiarize myself with these materials and this issue.

116. OIG's September 19, 2017 report (Report No. 17-P-0396) on animal feeding operations cited a lack of EPA agricultural air expertise and committed resources as a factor in delays in developing emission estimating methodologies.

    a. Given President Trump's proposed cuts to EPA's budget, how do you envision implementing the actions agreed to by OAR in Report No. 17-P-0396?

    b. What is your vision for protecting public health by ensuring animal feeding operations are meeting CAA and other statutory requirements?

    I am not familiar with the OIG report, so cannot comment on its findings. In my experience, OAR career staff and executives have ample experience and expertise with agricultural issues, including those arising at CAFOs.

117. Until recently, Carl Icahn served as a special advisor to the President on overhauling regulations. Carl Icahn is also a majority owner of CVR Energy which is an oil refiner that has a compliance obligation under the RFS to blend its oils with renewable fuels. Icahn's company has repeatedly benefited when he has proposed changes to the RFS that would benefit CVR and through speculation in the Renewable Identification Numbers (RINs) market. For example, in February of 2017 Mr. Icahn reportedly presented the White House with draft Executive Order language that would reform the RFS to benefit CVR energy. The same day, CVR's stock value increased by 3.5%, representing a multi-million dollar windfall to Icahn.

    a. Please describe any interactions you've had with Carl Icahn, CVR Energy, Valero, or other entities about the RFS in the past two years.

    b. Do you think it is appropriate for an Administration official like Mr. Icahn to propose making changes to EPA regulations that clearly benefit a company he owns?

    c. If you are confirmed as AA of OAR, and Carl Icahn or CVR Energy approaches you about a matter related to the RFS, do you think would be appropriate to talk with him?

d. Will you commit to not talking with Carl Icahn about the RFS?

I have had no interactions with Carl Icahn, CVR Energy, or Valero on the RFS in the past two years. I do not recall interactions with other entities on the RFS in the past two years, although I occasionally offer implementation advice to clients on the RFS. If confirmed, I fully intend to have an open door policy on all issues, which might include meetings with both proponents and opponents of the RFS.

118. Since July, EPA has submitted two different proposals that would lower the volumes for biodiesel and renewable diesel. Congress told EPA to increase the volumes of biodiesel and renewable diesel, and both the President and Administrator Pruitt have pledged their support for the RFS. How do you explain EPA's actions?

I am not involved in EPA's decisions about RFS implementation, so I cannot explain their current thinking.

119. In your professional career you have specifically worked against the interests of biofuels and have represented the petroleum sector in multiple law suits. As Assistant Administrator how would the biodiesel and renewable diesel industries get a fair hearing from you?

Comprehensive rules of ethics govern the transition from private practice to government service. If confirmed, I will work closely with EPA ethics officials to understand and strictly comply with my ethical obligations. Further, I commit to implementing an open door policy in meeting with all relevant stakeholders within OAR and will work to faithfully implement all aspects of the CAA, including the RFS in an impartial manner.

120. In July, the DC Circuit Court in ACE vs. EPA said, EPA can't use general waive authority to regulate supply under the RFS. Yet in the most recent proposal from EPA, EPA is proposing exactly that and is working to use general waive authority to decrease the volumes based on supply. Clearly we have billions of gallons of biodiesel and renewable diesel that qualify for the program and are ready to be produced here in the United States, in Canada and throughout the world. Isn't EPA setting itself up for another lawsuit?

I am not familiar with EPA's recent RFS proposals or on the Agency's view as to how they relate to the recent court decision.

121. The EPA has signaled its planned rejection of the proposal to change the point of obligation under the law. The Agency has yet to issue a decision. If confirmed, will you finalize and issue the Agency's rejection of this proposal, and if so, when? Have you ever expressed a view on proposals to change the point of obligation and if so, what was it?

I expressed a view on this topic when the RFS1 rules were established during my prior tenure at EPA. At that time, I supported the point of obligation that, then and

now, is contained in the rules. I have not expressed a view on the possibility of changing the point of obligation. I cannot prejudge any decision that might be made by EPA if I am confirmed.

122. On September 26, the EPA issued a Notice of Data Availability that proposed to make significant, substantial changes to its proposed 2018 RVO and provided for a 15-day comment period. NODAs are generally used to provide data and supplement information in the record. In this case, the EPA has proposed to make material changes to its original proposal, offering stakeholders only 15 days to comment on something that, if adopted, would negatively impact the U.S. biodiesel industry and set the stage for unjustified reductions in perpetuity. In your experience, is this a typical use of a NODA, and can you give me another example when the EPA has used a NODA in this manner? Do you believe that 15 days is an appropriate comment period for a proposed rule under the RFS? In your opinion, is inventing a new methodology to justify a pre-determined outcome an appropriate process to apply in EPA rulemakings under the RFS?

I do not know why EPA decided to issue a NODA rather than a supplemental proposal. What matters most is whether interested parties have received adequate notice of a possible rule change. I believe the NODA provided such notice. The CAA does not specify a minimum period for public comments. I know that issuing RVOs takes a lot of work and meeting the annual schedule is always a challenge. A short comment period on a set of narrow issues may be what is needed to keep this rule on schedule.

123. Do you believe methane is a greenhouse gas? What is methane's global warming potential, and from what source does that number come?

Yes, methane is a GHG. When it established NSPS limits on methane for the oil and gas industry, EPA estimated the global warming potential of methane to be 25. *See*, 81 Fed. Reg. 35824, 35827 (June 3, 2016).

124. Is it your understanding that EPA will enforce the methane rule on a case-by-case basis? Please explain how EPA's case-by-case approach to compliance with the Methane Rule is consistent with EPA's "No Action Assurance" policy, which dates back to 1984.

I do not know what it means to "enforce the methane rule on a case-by-case basis." I have no official knowledge of EPA potentially issuing a no-action assurance with regard to aspects of the "Quad Oa" methane rule, nor am I aware that any such document has been issued.

125. Which states have been delegated enforcement authority over the Methane Rule? What oversight and/or assistance will EPA provide these states to ensure that regulated entities are complying with the rule?

I do not know which states have been delegated enforcement authority for the

Methane Rule. When such delegation is made, EPA retains authority to interpret and enforce the rule.

126. What types of reports and notifications should EPA require states with delegated enforcement authority to submit to the agency to ensure that the states are enforcing the methane rule?

The rules (such as they are) that govern delegation appear at 40 CFR Part 60 Subpart A.

127. Administrator Pruitt has been criticized for spending a disproportionate amount of his time meeting with industry and virtually no time with public-interest groups. If confirmed, will you commit to meet with and listen to all parties, including environmental and public health groups, in a balanced fashion?

If confirmed, I fully intend to have an open door policy on all issues.

128. If confirmed, do you commit to notifying the Committee of all of the email addresses you plan to use upon confirmation and within seven days of using a new email address, including any aliases or pseudonyms? Do you commit do conducting all business using official email addresses and other means and to refrain from any mediums that are outside the Freedom of Information Act's reach?

I intend to conduct all official business using my published EPA e-mail address. I do not intend to use my personal e-mail address or any pseudonym.

129. Do you believe the U.S. should remain a party to the United Nations Framework Convention on Climate Change?

The UNFCC is a treaty. The US Department of State has primary responsibility for treaties. I defer to State on this issue.

130. Do you believe the U.S. should remain a party to the Paris Agreement?

The Paris Agreement is an international agreement. The US Department of State has primary responsibility for such matters. I defer to State on this issue.

131. If confirmed, do you commit to providing complete and accurate responses to inquiries from EPW members in a timely fashion.

Administrator Pruitt has made responsiveness to Congress an important priority. The 2800 pages of EPA responses provided to Members of the Environment and Public Works Committee on display at the nomination hearing is a testament to this commitment. Accordingly, I will continue to be a part of EPA's transparent and responsive culture.

132. Do you think there should be a standardized social cost of carbon? Is the social cost of carbon greater than zero dollars per metric ton? If so, what is the most accurate social cost of carbon in 2017 and what is the best way to calculate this number?

EPA develops benefits estimates for many CAA-regulated pollutants. The "social cost of carbon" is a benefits estimate and it would be consistent with EPA practice to develop such a value. I do not know enough about the underlying data to suggest an appropriate value. It is worth noting that the global scale, long lag time, and indirect nature of the effects of GHG emissions make it particularly difficult to develop a reliable benefits estimate, as compared to other CAA pollutants, which have more direct and immediate effects.

133. A 2007 legal challenge prompted the courts to direct the government to further quantify the costs and benefits of a ton of carbon pollution in federal government rulemakings. Specifically, the U.S. Court of Appeals for the 9th Circuit agreed that in quantifying the benefit of cutting carbon pollution but admonished that the value is "certainly not zero."[24] The Court asked National Highway Traffic Safety Administration to do a new rule that addressed this issue. This court decision has led the Bush and Obama Administrations to further refine a value for the SCC. Do you agree with the reasoning in this decision?

    a. If no, please explain why not and how that would affect how you would approach your responsibilities.

    I am not familiar with that decision. As noted above, there are many challenges to developing a reliable benefits estimate for GHGs.

134. In 2009, the Obama administration created an interagency working group (IWG) in an effort to create a governmental value for the social cost of carbon, which based its calculations on peer-reviewed economic models and expert opinions. The models included in their analysis were the Dynamic Integrated Climate-Economy (DICE)[25], Policy Analysis of the Greenhouse Effect (PAGE)[26], Climate Framework for Uncertainty, Negotiation and Distribution (FUND)[27], and World Induced Technical Change Hybrid (WITCH)[28] models. The IWG was comprised of scientists and economists from the Office of Management Budget, the Council for Environmental Quality, the National Economic Council, the EPA, the U.S. Department of Agriculture, Energy, Transportation, and Treasury.

    a. Can you discuss whether you think the models used by the IWG are appropriate and credible tools for calculating the social cost of carbon?

---

[24] *Center for Biological Diversity v. National Highway Traffic Safety Administration*, 508 F.3d 508, U.S. Court of Appeals for the 9th Circuit (2007), available at http://caselaw.findlaw.com/us-9th-circuit/1024716.html.

[25] Dynamic Integrated Climate-Economy model (DICE), http://www.econ.yale.edu/~nordhaus/homepage/dicemodels.htm

[26] Policy Analysis of the Greenhouse Effect (PAGE), http://climatecolab.org/resources/-/wiki/Main/PAGE

[27] The Climate Framework for Uncertainty, Negotiations and Distribution (FUND), http://www.fund-model.org/

[28] World Induced Technical Change Hybrid model (WITCH), http://www.witchmodel.org/

b. Can you comment on whether the IWG was comprised of the right governmental stakeholders and actors?

I am not familiar with the models used by the IWG. I believe it is appropriate to be inclusive in establishing a benefits estimate for GHGs.

135. On March 28, 2017, the President issued a Presidential Executive Order on Promoting Energy Independence and Economic Growth, which disbanded the IWG, withdrew the guidance it issued, and reverted to OMB Circular A-4 of September 17, 2003 (Regulatory Analysis). This in effect requires each agency to estimate the value of changes in greenhouse gas emissions resulting from regulations. Do you believe the regulatory process will be more effective and efficient in the absence of unified guidance on how to monetize the value of changes in greenhouse gas emissions?

Any benefits estimate – even if developed as part of an EPA rule – likely will be developed in coordination and conjunction with other departments and agencies.

136. Part of the social cost of carbon calculation assumes a value for discount rates. The IWG after reviewing past OMB guidance recommended using a 3% discount rate[29].

a. Do you have an opinion on what the discount rate value should be when calculating the social cost of carbon?

b. Scientific research has found that it would be more accurate to use a declining discount rate instead of a fixed one. Do you agree that a declining discount rate would be more accurate?

c. Do you have an opinion on what the discount rate value should be used for inter-generational impacts?

I currently do not have an opinion on the proper discount rate.

137. Do you believe that it is appropriate for a cost-benefit analysis to consider the harm caused in other countries from pollution emitted in the United States?

The CAA has provisions that address international pollution transport. For example, CAA § 179B deals with "international border areas." I believe that international pollution transport and effects should be addressed as specified by the Act.

[29] Interagency Working Group on Social Cost of Greenhouse Gases, *Technical Support Document*, pp. 15–16.

Senator Wicker:

138. As you consider policies at the EPA that affect emissions, will you consider the future uses of biomass in the U.S. as part of the power generation mix? Will you consider and institute policies related to emissions that will allow new market opportunities for American biomass and wood pellet resource?

Biomass is an important domestic source of fuel for power generation. It has been and will continue to be considered as EPA formulates policies and emissions control programs for the power sector.

139. For most of its existence, the ENERGY STAR program has been housed at EPA. Since a 2009 MOU between EPA and DOE, EPA has been administering the voluntary ENERGY STAR program on home appliances.

I am concerned about the proposals to move the ENERGY STAR program for home appliances to DOE. There is the potential that this change could result inefficiencies and lead to additional regulatory burdens. In particular, DOE may not update specifications to incorporate evolving technologies as EPA has through the voluntary program in partnership with stakeholders.

Can you share your perspective on this issue?

ENERGY STAR is a unique and successful program. Its ongoing success highly depends on maintaiuing credible specifications for covered products and services. Responsibility for implementing ENERGY STAR is split between EPA aud DOE. Close coordinatiou is vital to effective program implementation. If confirmed, I intend to make such coordination a priority.

Wehrum – Pending Cases
October 12, 2017

Case Number Title	Party Attorney	Originating Case Number Origin
08-1277 American Petroleum Institute v. EPA	American Fuels & Petrochemical Manufacturers Association; American Petroleum Institute; National Petrochemical & Refiners Association; Western States Petroleum Association	EPA-1 : EPA-73FR35838 Environmental Protection Agency
08-1281 Env. Integrity Project v. EPA	American Fuels & Petrochemical Manufacturers Association; American Petroleum Institute; National Petrochemical & Refiners Association	EPA-1 : EPA-73FR35838 Environmental Protection Agency
09-1332 Kinder Morgan CO2 Co., LP v. EPA	Kinder Morgan CO2 Co., LP	EPA-1 : EPA-74FR56260 Environmental Protection Agency
11-1023 Gas Processors Association v. EPA	Gas Processors Association	EPA-1 : EPA-75FR74458 Environmental Protection Agency
11-1309 American Petroleum Institute, et al v. EPA	American Petroleum Institute; Independent Petroleum Association of America	EPA-1 : EPA-76FR38748 Environmental Protection Agency
12-1208 National Rural Electric Coop. v. EPA	National Rural Electric Cooperative Association	EPA-1 : EPA-77FR10324 Environmental Protection Agency
12-1352 National Rural Electric Cooper v. EPA	National Rural Electric Cooperative Association	EPA-1 : EPA-77FR34830 Environmental Protection Agency
12-1405 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-77FR49490 Environmental Protection Agency
12-1406 Gas Processors Association v. EPA	American Petroleum Institute	EPA-1 : EPA-77FR49490 Environmental Protection Agency
12-1442 American Petroleum Institute, et al v. EPA	11/13/2012 Open American Fuel & Petrochemical Manufacturers; American Petroleum Institute	EPA-1 : EPA-77FR56422 Environmental Protection Agency
13-1063 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-78FR2210 Environmental Protection Agency

13-1108 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-77FR49490 Environmental Protection Agency
13-1233 Conservation Law Foundation, et al v. EPA	National Rural Electric Cooperative Association	EPA-1 : EPA-78FR6674 Environmental Protection Agency
13-1256 Sierra Club, et al v. EPA	American Coke and Coal Chemicals Institute; American Forest & Paper Association; American Iron and Steel Institute; American Wood Council; Biomass Power Association; Chamber of Commerce of the United States of America; Corn Refiners Association; National Association of Manufacturers; National Oilseed Processors; Rubber Manufacturers Association; Southeastern Lumber Manufacturers Association	EPA-1 : EPA-76FR15608 Environmental Protection Agency
13-1289 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-78FR58416 Environmental Protection Agency
14-1199 PSEG Power LLC, et al v. EPA	National Rural Electric Cooperative Association	EPA-1 : EPA-79FR48072 Environmental Protection Agency
14-1267 Georgia-Pacific LLC v. EPA	Georgia-Pacific LLC	EPA-1 : EPA-79FR60898 Environmental Protection Agency
15-1021 Gas Processors Association v. EPA	Gas Processors Association	EPA-1 : EPA-79FR70352 Environmental Protection Agency
15-1044 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-79FR79018 Environmental Protection Agency
15-1197 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-80FR25068 Environmental Protection Agency
15-1473 Gas Processors Association v. EPA	Gas Processors Association	EPA-1 : EPA-80FR64262 Environmental Protection Agency
15-1487 Sierra Club, et al v. EPA, et al	Brick Industry Association	EPA-1 : EPA-80FR65470 Environmental Protection Agency

15-1492 Brick Industry Association v. EPA	Brick Industry Association	EPA-1 : EPA-80FR65470 Environmental Protection Agency
16-1021 Sierra Club, et al v. EPA, et al	American Chemistry Council; American Coke and Coal Chemicals Institute; American Forest & Paper Association; American Iron and Steel Institute; American Wood Council; Biomass Power Association; Coalition for Responsible Waste Incineration; Council of Industrial Boiler Owners; National Association of Manufacturers; National Oilseed Processors Association; Southeastern Lumber Manufacturers Association, Inc.	EPA-1 : EPA-80FR72790 Environmental Protection Agency
16-1033 American Fuel & Petrochemical, et al v. EPA	American Fuel & Petrochemical Manufacturers; American Petroleum Institute	EPA-1 : EPA-80FR75178 Environmental Protection Agency
16-1035 Air Alliance Houston, et al v. EPA, et al	American Fuel & Petrochemical Manufacturers; American Petroleum Institute	EPA-1 : EPA-80FR75178 Environmental Protection Agency
16-1179 Brick Industry Association v. EPA	Brick Industry Association	EPA-1 : EPA-81FR31234 Environmental Protection Agency
16-1270 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-81FR35824 Environmental Protection Agency
16-1271 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-81FR35944 Environmental Protection Agency
16-1345 American Petroleum Institute v. EPA	American Petroleum Institute	EPA-1 : EPA-81FR51102 Environmental Protection Agency
16-1425 Natural Resources Defense Coun v. EPA	American Petroleum Institute	EPA-1 : EPA-77FR49490 Environmental Protection Agency
17-1088 Utility Air Regulatory Group v. EPA	Utility Air Regulatory Group	EPA-1 : EPA-82FR4594 Environmental Protection Agency

Senator BARRASSO. Well, thank you very much and congratulations, Mr. Wehrum.

Mr. Baran, welcome to the Committee.

STATEMENT OF JEFFERY BARAN, (REAPPOINTMENT) COMMISSIONER, U.S. NUCLEAR REGULATORY COMMISSION

Mr. BARAN. Thank you.

Chairman Barrasso, Ranking Member Carper, and members of the Committee, thank you for the opportunity to appear before you today. I am honored to have been nominated to continue my service on the Nuclear Regulatory Commission for another term.

I want to thank my wife, Michelle, and our kids, Mia, Gus, and Max for their love and support. My dad, Marty, also deserves special recognition for the many, many hours of Commission meetings he has watched online. He probably set some kind of record there.

When I was confirmed as a Commissioner almost 3 years ago, I committed to bringing an open minded and collegial approach to the issues that come before the Commission, and I have worked very hard to meet that commitment. My focus has been on crafting thoughtful, balanced, and timely votes after hearing from a broad range of stakeholders. I value the relationships I have formed with my Commission colleagues, the NRC staff, licensees, unions, States, and public interest organizations, and have benefited greatly from their ideas and input.

My frequent visits to nuclear plants and other NRC regulated facilities not only give me an opportunity to view equipment and technologies firsthand; they also give me the chance to hear directly from NRC's resident inspectors, as well as the workers and managers at the sites about their priorities and concerns.

If confirmed, I look forward to continuing to serve with Chairman Svinicki and Commissioner Burns. We work very well together. We don't always agree on policy, but we always have constructive and collegial discussions, and I think that is how the Commission is supposed to work, bringing together people with different backgrounds, perspectives, and experiences, and have them grapple with tough policy issues together. Ultimately, we make sure that important regulatory decisions are carefully and thoroughly considered.

If they are confirmed, I also look forward to working closely with my fellow nominees, Annie Caputo and David Wright.

Several important initiatives are underway at NRC, and I am eager to see them through to their conclusion. If I am confirmed for another term, I will continue to focus on these efforts, including the power reactor decommissioning rulemaking, implementation of post-Fukushima safety enhancements, development of an effective and an efficient licensing framework for advanced reactors, and the pending small modular reactor design review.

Managing the Project Aim reductions while fulfilling NRC's vital mission of protecting public health and safety and the environment is one of the Agency's most significant challenges in the coming years, so ensuring that the Agency has the resources, talent, and leadership to succeed is another top priority for me. I am happy to discuss these or any other issues of interest to members of the Committee in greater detail today or in the future.

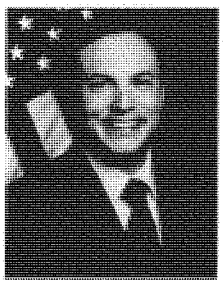
Prior to my service on the Commission, I had the privilege of working for Congress for more than a decade. I have a deep respect for the importance and value of congressional oversight. If confirmed, I will continue to do everything I can to ensure that the Committee has the information it needs to meet its oversight responsibilities.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Baran follows:]

UNITED STATES
NUCLEAR REGULATORY COMMISSION

Jeff Baran



The Honorable Jeff Baran was sworn in as a Commissioner of the U.S. Nuclear Regulatory Commission (NRC) on October 14, 2014, and is currently serving the remainder of the term ending on June 30, 2018.

Since joining the Commission, Commissioner Baran's priorities have included ensuring effective implementation of safety enhancements in response to the Fukushima Daiichi accident, improving oversight of power reactors entering decommissioning, and boosting the openness and transparency of agency decisionmaking. He has visited a number of NRC-licensed facilities, including operating power reactors, a nuclear plant undergoing active decommissioning, a research reactor, fuel cycle facilities, a low-level waste disposal facility, and a variety of facilities using radioactive materials for medical and industrial purposes. Commissioner Baran also traveled to Fukushima Daiichi for a first-hand look at conditions and activities at the site.

Before serving on the Commission, Commissioner Baran worked for the U.S. House of Representatives for over 11 years. During his tenure with the Energy and Commerce Committee, oversight of NRC was one of his primary areas of responsibility. As a senior counsel and later as Democratic Staff Director for Energy and Environment, Commissioner Baran worked on a range of NRC issues, including new reactor licensing, existing reactor oversight and decommissioning, high-level and low-level waste, and uranium mining, milling, and enrichment. He worked to coordinate the efforts of six federal agencies, including NRC, and two Native American tribes to clean up uranium contamination in and around the Navajo Nation. He also helped negotiate bills related to pipeline safety, energy efficiency, hydropower, and medical isotopes that were enacted with bipartisan support. From 2003 to 2008, he was counsel to the House Oversight and Government Reform Committee.

Prior to his work on Capitol Hill, Commissioner Baran served as a law clerk for Judge Lesley Wells of the U.S. District Court for the Northern District of Ohio.

Born and raised in the Chicago area, Commissioner Baran earned a bachelor's degree and a master's degree in political science from Ohio University. He holds a law degree from Harvard Law School.

January 2017

Statement of Jeff Baran
Committee on Environment and Public Works
September 20, 2017

Chairman Barrasso, Ranking Member Carper, and members of the Committee, thank you for the opportunity to appear before you today. I am honored to have been nominated to continue my service on the Nuclear Regulatory Commission for another term.

When I was confirmed as a Commissioner almost three years ago, I committed to bring an open-minded and collegial approach to the issues that come before the Commission. And I have worked very hard to meet that commitment. My focus has been on crafting thoughtful, balanced, and timely votes after hearing from a broad range of stakeholders. I value the relationships I have formed with my Commission colleagues, the NRC staff, licensees, unions, states, and public interest organizations, and have benefitted greatly from their ideas and input. My frequent visits to nuclear plants and other NRC-regulated facilities not only give me an opportunity to view equipment and technologies firsthand; they also give me the chance to hear directly from NRC's resident inspectors, as well as the workers and managers at the sites, about their priorities and concerns.

If confirmed, I look forward to continuing to serve with Chairman Svinicki and Commissioner Burns. We work very well together. We don't always agree on policy, but we always have constructive and collegial discussions. And I think that is how a commission is supposed to work. Bring together people with different backgrounds, perspectives, and experiences, and have them grapple with tough policy issues together. Ultimately, we make sure that important regulatory decisions are carefully and thoroughly considered. If they are confirmed, I look forward to working closely with my fellow nominees, Annie Caputo and David Wright.

Several important initiatives are underway at NRC, and I am eager to see them through to their conclusion. If I am confirmed for another term, I will continue to focus on these efforts, including the power reactor decommissioning rulemaking, implementation of post-Fukushima safety enhancements, development of an effective and efficient licensing framework for advanced reactors, and the pending small modular reactor design review. Managing the Project Aim reductions while fulfilling NRC's vital mission of protecting public health and safety and the environment is one of the agency's most significant challenges in the coming years. Ensuring that the agency has the resources, talent, and leadership to succeed is another top priority for me. I am happy to discuss these or any other issues of interest to members of the Committee in greater detail today or in the future.

Prior to my service on the Commission, I had the privilege of working for Congress for more than a decade. I have a deep respect for the importance and value of Congressional oversight. If confirmed, I will continue to do everything I can to ensure that the Committee has the information it needs to meet its oversight responsibilities.

Thank you, and I look forward to your questions.

Senator BARRASSO. Well, thank you all for your testimony.

Throughout the hearing and with questions for the record, the Committee members are going to have an opportunity to learn more about your commitment to public service and this nation. I would ask that throughout the hearing please respond to the questions, as well as those written questions that will be submitted after the hearing. Please submit those for the record.

I have to ask the following questions that we ask all nominees. I do this on behalf of the entire Committee.

Do you agree, if confirmed, to appear before this Committee or designated members of the Committee and other appropriate committees of the Congress and provide information subject to appropriate and necessary security protection with respect to your responsibilities?

Mr. DOURSON. Yes, I will.

Mr. LEOPOLD. Yes, I will.

Mr. ROSS. Yes, I will.

Mr. WEHRUM. Yes, Mr. Chairman.

Mr. BARAN. Yes.

Senator BARRASSO. Do you agree to ensure that testimony, briefings, documents, and electronic and other forms of information are provided to this Committee and its staff and other appropriate committees in a timely manner?

Mr. DOURSON. Yes, Senator.

Mr. LEOPOLD. Yes, Mr. Chairman.

Mr. ROSS. Yes, I will.

Mr. WEHRUM. Yes, Mr. Chairman.

Mr. BARAN. Yes.

Senator BARRASSO. Do you know of any matters which you may or may not have disclosed that might place you in a conflict of interest if you are confirmed?

Mr. DOURSON. No, Mr. Chairman.

Mr. LEOPOLD. No, Mr. Chairman.

Mr. ROSS. No, I do not, Mr. Chairman.

Mr. WEHRUM. No, Mr. Chairman.

Mr. BARAN. No, I do not.

Senator BARRASSO. Based on a prior agreement with the Ranking Member, we will have two rounds of questions, not the customary one round. Each Senator will have 5 minutes of questions per round. I will begin with my questions.

Commissioner Baran, as you know, in 2013 the U.S. Court of Appeals for the D.C. Circuit ordered the NRC to resume the licensing process for Yucca Mountain. The Court found that the NRC, under former Chairman Jaczko, had illegally terminated the licensing process. Under that Chairman, the NRC argued that it suspended the licensing process because it said Congress had not appropriated the funds necessary to complete it. The NRC also speculated that Congress would not appropriate additional funds in the future.

In the order, the Court rejected the NRC's rationale. It explained, "Federal agencies may not ignore statutory mandates simply because Congress has not yet appropriated all of the money necessary to complete a project." The Court also stated, "An agency may not rely on political guesswork about future congressional appropriations as a basis for violating existing legal mandates."

Well, last month the NRC, under Chairman Svinicki, voted to spend funds on activities related to the licensing process of Yucca Mountain. The NRC took this step to comply with the Court's order. The NRC took this step on a bipartisan basis, and you were the lone person to dissent. You wrote that you did not believe, you said, that the NRC should take such a step without knowing whether Congress will decide to appropriate funds for the licensing proceeding. You suggested that Congress might not appropriate the funds. You stated, "It has been 6 years since Congress last appropriated moneys for the Nuclear Waste Fund."

Commissioner, I just find your rationale deeply troubling. The Court has ordered the NRC to resume the licensing process. Why are you following the footsteps of former Chairman Jaczko and using a discredited rational—uncertainty about appropriations—as an excuse not to follow the law in the courts?

Mr. BARAN. Well, thank you for the opportunity to clarify my vote. Back when the D.C. Circuit looked at this issue, I believe there were about $13 million of appropriated funds remaining, and at that time the D.C. Circuit said there is more you can do with those funds, NRC; you should go ahead and do that; and in the intervening years that is exactly what NRC has done. In that time, the NRC staff completed the safety evaluation report, prepared a supplemental environmental impact statement that addressed groundwater issues, worked on making sure documents were available online that were previously held in the system for the adjudication.

In that time, the amount of appropriated funds we have left that were previously appropriated has dropped to, I think, around $600,000 or $700,000. We are also in the midst of some litigation that requires the use of some of those funds.

So the question that was presented to the Commission is does it make sense, in fiscal year 2017, to use most of those remaining funds to start doing some preliminary steps toward a potential adjudication. My view is that it did not make sense to expend the very little that we had left of those Nuclear Waste Fund moneys during the fiscal year to prepare for an adjudication until we knew whether Congress was going to appropriate funds for the adjudication in fiscal year 2018.

And I kind of share the view that you expressed, which is that we shouldn't, as a Commission, be making predictions about what Congress is going to do. My view is we should wait a few months, see what Congress decides to do. Some of the items that would have been funded, for example, like a real estate search for a facility to hold the hearing in Nevada, are very kind of short shelf life type items, so I didn't think it made sense to start doing that work until we knew we were actually going to begin the adjudication in fiscal year 2018.

Senator BARRASSO. With all due respect, it just seems that agencies do rely on guesswork about appropriations in an effort to comply with the law. What the Court said is that agencies may not rely on guesswork about appropriations to avoid complying with the law. So I just find it disturbing that perhaps your opposition to Yucca Mountain is so strong that you wouldn't even follow the legal court order on this one.

Mr. Wehrum, last week you argued a case before the U.S. Court of Appeals for the D.C. Circuit. You did it on behalf of clients who were challenging the Silica Rule. Do you have any concerns that this litigation is going to interfere with your work, if confirmed as the EPA Assistant Administrator for the Office of Air and Radiation?

Mr. WEHRUM. No, Mr. Chairman, no concerns whatsoever. The issues related to the Silica Rule we were litigating have absolutely nothing to do with the issues for which I would be responsible, if confirmed to the position of AA for OAR at EPA.

Furthermore, as we all know, there are comprehensive ethics rules that will govern my transition from private practice into Government service. I already am working very closely with EPA's ethics officers to make sure I fully understand those obligations and have their counsel, and I commit that I will strictly follow the regulations that apply to this transition, Mr. Chairman.

Senator BARRASSO. Thank you very much.

Senator Carper.

Senator CARPER. Thanks, Mr. Chairman.

Again, our thanks to all of you for joining us today and for your statements.

I want to go back to something that Mr. Leopold said, and I thought he really nailed it, and I thought he spoke from his heart with respect to his commitment to protecting our air and our water and our natural resources in this role, if he is confirmed. Here is what he said. He said the environmental laws passed by Congress in the decades that followed EPA's creation have been essential to securing the promise of environmental and human health protections while at the same time allowing for economic growth and prosperity. He went on to say there is no question that EPA has made great strides, significantly improving the quality of the air we breathe and the waters we depend on. EPA must always continue to make sure that we don't backslide from these important protections.

When our four nominees for EPA appeared before, I was looking for that kind of commitment to protecting our air, our water, our natural resources, and I must say I was disappointed not to hear it today from at least two of our witnesses, and sadly, not to hear it in the meetings that we had in my office.

I repeated those words because that is the kind of commitment we are looking for. That is what we are looking for.

I have a poster I just want to hold up, if I can, and probably ask my first question, if I may, of Dr. Dourson.

As I mentioned in my opening statement, Dr. Dourson, one of the main reasons that Congress worked so hard to reauthorize the Toxic Substances Control Act was because everyone recognized that EPA needed to have the authority to credibly and impartially assess chemical safety and regulate the chemicals that were found to be dangerous.

This poster shows some examples of the chemicals that you were funded by industry to study. In each and every case you concluded that the right safety standard for the chemicals should be tens, hundreds, even thousands of times less protective, less protective than the Federal or State regulators did. It is regrettably difficult

to look at your record and conclude that you could be an impartial regulator.

One way you could remedy the perception that you may not be able to be an impartial regulator would be to promise to recuse yourself, if you are confirmed, from working on any chemical that industry has paid you, has paid you to study. And I am not interested in a long answer, but I would like a very brief answer. Yes or no will do. Would you make that commitment today?

Mr. DOURSON. Senator, I can give you as many or more examples of situations where the science that we brought forward as a team actually lowered the safe dose or risk position for various sponsors. If confirmed, I will rely on the guidance of EPA ethics officials to determine any issues for which I am to be recused.

Senator CARPER. Let me just say all of us here try to figure out the right thing to do and do it: not the easy thing, not the expedient thing. When I apply the "right thing to do" test to this, the idea that I represented industry combating EPA on a particular substance, and later on I am going to have the opportunity, as part of the EPA leadership team, to determine whether or not, presumably impartially, we are going to allow that substance to be approved or in our environment, I would recuse myself. I would just say I am going to recuse myself. It wouldn't be right for me to represent industry opposing EPA with respect to that particular substance and then turn around and go to work for EPA and take the other position. I just don't see why you can't just say I would recuse myself. I don't get it.

Mr. DOURSON. Well, Senator, again, the majority of our work is done for government organizations, and several of the chemicals up there we were doing, we did work with teams of individuals and groups, including government and industry organizations. So, again, I will rely on the guidance of U.S. EPA ethics officials to determine any issue for which I am to be recused.

Senator CARPER. Mr. Chairman, I want to just ask unanimous consent to submit for the record a list of over 150 organizations from across our country who are opposed to Dr. Dourson's nomination. This list consists of environmental groups, labor groups, health, justice and consumer groups, and the American Association of Justice. I submit this list for the intention that it will allow the record to better reflect the considerable national opposition to his nomination.

Senator BARRASSO. Without objection.

[The referenced information follows:]

List of groups opposing Dourson:

1. 5 Gyres
2. Alaska Community Action on Toxics
3. Alliance of Nurses for Healthy Environments
4. *American Academy of Pediatrics
5. American Association for Justice
6. *American Congress of Obstetricians and Gynecologists
7. American Sustainable Business Council
8. As You Sow
9. Asbestos Disease Awareness Organization
10. Black Women's Health Imperative
11. Blue Green Alliance
12. Breast Cancer Action
13. Breast Cancer Prevention Partners
14. Build a Better Planet
15. Cape Fear River Watch
16. Capital District Against Fracking
17. Catskill Mountainkeeper
18. Center for Biological Diversity
19. Center for Environmental Health
20. Center for Health, Environment & Justice
21. Center for Progressive Reform
22. Center for Reproductive Health
23. Center for Science in the Public Interest
24. Central California Environmental Justice Network
25. Citizens' Environmental Coalition
26. Clean and Healthy New York
27. Clean Production Action
28. Clean Water Action
29. Clean Water Action California
30. Clean Water Action Connecticut
31. Clean Water Action Massachusetts
32. Clean Water Action Minnesota
33. ClimateMama
34. Coalition for Clean Air
35. Collaborative on Health and the Environment
36. Coming Clean
37. Comit Civico del Valle
38. Communications Workers of America
39. Community Food and Justice Coalition
40. Conservation Minnesota
41. Conservation Voters for Idaho

42. Cook Inletkeeper
43. CRLA Foundation
44. Democracy Initiative
45. Earthjustice
46. Ecology Center
47. Empire state Consumer Project
48. Environmental Advocates of New York
49. Environmental Defense Action Fund
50. Environmental Health Strategy Center
51. Environmental Justice and Health Alliance
52. Environmental Working Group
53. In Our Own Voice: National Black Women's Reproductive Justice Agenda
54. Farmworker Association of Florida
55. Farmworker Justice
56. Farmworker Self-Help
57. Food & Water Watch
58. Food Chain Worker's Alliance
59. Fresnans against Fracking
60. Friends of the Earth
61. Global Alliance for Incinerator Alternatives (GAIA)
62. Grassroots Environmental Education
63. Green for All
64. Green Inside and Out
65. Greenaction for Health and Environmental Justice
66. GreenFaith
67. Greenpeace
68. Headwater LLC
69. Health Care Without Harm
70. Health Professionals and Allied Employees
71. Healthy Building Network
72. Healthy Legacy Coalition
73. Healthy Schools Network
74. Hillsborough Clean Investment Coalition
75. Hip Hop Caucus
76. Huntington Breast Cancer ACTION Coalition, Inc
77. If/When/How
78. International Association of Fire Fighters
79. International Center for Technology Assessment
80. Labor Council for Latin American Advancement
81. League of Conservation Voters
82. League of United Latin American Citizens
83. Learning Disabilities Association of America
84. Learning Disabilities Association of Georgia

85. Learning Disabilities Association of Illinois
86. Learning Disabilities Association of Maine
87. Learning Disabilities Association of New Jersey
88. Learning Disabilities Association of South Carolina
89. Learning Disabilities Association of Tennessee
90. Lenape Indian Tribe of Delaware
91. Los Jardines Institute
92. *March of Dimes
93. Marin City Parent Academy
94. Mi Familia Vota
95. Migrant Legal Aid
96. Mixteco Indigena Community Organizing Project
97. Moms Clean Air Force
98. National Alliance of Farmworker Women
99. National Asian Pacific American Women's Forum
100. National Council of Jewish Women
101. National Health Law Program
102. National Hispanic Medical Association
103. National Institute for Reproductive Health
104. National LGBTQ Task Force Action Fund
105. National Latina Institute for Reproductive Health
106. National Organization for Women
107. National Partnership for Women and Families
108. National Women's Health Network
109. National Women's Law Center
110. Natural Resources Defense Council
111. NextGen America
112. New Mexico Center on Law and Poverty
113. New York Environmental Law and Justice Project
114. NC Child
115. Nontoxic Certified / Made Safe
116. North Carolina Conservation Network
117. Northwest Atlantic Marine Alliance
118. Northwest Forest Worker Center
119. Northwest Treeplanters and Farm Workers United
120. Oil Change International
121. Oregon Environmental Council
122. Organización en California de Líderes Campesinas, Inc.
123. Organize Florida
124. PAI
125. People for Clean Air & Water of Kettleman City
126. Pesticide Action Network
127. Physicians for Reproductive Health

128. Physicians for Social Responsibility
129. Planned Parenthood Federation of America
130. PODER
131. Power Shift Network
132. Public Citizen
133. Rachel Carson Council
134. Safe Climate Campaign
135. Safer Chemicals Healthy Families
136. Safer States
137. San Francisco Firefighters Cancer Prevention Foundation
138. Save EPA
139. Science and Environmental Health Network
140. Sexuality Information and Education Council of the United States
141. Sierra Club
142. Stupid Cancer, Inc.
143. Texas Campaign for the Environment
144. Texas Environmental Justice Advocacy Services (TEJAS)
145. The Environmental Justice Coalition for Water
146. The Farmworker Support Committee
147. The Institute of Neurotoxicology and Neurological Disorders (INND)
148. The Progressive Hub, Saratoga
149. Toxic-Free Future
150. Toxics Action Center Campaigns
151. Tri-Valley CAREs
152. URGE: Unite for Reproductive & Gender Equity
153. Union of Concerned Scientists
154. United Automobile, Aerospace and Agricultures Implement Workers of America
155. United Farm Workers
156. USW
157. Utility Workers Union of America
158. Vermont Conservation Voters
159. Vermont Public Interest Research Group (VPIRG)\
160. Warehouse Worker Resource Center
161. Waterkeeper Alliance
162. WE ACT for Environmental Justice
163. West Berkeley Alliance for Clean Air and Safe Jobs
164. Worker Justice Center of NY
165. Women's Voices for the Earth

*These organizations do not take positions on nominees but have sent a letter requesting that the Committee ensure the Director of the EPA's Office of Chemical Safety and

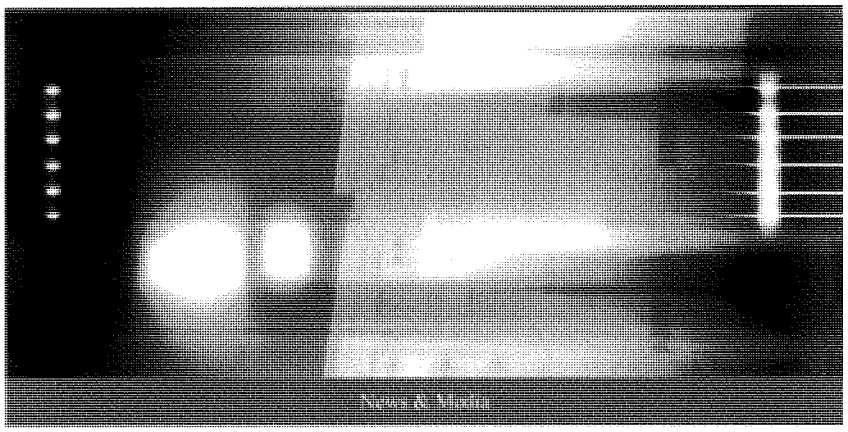
Pollution Prevention vigorously upholds the mission of the office to protect individuals, families, and the environment from potential risks from pesticides and toxic chemicals.

Senator CARPER. I also want to ask unanimous consent to back up the re-nomination of Mr. Baran to submit for the record a release, I guess it was just yesterday, October 3rd, a release from the Nuclear Energy Institute, the nuclear industry's association. This press release echoes my support for Mr. Baran and his re-nomination to serve as Commissioner to the Nuclear Regulatory Commission. I ask unanimous consent.

Senator BARRASSO. Without objection.

Senator CARPER. Thank you.

[The referenced information follows:]



Print

Nuclear Energy Institute
FOR IMMEDIATE RELEASE: October 03, 2017
Contact: media@nei.org, 202.739.8000 or 703.644.8805 (after hours and weekends)

NEI Urges Senate To Advance NRC Commissioner Nominations

WASHINGTON, D.C.—*In a hearing tomorrow the Senate Committee on Environment and Public Works will hear testimony in consideration of Jeff Baran to be renominated as commissioner to the Nuclear Regulatory Commission. Commissioner Baran's reappointment, joined by the approved nominations for David Wright and Ann Caputo, would afford the NRC a full complement of five commissioners at the agency. Following is a statement from NEI president and chief executive officer Maria Korsnick.*

"Today the Nuclear Regulatory Commission is staffed with three committed and safety-conscious commissioners. Jeff Baran is one of them. NEI has long held that the industry's regulator is best positioned to fulfill its vital mission of ensuring public safety and executing a disciplined licensing process when the commission is fully staffed.

"Commissioner Baran has been a strong advocate of safety and transparency and openness in the regulatory process. We share this commitment, and we have every expectation that Mr. Wright and Ms. Caputo would also meet the expectation of high-quality commissioners the Trump administration and our nation expects.

"This is a moment when Congress and the administration are rightly raising concerns relative to efficient and effective federal regulatory environments. The Nuclear Regulatory Commission is most effective when operating under the leadership of five well qualified commissioners, and we urge the Senate to move expeditiously to achieve that."



Senator CARPER. Thanks very much.

Senator BARRASSO. Thank you, Senator Carper.

For the record, on September 15th of this year, 14 doctors, each of whom has won the Arnold Lehman Award, the Society of Toxicology's highest honor, submitted a letter of support for Dr. Dourson's nomination. They wrote, "Dr. Dourson is highly qualified to serve as an Assistant Administrator of the Office of Chemical Safety and Pollution Prevention." They go on to say, "Dr. Dourson's deep understanding of the scientific elements of toxicity testing, data interpretation, weight of evidence evaluation procedures, and risk assessment is just what it will take to ensure effective implementation of the TSCA reform legislation."

I ask unanimous consent to enter this letter into the record.

[The referenced information follows:]

September 15, 2017

The Honorable John Barrasso
U.S. Senate Environment and
Public Works Committee
Majority Office
410 Dirksen Senate Office Building
Washington DC 20510

The Honorable Tom Carper
U.S. Senate Environment and
Public Works Committee
Minority Office
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Barrasso and Ranking Member Carper:

We are pleased to recommend Dr. Michael Dourson to you, with enthusiasm and without reservation, for confirmation as the Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention (OCSPP).

Dr. Dourson will bring his exceptional knowledge, skills and leadership in the fields of toxicology and risk assessment to EPA's OCSPP. Dr. Dourson's contributions to the science and practice of toxicology and risk assessment are widely acknowledged, and reflected by the widespread recognition and numerous awards he has received from professional societies such as the Society of Toxicology, the Academy of Toxicological Sciences, and the Society for Risk Analysis. Of particular note, Dr. Dourson received the Arnold J. Lehman Award from the Society of Toxicology, the Society's highest honor for scientific achievement in risk assessment and the regulation of chemical substances. In reviewing Dr. Dourson's credentials and achievements during the confirmation process, his research publications should be judged on the basis of scientific merit, without regard for the funding source, just as the Society of Toxicology did when it bestowed upon him the Lehman Award. Dr. Dourson is highly qualified to serve as the Assistant Administrator of OCSPP.

Best available science, as called for in the legislation, must form the foundation of the Agency's implementation of Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). Dr. Dourson's deep understanding of the scientific elements of toxicity testing, data interpretation, weight of evidence evaluation procedures, and risk assessment is just what it will take to ensure effective implementation of the LCSA. Moreover, as advanced 21st century biological profiling and computational methods accelerate toward replacing and augmenting traditional animal toxicity tests, there is no one more qualified than Dr. Dourson to actualize the promise of these methods by creating the collaborations, the scientific confidence evaluation procedures, and the stakeholder education and outreach activities that are needed to bring these methods from the research bench into regulatory use at EPA.

As scientists and fellow Society of Toxicology Lehman Awardees, we urge you to swiftly confirm Dr. Dourson as the Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention.

Sincerely,

Society of Toxicology Lehman Awardees

Richard A. Becker PhD. DABT
Thomas W. Clarkson PhD
Helmut Greim MD ATS
Alan R. Boobis OBE, BSc, PhD, FRSB, FBTS
Samuel M. Cohen MD, PhD, ATS, DABP
Carole A. Kimmel PhD
Dennis J. Paustenbach PhD DABT
Mike Bolger, PhD, DABT
Lorenz R. Rhomberg, PhD, ATS
Melvin Andersen PhD
Gary M. Williams, MD, DABT
Bruce N. Ames PhD
Harvey J. Clewell III PhD, DABT, ATS
Richard H Adamson PhD

Senator BARRASSO. Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

Mr. Baran, a recent report from the Energy Futures Initiative, a group formed by former Secretary of Energy Ernest Moniz, and a lot of other people, too, were involved in this, concluded that a healthy U.S. civilian nuclear power industry is a national security imperative—not opportunity, imperative. The report found, "The nuclear sector helps the U.S. military meet specific defense priorities, supports implementation of U.S. nonproliferation policy, and is essential to the global protection of U.S. military capability. The flip side is that an eroding nuclear enterprise will compromise nuclear securities capabilities and make them more costly."

Do you agree that the erosion of the U.S. commercial nuclear power industry presents a threat to the United States' national security?

Mr. BARAN. As an NRC Commissioner, Senator, it is my job to focus on nuclear safety and security, not to weigh in on——

Senator INHOFE. No, I think it is an easy answer. Do you believe that that is related to our national security?

Mr. BARAN. Well, again, as a Commissioner, it is not my job to weigh in on the pros and cons of the merits of nuclear power.

Senator INHOFE. All right, let me reword something, then. As the former report said, the U.S. ability to influence nonproliferation was "rooted in the historically unique capabilities in U.S. technology, services, and know-how."

At this time, at this time, Mr. Baran, there is one new nuclear plant under active constructive and at least 16 existing nuclear plants under the threat of closure. Meanwhile, the rest of the world is advancing. We are falling behind. Does this bother you?

Mr. BARAN. Well, again, it is our job at NRC, we stay focused on our mission, which is to ensure the safe, secure use of nuclear power to protect human health and the environment. That is our focus. It is our responsibility to make sure that we have——

Senator INHOFE. You don't have an opinion on this as to whether or not this affects our national security? You have a problem with the fact that the rest of the world is passing us up in nuclear progress?

Mr. BARAN. Well, the part I focus on, and my job as a Commissioner, is to make sure we have an effective, efficient process for licensing new reactors, and that we do a good job overseeing the construction that is underway.

Senator INHOFE. All right. Thank you very much.

Mr. Wehrum, in 2015 the Supreme Court found that the EPA, under the Obama administration, violated the Clean Air Act by not looking at the cost of compliance. This is required, looking at the cost of compliance before issuing new regulations on the emission of mercury and other toxins from coal fired power plants, as Congress required. That is in the law. In fact, the Clean Air Act calls for EPA to conduct ongoing evaluations of job losses, economic shifts in costs, and so forth.

Do you believe that EPA should follow that law?

Mr. WEHRUM. Senator Inhofe, absolutely.

Senator INHOFE. You have demonstrated that in the past, haven't you?

Mr. WEHRUM. I have tried very hard to achieve the dual goals of the Clean Air Act, Senator, which is to protect human health and the environment, but also promote the economic vitality of this nation.

Senator INHOFE. And if you are confirmed to this position, you will do so and continue to do it?

Mr. WEHRUM. Yes, Senator, I will.

Senator INHOFE. Mr. Wehrum, you previously served for 6 years on the EPA. You did great work, and I thank you for that service. Can you talk about a project that you worked on which you are most proud? You and I talked about this in the past. I think we should share it on the record here. How did that project protect the public health and our environment?

Mr. WEHRUM. Well, Senator, one of the key achievements during my time at EPA was implementation of the so-called Tier 4 Nonroad Rule, which is a comprehensive set of emissions limits and fuel requirements for engines in vehicles that are used off the highway. That program was unprecedented at the time, achieved millions of tons of emissions reductions, and did it in a very smart way, such that was also achieved even greater amounts of benefits to health and the environment.

Senator INHOFE [presiding]. It has been very effective.

Senator Whitehouse.

Senator WHITEHOUSE. Thank you very much, Chairman.

Mr. Dourson, the tobacco industry has manipulated and obfuscated scientific research into the dangers of smoking for decades. Your name comes up over 460 times in the tobacco industry documents made public as part of the tobacco master settlement agreement. Some of your e-mails are there, corresponding with Philip Morris over the work they hired you to do. Even the articles of incorporation for your organization, TERA, are there in the files of R.J. Reynolds, with a handwritten note next to your bio that the document should be filed under Consultants: Dourson.

In the late 1990s TERA, the organization you founded, received funding from the Center for Indoor Air Research to study the effects of secondhand smoke. TERA's name pops up throughout the tobacco data base, and it has been well documented that the Center for Indoor Air Research was a front group for the tobacco industry.

In 1999 you were the co-author of a paper that underestimated the effects of exposure to secondhand smoke in the workplace. To reach this industry favored conclusion, you and the other authors relied on inappropriately combined exposure data collected from workplaces that allowed smoking anywhere and those that allowed it only in designated areas, which skewed the results. That study is also in the tobacco data base, compliments of the Philip Morris collection.

Can you and will you provide a full accounting of all the work you and TERA did for the tobacco industry, all the money you and TERA received from the tobacco industry, and the role that you played in the campaign to hide the truth about the dangers of smoking?

Mr. DOURSON. Senator, the roles that we played in the tobacco work are a matter of public record in the House Science Space and

Technology 2015 hearing. The total value of our tobacco work was approximately $13,000.

The bottom line is that throughout my career, with EPA, TERA, and now with the University of Cincinnati, I have been objective in my work and applied sound science to come to my conclusions.

Senator WHITEHOUSE. And Mr. Wehrum, you have been leading the fight against EPA's air standards, so it is unclear to me how you are appropriate to serve in the position to enforce those standards. In particular, Executive Order 13770, Ethics Commitments by Executive Branch Appointees, prohibits appointees from participating in any particular matter involving specific parties that is directly and substantially related to their former employer or former clients for the first 2 years after their appointment. Your ethics agreement states that you intend to sign the pledge.

We are aware of dozens of separate air cases you have worked on during your time at Hunton & Williams. To ensure compliance with the pledge, will you provide for the record all of Hunton & Williams' clients and cases or work from the past 2 years, noting all clients with whom you have worked, cases on which you have worked, and regulatory work you have done?

Mr. WEHRUM. Senator, as I stated previously, there are comprehensive rules of ethics that govern transition of someone like myself from private practice into Government service. I already have had extensive conversations with EPA ethics officials, and will continue to consult with them closely if this transition goes forward, if confirmed.

Senator WHITEHOUSE. Do you understand that the Senate has an independent role and has a right to independent investigation and independent information, that we aren't just an adjunct of the EPA ethics department?

Mr. WEHRUM. I am sorry, Senator, I missed the beginning of your question. I apologize.

Senator WHITEHOUSE. Do you understand that the Senate has its own independent oversight responsibility here and that we are not an adjunct to the EPA ethics office?

Mr. WEHRUM. I understand, Senator, yes.

Senator WHITEHOUSE. And will you provide the materials to us so we can engage in that oversight?

Mr. WEHRUM. Senator, as I said, my commitment is to understand the comprehensive rules of ethics that apply, to get the best advice that I can in understanding what I am required to do and to comply with them and to make every effort to strictly comply.

Senator WHITEHOUSE. Well, that sounds like a no with regards to the Senate.

Did you or your firm do any pro bono work? Pro bono work need not be disclosed. Did you do any pro bono work for the Oklahoma Attorney General's Office while Scott Pruitt was the attorney general?

Mr. WEHRUM. I personally have done no work for the State of Oklahoma, and I can't speak for the rest of my partners and associates; I have never made that inquiry, Senator.

Senator WHITEHOUSE. You don't know whether the firm did or did not?

Mr. WEHRUM. I do not know, Senator.

Senator WHITEHOUSE. Would you provide the Committee a list of the firm's pro bono work so that we can make an assessment of whether or not pro bono clients ought to be covered by the ethics pledge? At the moment, we simply would never know.

Mr. WEHRUM. Well, as I said, Senator, there are comprehensive rules that apply, very strict, including the voluntary agreement that you referred to, which I have committed to sign and——

Senator WHITEHOUSE. And which pro bono work does not apply to, right?

Mr. WEHRUM. I am sorry, Senator, I don't understand your question.

Senator WHITEHOUSE. The ethics pledge does not require you to disclose pro bono work, does it?

Mr. WEHRUM. I don't know the answer to that, Senator. I believe it applies to any work. There is no difference between pro bono work and work that is done for pay. We owe all clients a common commitment of zealous representation.

Senator WHITEHOUSE. Well, my time has gone by. I hope that these questions and the independent role of this Committee to do oversight is not something that is going to be overrun in the pursuit of getting these nominees in place.

Senator INHOFE. Thank you.

Senator Capito.

Senator CAPITO. Thank you, Mr. Chairman.

Thank all of you for being here today.

Dr. Dourson, you have a long career in industrial chemical risk assessments, including with your consulting firm. As you know, TERA, we talked about this when you came to my office, you have been involved with two cases that very much touched the lives of my fellow West Virginians, one being the DuPont C8 and Teflon manufacturing issues and the other being the Freedom Industry spills of 2014, a spill of MCHM and PPH.

The accuracy of these safety standards, having lived through these spills personally, myself, the accuracy of safety standards is absolutely critical. It is imperative to have it as quickly as possible and as accurately as possible to protect constituents and to also can have significant implications for liabilities.

This issue is particularly sensitive, as I mentioned earlier, so I believe that we must conduct rigorous enforcement of appropriate safety standards, that we must hold those illegally exposing human health and the environment to harmful substances accountable, and that we must support timely and effective mitigation and cleanup efforts when spills do occur, and we need to apply the lessons of past incidents to prevent a recurrence of harmful spills and emissions.

Do you share those goals, Dr. Dourson?

Mr. DOURSON. Yes, Senator, I share those goals.

Senator CAPITO. If you are confirmed, how would you direct the Office of Chemical Safety and Pollution Prevention to achieve these goals?

Mr. DOURSON. Well, several of these goals reside in the authorities of other EPA offices, but if confirmed with the Office of Chemical Safety and Pollution Prevention, I will work with other EPA offices, as appropriate, to fulfill these goals.

Senator CAPITO. In the past, in your past work, I would imagine, in order to get the appropriate process for setting scientifically sound safety levels, that you need to advocate for a transparent peer reviewed body of science to back reviews of safe levels of potentially harmful substances. Would you agree with that, and what have you done in the past that would convince me that this is the direction you would take the office?

Mr. DOURSON. Well, absolutely I agree with this. TERA, the capacity of TERA as the non-profit 501(c)(3) organization, and then University of Cincinnati, we have had over 100 independent peer review panels. We have different groups come to the panels, different sector representation. We have well established conflict of interest statements, and also we have been reviewed by the EPA's Inspector General in 2009 as a way of showcasing our particular independent peer review panel. So I very much agree with your views of independent peer review and transparency as paramount.

Senator CAPITO. Thank you, Dr. Dourson.

Mr. Ross, you and I talked about intractable water systems. I am still on water because we have had some issues. We have a lot of kind of abandoned former coal camps where the systems are just defunct, but they don't have the money, or there isn't the money there to maintain or to get them back into compliance. A lot of these communities, unfortunately, are under boil water orders, and in many cases the EPA continues to issue citations, including fines, but there is no real help here for them in an official management capacity to get them into compliance, and it is my understanding that we really haven't studied this issue as deeply as we should.

I am working on a legislative solution to help deal with this problem and hope that the EPA will be a willing partner. So, I am asking you are you willing to work with me and others to study the challenge posed by intractable water systems?

Mr. ROSS. Yes, Senator, very much so. You have put your finger on a very critical priority for me, should I be confirmed, addressing these challenges going forward. It is an issue that we addressed in Wyoming, we struggle with, and we deal with in Wisconsin, and I look forward to working on that at a national level.

Senator CAPITO. Last, Mr. Ross, I would like to give you the opportunity to respond a little bit to what Senator Carper had mentioned. At least the implication that I heard was that because it wasn't expressly in your statements, several of your statements, that you are less committed to the end goal of clean water and environmental safety standards of the highest order, and I would like to know if you have a response to that.

Mr. ROSS. Thank you, Senator, for that opportunity. I do. In fact, I wish Senator Carper was here because he gave me a research assignment when I met with him, and to go to him, and the opening lines were for the beauty of this earth and for the beauty of the skies. And he put his finger on why I do what I do for a living. Now, I may disagree a little bit on some approaches, but the ultimate objective I share deeply. So I am fully committed to protecting public health and the environment, should I be confirmed.

Senator CAPITO. Thank you.

Thank you, Mr. Chair.

Senator INHOFE. Thank you, Senator.

Senator Duckworth.

Senator DUCKWORTH. Thank you, Mr. Chairman.

Mr. Dourson, when your nomination was announced in July of this year, the Trump administration's EPA circulated press releases proclaiming that there was a "widespread praise for Dr. Michael Dourson." Yet, when I reviewed this glowing yet highly misleading document, I was struck by the absence of public health leaders and dug a little deeper to figure out why. And I say what I found was not pretty.

From the American Petroleum Institute to the Koch brothers, it appears that you have no compunction about accepting millions of dollars from the chemical industry to conduct scientific studies on their behalf. This included a study conducted in Chicago that was paid for by a Koch Industry subsidiary, KCBX Terminals, which is an amazing coincidence. Their study concluded that petroleum coke, or petcoke, as it is known, which KCBX was pushing into the air and lungs of my constituents in the south side of Chicago, was unlikely to harm human health.

This finding, that was bought and paid for by the Koch brothers, dramatically diverges from health assessments published last year by the U.S. Department of Health and Human Services experts on toxic substances and related diseases. Their assessment was consistent with the common sense observations of Illinois families who literally could see the chemical byproducts floating in the air that they and their children were breathing in.

My constituents needed experts such as yourself to stand up for them and their health, rather than running cover for polluters who are wealthy and willing to poison our children as they put profits first.

Now, look, I understand that you were being paid by a client to produce a result that would benefit the client's own financial interests, and frankly, over the years, you seem to have become quite good and quite comfortable at producing this type of pseudoscience for the highest bidders. But manipulating science to achieve a predetermined outcome is not what the EPA's Office of Chemical Safety and Pollution Prevention should be about. So you are applying for a very different job now.

In fact, EPA's own Web site makes clear that petcoke is dangerous to human health. It defies common sense that inhaling toxic particulate matter could be anything but poisonous for people, and especially for children.

Olga Batista, one of my constituents who fought for her family's right to clean air, told me, "When I fought to get the industrial petcoke out of our neighborhood in Chicago, Michael Dourson was working with Koch Industries to minimize our concerns. To charge him with seeing the chemical safety for the entire country might be good for families like the Kochs, but it certainly would not be good for families like mine."

Anyone who could turn a blind eye to the environmental injustices that the residents of Chicago have had to bear, as you did, does not deserve my support, and I urge all of my colleagues to join me in opposing your nomination.

Mr. Chairman, I would like to ask unanimous consent to submit for the record a September 7 article from Midwest Energy News.

Senator FISCHER [presiding]. Without objection.
[The referenced information follows:]

http://midwestenergynews.com/2017/09/07/epa-toxics-nominee-provided-koch-funded-study-in-chicago-petcoke-battle/

EPA toxics nominee provided Koch-funded study in Chicago petcoke battle

WRITTEN BY Kari LydersenSeptember 7, 2017
PHOTO BY

Josh Mogerman / Creative Commons

Advocates concerned about pollution from petroleum coke are worried an Ohio professor's study downplaying the risks will gain new prominence now that he has been named to a key EPA post.

In July President Trump announced his intent to nominate University of Cincinnati environmental health professor Michael Dourson to head the division of the Environmental Protection Agency responsible for chemical safety and enforcing the Toxic Substances Control Act.

Environmental and consumer watchdogs quickly raised concerns about Dourson's history working for industry, authoring studies commissioned by DuPont, Dow and other chemical companies and the tobacco industry.

Dourson was also hired by Koch Industries to study the health impacts of petroleum coke (petcoke) in Chicago, with his research starting soon after residents began raising concerns about the piles of petcoke quickly growing at Koch subsidiary KCBX Terminals on the city's Southeast Side.

The study, funded by Koch Industries and carried out by Dourson and two other scientists paid by Koch, found no risk of adverse health impacts from exposure to petcoke in the air or on surfaces in neighborhoods around KCBX's two petcoke transfer and storage facilities.

One of those has since been closed, and the other one was forced by a city ordinance, following intense community pressure, to stop storing petcoke in the open. But residents are still concerned about petcoke escaping into the air and the Calumet River during the transfer process between barges and trains.

And as they also fight other environmental battles, including around manganese contamination from a facility next to KCBX, Dourson's role in the petcoke battle underscores the odds residents are up against when fighting big business, especially with such an industry-friendly administration in the White House.

"I'm not surprised that this person is being promoted. We've seen it happen on the national scale, we also see it on the local level," said Olga Bautista, a leader of the Southeast Side Coalition to Ban Petcoke.

"When you fall in line with these industries and people of power, you get rewarded and put in positions that have a lot of influence. And the people who are actually suffering from the pollution have very little recourse. They're calling the shots and deciding what is deemed dangerous and what is not deemed dangerous. When we try to speak for ourselves and defend ourselves, they say we are not experts."

KCBX spokesman Jake Reint provided a statement about Dourson's work for the company, saying: "Dr. Dourson was one of several experts KCBX retained to make sure our bulk material terminals in Chicago were operating in compliance with all rules and regulations, and with respect for the environment and our neighbors. This work included analysis of several years of air monitoring data and tests on more than 100 soil and surface samples collected from the neighborhoods near the KCBX terminals."

Science in the service of industry

The Environmental Defense Fund and Greenpeace USA are among the groups raising alarms about Dourson's ties to industry and urging Congress not to confirm his nomination when hearings are convened.

Richard Denison, lead senior scientist for EDF, wrote in a blog post about Dourson's "extensive, longstanding financial ties to the chemical industry – an industry that, if he is confirmed, he will be in charge of regulating. And not only does Dourson have these financial ties to the industry, he has made a career of helping industry play down concerns about chemicals."

Denison said that a review of Dourson's published papers between 2005 and 2017 showed half of those where funding sources were revealed were fully funded by industry, and most were at least partially funded by industry. These studies covered controversial pesticides and other chemicals that are currently undergoing EPA review and which Dourson if confirmed would be in charge of regulating.

After Trump's announcement, The Intercept published a chronicle of how Dourson's work for DuPont helped the company avoid providing clean water to West Virginia residents after the company's chemicals used in making Teflon polluted local groundwater. DuPont later was found liable and ordered to pay $1.6 million to a woman who developed kidney cancer linked to the contaminated water.

Petcoke study

Environmental groups say such a record casts doubt on all of Dourson's work, including the petcoke study in Chicago.

"I certainly wouldn't trust any study he did on its face," said Charlie Cray, a research specialist for Greenpeace USA. "It doesn't mean all the work he's done is suspect or biased, but when it's underwritten by a company like Koch Industries I would be skeptical from the start."

Dourson and his colleagues sought to monitor petcoke in the air around the facilities and accumulated in soil and on surfaces.

Their paper notes that the only significant study to previously examine health impacts of petcoke exposure in humans involved Canadian petroleum workers and found an increased risk of lung cancer. But once smoking and asbestos exposure were accounted for among those workers, Dourson wrote, petcoke was not found to be a risk factor.

Since human studies are lacking, Dourson used studies in rats to determine what levels of petcoke exposure could be considered harmful. Those studies showed no significant impacts from the chemicals in petcoke, including when petcoke was applied to rats' skin. Exposure to petcoke dust at certain levels was found to cause accumulation of petcoke in the lungs and lung inflammation in rats.

In November 2013 and April 2014, Dourson's team gathered petcoke dust accumulated on surfaces in bus stops, parks and rights-of-way near the Chicago petcoke facilities. The study determined that chemical indicators of petcoke contamination in the soil and on surfaces were no different than baseline accumulation elsewhere in the city.

Inhalation of particulate matter from petcoke has been the main health concern in the area. Particulate matter is known to cause cardiac, respiratory and other health problems regardless of the chemical makeup of the material.

Dourson's study found that based on KCBX's on-site air monitors, the level of PM10 (particulate less than 10 microns in size) dispersed was not likely to cause health impacts. The study concluded that "estimated human exposures, if any, are well below levels that could be anticipated to produce adverse health effects in the general population."

James Brusslan, an attorney who represented residents in a class action lawsuit that ultimately resulted in a $1.4 million settlement, disputed those results. He cited research commissioned by the city of Chicago and residents' own documentation of petcoke on their property.

"CDM, an environmental expert retained by the city of Chicago, issued several reports which flatly disagreed with the conclusions by Dourson's colleagues and others hired by KCBX that KCBX's operations were having little impact on the neighborhood," Brusslan said. "CDM determined that KCBX's periphery fence line monitoring was inconclusive, that its bulk sample testing had no persuasive value and that any air modeling performed in the area was unpredictable. As residents could see with their own eyes, dust from KCBX's facility inundated the neighborhood for years."

CDM's criticisms of Dourson's study include a finding that petcoke dust could migrate off the site into residential areas without being logged by the company's on-site air monitors, since it might settle on the ground and later be lifted into the air. CDM argued that Dourson's study did

not involve monitors between the company fence-line and the nearest residences, and found that PM10 impacts on nearby neighborhoods could be "substantially greater" than Dourson allowed.

Implications

By the time Dourson's study was officially published in May 2016, KCBX had already been ordered to remove its open piles of petcoke and the class action lawsuit was being settled. Brusslan said that Dourson's co-author Lyle Chinkin was involved in the lawsuit proceedings. The study notes that Chinkin, along with Dourson and co-author David MacIntosh, were "retained experts for litigation purposes" for Koch, and "Koch Industries was involved in the problem formulation phase of this research."

Dipro Bhowmik, a researcher for Greenpeace, analyzed Dourson's research record and related policy developments in different areas. He theorized that since Koch Industries was forced to stop storing petcoke in Chicago, and had previously been forced to stop storage in Detroit, the company may hope to use Dourson's findings to combat opposition in other cities or states where it seeks to store petcoke.

"It builds that cache of research that absolves petcoke of health impacts, so in the next community that's impacted, the industry is protected," Bhowmik said.

Public health and environmental watchdog groups have long complained that studies funded by industry are entered into the public and legal record as independent research.

KCBX portrayed Dourson's research this way, including in a statement the company made at the time of the class action lawsuit, saying that: "Independent laboratories also have conducted tests on more than 100 soil and surface samples from the neighborhoods near the terminal and found no evidence of coal or petcoke dust."

Bautista noted that community residents have partnered with universities and non-profit organizations to do their own data collection and studies, including using balloons for aerial mapping and systematic air testing.

"We've been using DIY methods for collecting data since the onset of this problem, which was absolutely crucial in how far we've gotten," said Bautista. "We can be experts in these fields because we're the ones who are impacted the most, and we have the most to gain from having this information available."

Senator DUCKWORTH. Thank you.

This article details the concerns of environmental consumer groups about Dr. Dourson's troubling history of working for Koch Industries to the detriment of public health. The article states, "A study funded by Koch Industries and carried out by Dourson and two other scientists paid for by Koch found no risk of adverse health impacts from exposure to petroleum coke in the air or on surfaces in neighborhoods around the company's two facilities. CDM environmental experts retained by the city of Chicago issued several reports which flatly disagreed with the conclusions by Dourson's colleagues and others hired by KCBX that KCBX's operations were having little impact on the neighborhood."

Mr. Dourson, on EPA's Web site it states, "Significant quantities of fugitive dust from petcoke storage and handling operations present a health risk." Yes or no, do you agree with this statement?

Mr. DOURSON. Senator, first of all, thank you very much. The people of Chicago have every right to——

Senator DUCKWORTH. No, reclaiming my time. My question is, yes or no, do you agree with the EPA's Web site as it currently states, "significant quantities of fugitive dust from petcoke storage and handling operations present a health risk." Do you agree with that, yes or no? You are looking to go to work at EPA. Do you agree with what is on their Web site right now?

Mr. DOURSON. With all due respect, Senator, what we did with the city of Chicago was looked specifically——

Senator DUCKWORTH. I am not asking about what you did with the city of Chicago. I would like to know do you agree with the current statement. And if you are not willing to answer, that is fine, but I am asking a very simple question. You are applying for a job here at the EPA, and they say on their Web site, right now, "significant quantities of fugitive dust from petcoke storage and handling operations present a health risk." Yes or no?

Mr. DOURSON. Senator, I am not really ready to answer that question without——

Senator DUCKWORTH. OK. Then I don't think you are ready to go work at the EPA. Thank you.

I yield back.

Senator BARRASSO [presiding]. Thank you very much, Senator.

Senator Ernst.

Senator ERNST. Thank you, Mr. Chair.

And thank you to all of our witnesses for appearing today.

Mr. Wehrum, I would like to start with you, please. You had stated that Administrator Pruitt had stated, even during his own confirmation process, that he will uphold the law. And I know in my meetings with Administrator Pruitt he continuously told me time and again that he will uphold the law. And last week the EPA put forward a Notice of Data Availability that would lower the annual biodiesel blending targets by the number of gallons imported, yet still allow those imported gallons to receive compliance credits.

The EPA is also considering allowing exported ethanol gallons to qualify for compliance credits. Both of these moves are contrary to the spirit of the renewable fuel standard and would undermine the program.

Administrator Pruitt pledged to me, both in person and before this Committee, to enforce the RFS as intended by Congress. Will you pledge to uphold the spirit and the letter of this law?

Mr. WEHRUM. Senator, if I am confirmed, I would look forward to working on these issues with you.

Senator ERNST. It is a law. Will you uphold the law?

Mr. WEHRUM. As I said in my opening statement, Senator, I share the Administrator's commitment to rule of law. That is a big reason why I want to come to EPA and work with Administrator Pruitt. He has a palpable commitment to that outcome. The RFS is incorporated in the Clean Air Act, and my goal, if confirmed, is to understand the law and implement the law.

Senator ERNST. The intent would be to uphold the law, correct?

Mr. WEHRUM. Absolutely, Senator.

Senator ERNST. OK. That is the commitment that Administrator Pruitt has given to me, has given to many others, and this Committee, is to uphold the law. And I am hoping that you will also uphold the letter of the law, which is the renewable fuel standard.

Do you believe the major regulatory actions that change the underlying operation of the RFS should be subject to full notice and comment period?

Mr. WEHRUM. Yes, Senator. If the RFS regulations are changed, that should be done through notice and comment rulemaking.

Senator ERNST. Absolutely. Thank you.

And as part of the EPA's 2018 RVO Rule, the Agency proposed reducing the amount of cellulosic biofuel by 150 million gallons, despite evidence of growing production and demand for the second generation biofuel. If confirmed, can you commit to ensuring that the cellulosic RVO numbers are based on an objective analysis of expected production capability?

Mr. WEHRUM. Senator, I am going to take half a step back and just say this. The RFS is a very complex program, and there are extensive provisions within the law that govern how it should be implemented, and even more extensive regulations that EPA has adopted. So I have to say I know a bit about the RFS. I don't know everything about the RFS. So I said this before, but I really mean it, if confirmed, part of what I need to do is fully understand the program, and part of what I need to do is fully understand your concerns, and I commit to you that I will do that, Senator.

Senator ERNST. I do appreciate that, and we are happy to assist in any way with the education process there.

The RFS is part of our code, it is the law, and we need to ensure that that law is upheld. Regardless of ideology, the goals of the RFS should be upheld. It is the law.

President Trump has repeatedly stated his strong support for the renewable fuel standard on multiple occasions, and just a few weeks back President Trump made a personal phone call to Senator Chuck Grassley, reemphasizing how much he loves ethanol, loves those biofuels, and so far his EPA is on track to meet the deadline for annual rulemaking. That is important.

Will you commit to upholding the timeliness of the yearly renewable volume obligations required under the RFS?

Mr. WEHRUM. Senator, if confirmed, I will do everything I can to make sure we stay on schedule. I understand that there have been

concerns with that in the past and EPA has had difficulty keeping up with the schedule, so, if I am confirmed, I will do everything I can to try to keep us on track.

Senator ERNST. OK. I appreciate your answers very much. We will hold Administrator Pruitt to his commitment to uphold the law. We will do the same of you. If there is a way that we can be helpful in the education process when it comes to the renewable fuel standard, I am ready to assist, my staff is ready to assist, and I appreciate your commitment.

Thank you very much, Mr. Chair.

Senator BARRASSO. Thank you, Senator Ernst.

Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

Mr. Dourson, chlorpyrifos is a pesticide that is widely used; you find it on a lot of the produce in the fresh vegetable aisle at the grocery store. A lot of that produce has been sprayed with this. A simple yes or no, has chlorpyrifos been linked to brain damage in children?

Mr. DOURSON. Although it would be inappropriate for me to prejudge an issue within U.S. EPA since there are some staff deliberations I am not privy to, if confirmed, I will ensure that the issue is fully and fairly——

Senator MERKLEY. You have no knowledge about the studies that have been done on this insecticide?

Mr. DOURSON. No, I am knowledgeable of the studies.

Senator MERKLEY. Has it been linked to brain cancer in peer reviewed studies?

Mr. DOURSON. I am aware of the studies.

Senator MERKLEY. Brain damage. Has it been linked in these studies? Can you answer yes or no? Has it been linked to brain damage in children in peer reviewed studies?

Mr. DOURSON. There are peer reviewed epidemiology studies that show an association in one study and not others.

Senator MERKLEY. Mr. Chairman, I would like to submit for the record the following peer reviewed study showing that chlorpyrifos has been linked to brain damage in children.

Senator BARRASSO. Without objection.

[The referenced information follows:]

Seven-Year Neurodevelopmental Scores and Prenatal Exposure to Chlorpyrifos, a Common Agricultural Pesticide

Virginia Rauh,[1] Srikesh Arunajadai,[2] Megan Horton,[3,4] Frederica Perera,[4] Lori Hoepner,[4] Dana B. Barr,[5] and Robin Whyatt[4]

[1]Heilbrunn Center for Population and Family Health, Mailman School of Public Health, [2]Department of Biostatistics, Mailman School of Public Health, [3]Sergievsky Center, and [4]Columbia Center for Children's Environmental Health, Mailman School of Public Health, Columbia University, New York, New York, USA; [5]Emory University, Atlanta, Georgia, USA

BACKGROUND: In a longitudinal birth cohort study of inner-city mothers and children (Columbia Center for Children's Environmental Health), we have previously reported that prenatal exposure to chlorpyrifos (CPF) was associated with neurodevelopmental problems at 3 years of age.

OBJECTIVE: The goal of the study was to estimate the relationship between prenatal CPF exposure and neurodevelopment among cohort children at 7 years of age.

METHODS: In a sample of 265 children, participants in a prospective study of air pollution, we measured prenatal CPF exposure using umbilical cord blood plasma (picograms/gram plasma) and 7-year neurodevelopment using the Wechsler Intelligence Scale for Children, 4th edition (WISC-IV). Linear regression models were used to estimate associations, with covariate selection based on two alternate approaches.

RESULTS: On average, for each standard deviation increase in CPF exposure (4.61 pg/g), Full-Scale intelligence quotient (IQ) declined by 1.4% and Working Memory declined by 2.8%. Final covariates included maternal educational level, maternal IQ, and quality of the home environment. We found no significant interactions between CPF and any covariates, including the other chemical exposures measured during the prenatal period (environmental tobacco smoke and polycyclic aromatic hydrocarbons).

CONCLUSIONS: We report evidence of deficits in Working Memory Index and Full-Scale IQ as a function of prenatal CPF exposure at 7 years of age. These findings are important in light of continued widespread use of CPF in agricultural settings and possible longer-term educational implications of early cognitive deficits.

KEY WORDS: chlorpyrifos, neurodevelopment, pesticides. *Environ Health Perspect* 119:1196–1201 (2011). doi:10.1289/ehp.1003160 [Online 21 April 2011]

Each year, thousands of new chemicals are released in the United States, with very little documentation about potential long-term human health risks (Landrigan et al. 2002). First registered in 1965 for agricultural and pest control purposes, chlorpyrifos (CPF; 0,0-diethyl-0-3,5,6-trichloro-2-pyridyl phosphorothioate) is a broad-spectrum, chlorinated organophosphate (OP) insecticide. Before regulatory action by the U.S. Environmental Protection Agency (EPA) to phase out residential use beginning in 2000, CPF applications were particularly heavy in urban areas, where the exposed populations included pregnant women (Berkowitz et al. 2003; Whyatt et al. 2002, 2003). In a sample of pregnant women in New York City (Perera et al. 2002) detectable levels of CPF were found in 99.7% of personal air samples, 100% of indoor air samples, and 64–70% of blood samples collected from umbilical cord plasma at delivery (Whyatt et al. 2002).

Early concerns about the possible neurotoxicity of OP insecticides for humans derived from rodent studies showing that prenatal and early postnatal exposures to CPF were associated with neurodevelopmental deficits, and these effects have been seen at exposure levels well below the threshold for systemic toxicity caused by cholinesterase inhibition in the brain (e.g., Slotkin and Seidler 2005). Evidence has accumulated over the past decade showing that noncholinergic mechanisms may play a role in the neurotoxic effects of CPF exposure in rodents, involving disruption of neural cell development, neurotransmitter systems (Aldridge et al. 2005; Slotkin 2004), and synaptic formation in different brain regions (Qiao et al. 2003). Such developmental disruptions have been associated with later functional impairments in learning, short-term working memory, and long-term reference memory (Levin et al. 2002).

In humans, OPs have been detected in amniotic fluid (Bradman et al. 2003) and are known to cross the placenta (Richardson 1995; Whyatt et al. 2005), posing a threat to the unborn child during a period of rapid brain development. Using urinary metabolites as the biomarker of exposure, several different birth cohort studies have reported that prenatal maternal nonspecific OP exposure was associated with abnormal neonatal reflexes (Engel et al. 2007; Young et al. 2005), mental deficits and pervasive development disorder at 2 years (Eskenazi et al. 2007), and attention problem behaviors and a composite attention-deficit/hyperactivity disorder indicator at 5 years of age (Marks et al. 2010).

Using a different biomarker of exposure (the parent compound of CPF in umbilical cord plasma), we have previously reported (in the same cohort as the present study) significant associations between prenatal exposure to CPF (> 6.17 pg/g) and reduced birth weight and birth length (Whyatt et al. 2004), increased risk of small size for gestational age (Rauh V, Whyatt R, Perera F, unpublished data), increased risk of mental and motor delay (< 80 points) and 3.5- to 6-point adjusted mean decrements on the 3-year Bayley Scales of Infant Development (Rauh et al. 2006), and evidence of increased problems related to attention, attention deficit hyperactivity disorder, and pervasive developmental disorder as measured by the Child Behavior Checklist at 2–3 years (Rauh et al. 2006). Taken together, these prospective cohort studies show a consistent pattern of early cognitive and behavioral deficits related to prenatal OP exposure, across both agricultural and urban populations, using different biomarkers of prenatal exposure.

We undertook the present study to identify the developmental consequences of prenatal exposure to CPF in a sample of New York City children at 7 years of age. Given the mechanisms proposed in the rodent literature, and early findings from prospective human studies involving nonspecific OP exposures, we hypothesized that prenatal exposure to CPF would be associated with

Address correspondence to V.A. Rauh, Heilbrunn Center for Population and Family Health, Mailman School of Public Health, 60 Haven Ave., B-2, New York, NY 10032 USA. Telephone: (212) 304-7438. Fax: (212) 305-7024. E-mail: var1@columbia.edu

Supplemental Material is available online (doi:10.1289/ehp.1003160 via http://dx.doi.org/).

We are grateful to the families of northern Manhattan who have so generously contributed their time and effort to the study.

This study was supported by the National Institute of Environmental Health Sciences (grants 5P01ES09600, P50ES015905, and 5R01ES08977), the U.S. Environmental Protection Agency (grants R827027, 8260901, and RR00645), the Educational Foundation of America, the John and Wendy Neu Family Foundation, the New York Community Trust, and the Trustees of the Blancherte Hooker Rockefeller Fund.

The authors declare they have no actual or potential competing financial interests.

Received 2 November 2010; accepted 12 April 2011.

neurodevelopmental deficits persisting into the early school years, when more refined neuropsychological tests are available to identify particular functional impairments.

Materials and Methods

Participants and recruitment. The subjects for this report are participants in an ongoing prospective cohort study (Columbia Center for Children's Environmental Health) of inner-city mothers and their newborn infants (Perera et al. 2002). The cohort study was initiated in 1997 to evaluate the effects of prenatal exposures to ambient pollutants on birth outcomes and neurocognitive development in a cohort of mothers and newborns from low-income communities in New York City. Nonsmoking women (classified by self-report and validated by blood cotinine levels < 15 ng/mL), 18–35 years of age, who self-identified as African American or Dominican and who registered at New York Presbyterian Medical Center or Harlem Hospital prenatal clinics by the 20th week of pregnancy, were approached for consent. Eligible women were free of diabetes, hypertension, known HIV, and documented drug abuse and had resided in the area for at least 1 year. The study was approved by the Institutional Review Board of Columbia University. Informed consent was obtained from all participating mothers, and informed assent was obtained from all children as well, starting at 7 years of age.

Of 725 consenting women, 535 were active participants in the ongoing cohort study at the time of this report, and 265 of their children had reached the age of 7 years with complete data on the following: *a*) prenatal maternal interview data, *b*) biomarkers of prenatal CPF exposure level from maternal and/or cord blood samples at delivery, *c*) postnatal covariates, and *d*) neurodevelopmental outcomes.

Maternal interview and assessment. A 45-min questionnaire was administered to each woman in her home by a trained bilingual interviewer during the third trimester of pregnancy and annually thereafter. From the interviews and medical records, the following sociodemographic and biomedical variables, among others, were available: race/ethnicity, infant sex, household income, maternal age, maternal completed years of education at child's age 7 years, birth weight, gestational age, and self-reported maternal exposure to environmental tobacco smoke (ETS) during pregnancy.

We measured maternal nonverbal intelligence by the Test of Nonverbal Intelligence, 3rd edition (TONI-3) (Brown et al. 1997), a 15-min language-free measure of general intelligence, administered when the child was 3 years of age. The quality of the care-taking environment was measured by the Home Observation for Measurement of the Environment (HOME) inventory when the child was 3 years of age (Caldwell and Bradley 1979) to assess physical and interactive home characteristics. The mother report version of the Child Behavior Checklist for ages 6–18 years, a well-validated measure of child behavior problems occurring in the preceding 2 months (Achenbach and Rescorla 2001), was administered at 7 years as part of the larger cohort study.

Biological samples and pesticide exposure. A sample of umbilical cord blood (30–60 mL) was collected at delivery, and a sample of maternal blood (30–35 mL) was collected within 2 days postpartum by hospital staff. Portions were sent to the Centers for Disease Control and Prevention (Atlanta, GA) for analysis of CPF in plasma, as well as lead and cotinine, described in detail elsewhere (Perera et al. 2002; Whyatt et al. 2003). Methods for the laboratory assay for CPF, including quality control, reproducibility, and limits of detection (LODs), have also been previously published (Barr et al. 2002). In cases where the umbilical cord blood sample was not collected (12% of subjects), mothers' values were substituted, using a formula previously derived from regression analyses (Whyatt et al. 2005). As previously reported, maternal and umbilical cord blood CPF concentrations were similar (arithmetic means ± SDs of 3.9 ± 4.8 pg/g for maternal blood and 3.7 ± 5.7 pg/g for cord blood) (Whyatt et al. 2005), and CPF levels in paired maternal and umbilical cord plasma samples were highly correlated ($r = 0.76$; $p < 0.001$, Spearman's rank), indicating that CPF was readily transferred from mother to fetus during pregnancy. Prenatal blood lead levels were available for a subset of children ($n = 89$). ETS exposure, measured by maternal self-report, was validated by cotinine levels in umbilical cord blood, as described in detail elsewhere (Rauh et al. 2004). We measured polycyclic aromatic hydrocarbon (PAH) exposure by personal air monitoring during the third trimester, using a previously described method, and excluding poor-quality samples (Perera et al. 2003). As previously described (Perera et al. 2003), we computed a composite log-transformed PAH variable from the eight correlated PAH air concentration measures (*r*-values ranging from 0.34 to 0.94; all *p*-values < 0.001 by Spearman's rank).

In the larger cohort study, > 40% of CPF exposure values for combined maternal and umbilical cord blood samples were below the LOD. Using a method suggested by Richardson and Ciampi (2003), we made a distributional assumption for the exposure variable (log-normal CPF), computed the expected value of the exposure (E) for all nondetects [$E(X|X < \text{LOD})$], and assigned this value to all nondetects.

Measures of neurodevelopment. For the 7-year assessment, we selected the Wechsler Intelligence Scale for Children, 4th edition (WISC-IV), because of its revised structure based on the latest research in neurocognitive models of information processing (Wechsler 2003). The WISC-IV is sensitive to low-dose neurotoxic exposures, as demonstrated by studies of lead toxicity in 6- to 7.5-year-old children (Chiodo et al. 2004; Juskn et al. 2008; Rothenberg and Rothenberg 2005). The instrument measures four areas of mental functioning that are associated with, but distinct from, overall intelligence quotient (IQ) and is sensitive to cognitive deficits related to learning and working memory, which have been linked to CPF exposure in rodent studies (e.g., Levin et al. 2002). Each standardized scale has a mean of 100 and SD of 15. The Verbal Comprehension Index is a measure of verbal concept formation, a good predictor of school readiness (Hecht et al. 2000; Wechsler 2003); the Perceptual Reasoning Index measures nonverbal and fluid reasoning; the Wnrking Memory Index assesses children's ability to memorize new information, hold it in short-term memory, concentrate, and manipulate information; the Processing Speed Index assesses ability to focus attention and quickly scan, discriminate, and sequentially order visual information; and the Full-Scale IQ score combines the four composite indices. The General Ability Index score is a summary score of general intelligence, similar to Full-Scale IQ, but excludes contributions from both Working Memory Index and Processing Speed Index (Wechsler 2003). WISC-IV scores may be influenced by socioeconomic background and/or child behavior problems particularly those related to anxiety (Wechsler 2003).

Data analysis. We conducted all analyses using the statistical program R (R Development Core Team 2010). We treated CPF exposure level (picograms per gram) as a cnntinuous variable. We natural log (ln) transformed the WISC-IV Composite Index scores to stabilize the variance and to improve the linear model fit, based on regression diagnostics. Unadjusted correlation analyses were used to explore associations between CPF exposure and WISC-IV scores. We constructed smoothed cubic splines to explore the shape of the functional relationships between CPF exposure and each of the log-transformed WISC-IV indices. We compared the models in which CPF is entered as a single continuous outcome with those in which CPF is modeled using B-splines, using the Davidson–MacKinnon *J*-test for comparing nonnested models (Davidson and MacKinnon 1981).

Demographic, biomedical, and chemical expnsure variables collected for the larger cohort study were available for possible inclusion in the present analysis. We used two different approaches for covariate selection and

model fitting, for the purpose of determining the robustness of our results with respect to alternate methods. Covariates were initially selected based on prior literature and retained in the models if associated with either CPF exposure or the WISC-IV scales ($p < 0.10$ in univariate analyses). Multiple linear regression was used to test the effects of prenatal CPF exposure on each 7-year WISC-IV Index. We examined residuals for normality and homoscedasticity and detected no problems. In addition, we employed the least absolute shrinkage and selection operator (LASSO), a shrinkage with selection procedure that provides a more parsimonious approach to covariate selection and model fitting (Houwelingen 2001; Tibshirani 1996). This method minimizes the usual sum of squared errors, with a bound on the sum of the absolute values of the coefficients, thereby shrinking very unstable estimates toward zero, excluding redundant/irrelevant covariates, and avoiding overfitting (Zhao and Yu 2006). We used Sobel's indirect test to assess the influence of child behaviors on the estimates of CPF effect (MacKinnon et al. 2002; Sobel 1982). We used Sobel's indirect test to assess mediation (MacKinnon et al. 2002; Sobel 1982). Interaction terms including CPF and each additional covariate were tested in the models. Effect estimates, 95% confidence intervals (CIs), and p-values were calculated for all analytic procedures. Results were considered significant at $p < 0.05$.

Results

The retention rate for the full cohort was 82% at the 7-year follow-up, with no significant sociodemographic differences between subjects retained in the study and those lost to follow-up (data not shown). Table 1 lists characteristics of the study sample with complete data on all variables ($n = 265$). Study families were predominantly low income, with 31% of mothers failing to complete high school by child's age 7 years, and 66% never married. The sample was largely full term (only 4% of children in the sample were < 37 weeks gestational age at delivery) and included very few low-birth-weight infants because *a*) we excluded high-risk pregnancies from the study cohort, and *b*) the timing of air monitoring in the third trimester of pregnancy eliminated early deliveries.

CPF exposure levels ranged from nondetectable to 63 pg/g. We imputed exposure levels in participants with nondetectable CPF ($n = 115$, 43%) according to assay-specific LOD values, with 93 subjects having LOD equal to 0.5 pg/g and 22 subjects having LOD equal to 1 pg/g.

Correlation analyses for exposures and cognitive outcomes. Unadjusted correlations between prenatal CPF exposure and log-transformed WISC-IV Composite Indices (Verbal Comprehension, Working Memory, Processing Speed, and Perceptual Reasoning), and Full-Scale IQ showed significant inverse associations between CPF exposure and *a*) Working Memory ($r = -0.21$, $p = < 0.0001$) and *b*) Full-Scale IQ ($r = -0.13$, $p = 0.02$). We observed a weak inverse correlation between CPF and Perceptual Reasoning ($r = -0.09$, $p = 0.09$), while associations of CPF with Verbal Comprehension ($r = -0.04$) and Processing Speed ($r = -0.01$) had p-values > 0.05.

Umbilical cord lead was not significantly correlated with CPF level ($r = -0.08$, $p = 0.49$) or WISC-IV scores (all p-values > 0.05) among the 89 children with lead data available. Lead was not significantly correlated with CPF level ($r = -0.08$, $p = 0.49$, as previously reported by Rauh et al. 2006) or with 7-year WISC-IV scores (all p-values > 0.05) among the 89 children with available data. To avoid excluding observations without lead data, we did not include lead as a covariate in regression models. ETS and (to a lesser extent) PAH were correlated with CPF (Spearman coefficients: 0.113, $p = 0.01$, and 0.07, $p = 0.09$, respectively) but were not significantly correlated (using the Mann–Whitney test for the dichotomous ETS variable) with any WISC-IV index (coefficients ranged from −0.02 to 0.03, and p-values ranged from 0.39 to 0.87). Birth weight was not significantly associated with any of the WISC-IV indices (all p-values > 0.05) and was not included in the final models.

Spline regression analysis. Examination of the smoothed cubic spline regression curves, superimposed over scatterplots, indicates subtle differences in shape of the functions (Figure 1). The log-transformed Working Memory Index and Full-Scale IQ appear to be approximately linear, whereas the other functions show some curvature across exposure levels, with sparse observations at the highest exposures. Using the Davidson–MacKinnon test for comparison of non-nested models (Davidson and MacKinnon 1981), we compared models in which CPF was entered as a single continuous outcome with those in which CPF was modeled using B-splines. We failed to reject the null hypothesis that the model with CPF as a continuous measure is adequate against the alternative that the model with CPF modeled using splines provided a better fit for each WISC-IV Index (p-values: Verbal Comprehension Index = 0.07, Perceptual Reasoning Index = 0.08, Processing Speed Index = 0.59, Working Memory Index = 0.40, and Full-Scale IQ = 0.08).

Estimation of linear models. Table 2 lists the estimated B-coefficients, 95% CIs, and p-values for the exposure variable and covariates for the best-fitting linear regression models predicting each WISC-IV outcome.

Table 1. Demographic characteristics of the sample at 7-year follow-up ($n = 265$).

Characteristic	*n* (%) or mean ± SD (range)
Home quality[a]	40.23 ± 4.81 (23–52)
Income	
< $20,000	138 (52)
≥ $20,000	127 (48)
Maternal education[b]	
Years	12.22 ± 2.58 (1–20)
< High school degree	82 (31)
High school degree	183 (69)
Maternal IQ[c]	85.97 ± 13.46 (60–135)
Maternal race/ethnicity[d]	
Dominican	145 (55)
African American	119 (45)
Marital status	
Never married	175 (66)
Ever married	90 (34)
Child sex	
Male	117 (44)
Female	148 (56)
Gestational age (weeks)	39.3 ± 1.5 (36–43)
Birth weight (g)	3389.8 ± 493.5 (1,295–5,110)
Child age at testing (months)	85.97 ± 2.65 (74.90–101.5)
Prenatal chemical exposures	
ETS[e]	
Exposed	93 (35)
Not exposed	172 (65)
Cotinine (ng/mL)[f]	0.25 ± 0.92 (0.01–8.79)
Lead (μg/dL)[g]	1.09 ± 0.88 (0.15–7.45)
CPF (pg/g)[f]	3.17 ± 4.61 (0.09–32)
PAHs (ng/m³)[g]	3.37 ± 3.51 (0.50–36.5)

[a]As measured by the HOME inventory. [b]Completed years of education at child's age 7 years. [c]As measured by TONI-3. [d]Self-reported race/ethnicity (African American = 1; Dominican = 0). [e]Self-reported ever exposed to secondhand smoke in pregnancy (yes = 1; no = 2). [f]Measured in cord blood. [g]Measured by personal air sampling.

Table 2 also includes the results of linear model selection using the LASSO technique, which eliminates covariates with unstable estimates and results in more parsimonious models. Because the LASSO method uses bootstrapping to obtain standard errors, the coefficient of any covariate may be shrunk to zero if that covariate is an unstable predictor—that is, if its significance depends on the particular subset of data used in the model. The two approaches yielded very similar estimates of CPF effect. Differences in estimates for the covariates in the two methods suggest that the contribution of some covariates to WISC-IV scores may be less stable. Results for both approaches show that, on average, a 1-pg/g increase in CPF is associated with a decrease of −0.006 points in the log-transformed Working Memory score and a decrease of −0.003 points in the log-transformed Full-Scale IQ score. Because of the log transformation, estimated associations between CPF and actual Working Memory and Full-Scale IQ scores vary across the continuum of scores, such that the estimated deficit in the Working Memory score with a 1-pg/g increase in CPF ranges between 0.35 and 0.81 points, and the estimated decrease in Full-Scale IQ is between 0.20 and 0.40 points. The magnitude of these effects is more easily understood by calculating the neurodevelopmental deficit associated with an increase in CPF exposure equal to 1 SD (4.61 pg/g). On average, for each standard deviation increase in exposure, Full-Scale IQ declines by 1.4% and Working Memory declines by 2.8%. We found no significant interactions between CPF and any of the potential or final covariates, including the other chemical exposures measured during the prenatal period (ETS and PAH). Full model results for the linear regressions are provided in Supplemental Material, Table 1 (doi:10.1289/ehp.1003160), for the reader who is interested in the estimates of association between the covariates and outcomes for all of the WISC-IV index scales.

Sensitivity analysis of additional influences on Working Memory Index. To determine whether the observed CPF effect on the Working Memory Index was partially explained by its effect on general intelligence, we added the log-transformed General Ability Index, a general intelligence scale that does not include the Working Memory Index or Processing Speed Index, to the linear regression model. Although the estimate of the General Ability Index effect on Working Memory Index was significant (B-coefficient = 0.57; 95% CI,0.44–0.70; $p < 0.001$), the estimate of the CPF effect remained unchanged (−0.006), and we found no evidence of interaction between CPF and General Ability Index ($p > 0.05$), suggesting that the Working Memory effect is targeted and does not depend upon level of general intelligence.

Because child performance on the Working Memory Index can be influenced by child behavior problems (Wechsler 2003), we conducted a supplementary analysis to rule out the possibility that the observed associations between CPF and the Working Memory Index might be affected by behavior problems, as measured by the clinically oriented diagnostic and statistical manual scales on the Child Behavior Checklist. We found no evidence of indirect "mediation" using Sobel's test, with p-values ranging from 0.31 to 0.99 (MacKinnon et al. 2002; Sobel 1982). Full model results are provided in Supplemental Material, Table 2 (doi:10.1289/ehp.1003160), for the reader who is interested in the estimates of association between child behavior problems and Working Memory Index.

Sensitivity analysis of the influence of LOD imputation. After obtaining all results, we recomputed all estimates of association between CPF and WISC-IV scores among

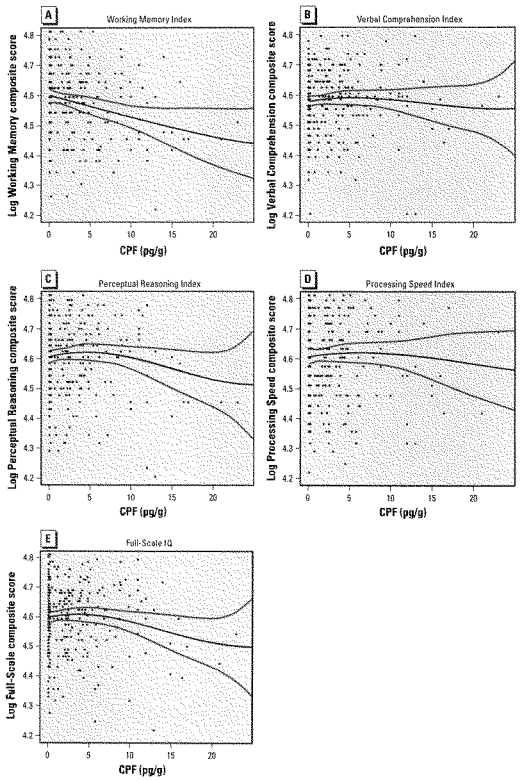


Figure 1. Smoothed cubic splines, superimposed over scatterplots, examining the shape of the associations between CPF exposure and (*A*) Working Memory Index, (*B*) Verbal Comprehension Index, (*C*) Perceptual Reasoning Index, (*D*) Processing Speed Index, and (*E*) Full-Scale IQ.

subjects with detectable CPF levels only. Analysis with detects alone is known to give unbiased estimates of the parameters of interest (Little 1992). In the present sample, we observed no consistent differences in estimates when we excluded imputed CPF data (data not shown).

Discussion

Results of this study showed that higher prenatal CPF exposure, as measured in umbilical cord blood plasma, was associated with decreases in cognitive functioning on two different WISC-IV indices, in a sample of urban minority children at 7 years of age. Specifically, for each SD increase in exposure (4.61 pg/g), Full-Scale IQ declined, on average, by 1.4% (0.94–1.8 points) and Working Memory Index scores declined by 2.8% (1.6–3.7 points). The dose–effect relationships between CPF exposure and log-transformed Working Memory Index and Full-Scale IQ scores are linear across the range of exposures in the study population, with no evidence for a threshold. Of the WISC-IV indices used as end points, the Working Memory Index was the most strongly associated with CPF exposure in this population.

Although no other epidemiologic studies have evaluated the neurotoxicity of prenatal CPF exposure on cognitive development at the time of school entry, several prior studies, using the present biomarker of exposure, have reported evidence of early cognitive and behavioral effects associated with a urinary biomarker of nonspecific OP exposure (Engel et al. 2007; Eskenazi et al. 2007; Young et al. 2005). Outcomes associated with exposure in these studies, as well as in our own earlier work (Rauh et al. 2006), have included attentional problems (e.g., Marks et al. 2010). These prior findings are consistent with the present 7-year results, because working memory skills involve attentional processes. More important, problems in working memory may interfere with reading comprehension, learning, and academic achievement, although general intelligence remains in the normal range (Blair 2006). Working memory is less likely than full-scale IQ to be affected by socioeconomic or cultural conditions (Wechsler 2003), providing a useful, more targeted measure of possible neurotoxic effects on brain function.

Several different theories or models address how working memory operates in the human brain, but most agree that it involves a system of limited attention capacity, supplemented by more peripherally based storage systems (Baddeley and Logie 1999). Some theories emphasize the role of attentional control in working memory (e.g., Cowan 1999), whereas others stress a multicomponent model, including a control system of limited attentional capacity (the central executive control system), assisted by phonological and visuospatial storage systems (see review by Baddeley 2003). To date, most studies of the anatomical localization of working memory problems are based on clinical populations (individuals with specific brain lesions) (Vallar and Pagano 2002) and some neuroimaging studies in small numbers of normal subjects (Smith and Jonides 1997). More refined neuropsychological tests and neuroimaging studies are needed to determine whether CPF-related working memory deficits are primarily auditory (part of a phonological loop with implications for language acquisition) or primarily related to visuospatial short-term memory (reflecting nonverbal intelligence tasks).

Few human studies have focused on possible mechanisms underlying neurodevelopmental deficits associated with OP exposure, but there is evidence that certain genetic polymorphisms can affect CPF metabolism (e.g., Berkowitz et al. 2004). Such findings suggest that some populations may be more vulnerable and may exhibit adverse neurodevelopmental effects at much lower exposures than other populations (Berkowitz et al. 2004). Again, neuroimaging studies would be useful to determine if population differences in vulnerability to CPF are also reflected in population differences in brain abnormalities associated with exposure.

Although behavioral alterations observed in rodents may be imperfect analogues for humans, they have guided human studies by identifying specific deficits in locomotor activity, learning, and memory (e.g., Aldridge et al. 2005). In light of experimental evidence suggesting that CPF effects in rodents may be irreversible (Slotkin 2005), it will be important to determine how any neurocognitive deficits associated with prenatal CPF exposure might respond to treatment or early intervention. Here, we may benefit from studies of lead-exposed children that have demonstrated evidence of reversals in learning deficits as a result of environmental enrichment (Guilarte et al. 2003).

Some limitations of this study should be noted. Our sample consists of low-income, urban, minority children who may experience other unmeasured exposures or underlying health problems that could potentially confound or modify associations with pesticide exposure. Furthermore, in the absence of firm mechanistic evidence linking brain anomalies to more refined neuropsychological testing, the observed functional deficits at 7 years of age should be interpreted with caution. We cannot directly compare our findings with the results from the other epidemiological studies that have relied on urinary OP concentrations as the biomarker of exposure.

In June 2000, the U.S. EPA announced a phase-out of the sale of CPF for indoor residential use, with a complete ban effective 31 December 2001 (U.S. EPA 2000, 2002). After the ban, levels of CPF in personal and indoor air samples in our own cohort decreased by more than 65%, and plasma blood levels dropped by more than 80% (Whyatt et al. 2005), despite some lingering residential residues (Whyatt et al. 2007). From other parts of the country, there is evidence of continued low-dose exposures in children from food residues (Lu et al. 2006). Because agricultural use of CPF is still permitted in the United States, it is important that we continue to monitor the levels of exposure in potentially vulnerable populations, including pregnant women in agricultural communities, and evaluate the long-term neurodevelopmental implications of exposure to CPF and other OP insecticides.

Table 2. Estimated associations between CPF (pg/g) and log-transformed Full-Scale IQ and each of four Composite Index scores from the WISC-IV from LASSO[a] and fully adjusted[b] linear regression models ($n = 265$).

WISC-IV scale[c]	B-coefficient[c]	95% CI	*p*-Value
Full-Scale IQ			
LASSO	−0.003	−0.006 to 0.001	0.064
Fully adjusted	−0.003	−0.006 to 0.000	0.048
Working Memory Index			
LASSO	−0.006	−0.009 to −0.002	< 0.001
Fully adjusted	−0.006	−0.010 to −0.002	0.003
Verbal Comprehension Index			
LASSO	NA[d]	NA	NA
Fully adjusted	−0.002	−0.005 to 0.001	0.208
Perceptual Reasoning Index			
LASSO	NA	NA	NA
Fully adjusted	−0.002	−0.006 to 0.002	0.290
Processing Speed Index			
LASSO	NA	NA	NA
Fully adjusted	0.001	−0.004 to 0.005	0.728

NA, not assessed.
[a]LASSO models were adjusted for maternal education, maternal IQ, and the HOME Inventory. [b]Fully adjusted models were adjusted for child sex, race/ethnicity, maternal IQ, maternal education income, child age at testing (months), ETS, and PAH. [c]All scales were ln transformed. [d]CPF was not retained in the final LASSO model.

References

Achenbach TM, Rescorla LA. 2001. Manual for the ASEBA School-Age Forms and Profiles. Burlington, VT:University of Vermont, Research Center for Children, Youth and Families.

Aldridge JE, Meyer A, Seidler FJ, Slotkin TA. 2005. Alterations in central nervous system serotonergic and dopaminergic synaptic activity in adulthood after prenatal or neonatal chlorpyrifos exposure. Environ Health Perspect 113:1027–1031.

Baddeley A. 2003. Working memory: looking back and forward. Nat Rev Neurosci 4(10):829–839.

Baddeley AD, Logie RH. 1999. Working memory: the multiple-component model. In: Models of Working Memory: Mechanisms of Active Maintenance AND Executive Control (Miyake A, Shah P, eds) New York:Cambridge University press, 28–61.

Barr DB, Barr JR, Maggio VL, Whitehead RD Jr, Sadowski MA, Whyatt RM, et al. 2002. A multi-analyte method for the quantification of contemporary pesticides in human serum and plasma using high resolution mass spectrometry. J Chromatog B Anal Technol Biomed Life Sciences 778:99–111.

Berkowitz GS, Obel J, Deych E, Lapinski R, Godbold J, Liu Z, et al. 2003. Exposure to indoor pesticides during pregnancy in a multiethnic, urban cohort. Environ Health Perspect 111:79–84.

Berkowitz GC, Wetmur JG, Birman-Deych E, Obel J, Lapinski RH, Godbold JH, et al. 2004. *In utero* pesticide exposure, maternal paraoxinase activity, and head circumference. Environ Health Perspect 112:388–391.

Blair C. 2006. How similar are fluid cognition and general intelligence? A developmental neuroscience perspective on fluid cognition as an aspect of human cognitive ability. Behav Brain Science 29:109–125.

Bradman A, Barr DB, Claus Henn BG, Drumheller T, Curry C, Eskenazi B. 2003. Measurement of pesticides and other toxicants in amniotic fluid as a potential biomarker of prenatal exposure: a validation study. Environ Health Perspect 113:1802–1807.

Brown L, Sherbenou RJ, Johnson SK. 1997. Test of Nonverbal Intelligence: A Language-Free Measure of Cognitive Ability. 3rd ed. Austin, TX:PRO-ED, Inc.

Caldwell BM, Bradley RH. 1979. Home Observation for Measurement of the Environment. Little Rock:University of Arkansas Press.

Chiodo LM, Jacobson SW, Jacobson JL. 2004. Neurodevelopmental effects of postnatal lead exposure at very low levels. Neurotoxicol Teratol 26:359–371.

Cowan N. 1999. An embedded-processes model of working memory. In: Models of Working Memory: Mechanisms of Active Maintenance and Executive Control (Miyake A, Shah P, eds). New York:Cambridge University Press, 62–101.

Davidson R, MacKinnon J. 1981. Several tests for model specification in the presence of alternative hypotheses. Econometrica 49:781–793.

Engel SM, Berkowitz GS, Barr DB, Teitelbaum SL, Siskind J, Meisel SL, et al. 2007. Prenatal organophosphate metabolite and organochlorine levels and performance on the Brazelton Neonatal Behavioral Assessment Scale in a multiethnic pregnancy cohort. Am J Epidemiol 165:1397–1404.

Eskenazi B, Marks AR, Bradman A, Harley K, Barr DB, Johnson C, et al. 2007. Organophosphate pesticide exposure and neurodevelopment in young Mexican-American children. Environ Health Perspect 115:792–798.

Guilarte TR, Toscano CD, McGlothan JL, Weaver SA. 2003. Environmental enrichment reverses cognitive and molecular deficits induced by developmental lead exposure. Ann Neurol 53:50–56.

Hecht SA, Burgess SR, Torgesen RK, Wagner RK, Rashotte CA. 2000. Explaining social class differences in growth of reading skills from beginning kindergarten through fourth-grade: the role of phonological awareness, rate of access and print knowledge. Read Writ Interdisciplin J 12:99–127.

Houwelingen JC. 2001. Shrinkage and penalized likelihood as methods to improve predictive accuracy. Stat Neerl 55(1):17–34.

Jusko TA, Henderson CR, Lanphear BP, Cory-Slechta DA, Parsons PJ, Canfield RL. 2008. Blood lead concentrations < 10 μg/dL and child intelligence at 6 years of age. Environ Health Perspect 116:243–248.

Landrigan PJ, Schechter CB, Lipton JM, Fahs MC, Schwartz J. 2002. Environmental pollutants and disease in American children: estimates of morbidity, mortality, and costs for lead poisoning, asthma, cancer, and developmental disabilities. Environ Health Perspect 110:721–728.

Levin ED, Addy N, Baruah A, Elias A, Cannelle CN, Seidler FJ, et al. 2002. Prenatal chlorpyrifos exposure in rats causes persistent behavioral alternations. Neurotoxicol Teratol 24:733–741.

Little RJA. 1992. Regression with missing X's: a review. J Am Stat Assoc 87:1227–1237.

Lu C, Toepel K, Irish R, Fenske RA, Barr DB, Bravo R. 2006. Organic diets significantly lower children's dietary exposure to organophosphate pesticides. Environ Health Perspect 114:260–263.

MacKinnon DP, Lockwood CM, Hoffman JM, West SG, Sheets V. 2002. A comparison of methods to test mediation and other intervening variable effects. Psychol Methods 7:83–104.

Marks AR, Harley K, Bradman A, Kogut K, Barr DB, Johnson C, et al. 2010. Organophosphate pesticide exposure and attention in young Mexican-American children: the CHAMACOS Study. Environ Health Perspect 118:1768–1774.

Perera FP, Illman SM, Kinney PL, Whyatt RM, Kelvin EA, Shepard P, et al. 2002. The challenge of preventing environmentally related disease in young children: community-based research in New York City. Environ Health Perspect 110:197–204.

Perera FP, Rauh V, Tsai WY, Kinney P, Camann D, Barr D, et al. 2003. Effects of transplacental exposure to environmental pollutants on birth outcomes in a multiethnic population. Environ Health Perspect 111:201–205.

Qiao D, Seidler FJ, Tate CA, Cousins MM, Slotkin TA. 2003. Fetal chlorpyrifos exposure: adverse effects on brain cell development and cholinergic biomarkers emerge postnatally and continue into adolescence and adulthood. Environ Health Perspect 111:536–544.

R Development Core Team. 2009. R: A Language and Environment for Statistical Computing. Vienna:R Foundation for Statistical Computing.

Rauh VA, Garfinkel R, Perera FP, Andrews H, Barr D, Whitehead D, et al. 2006. Impact of prenatal chlorpyrifos exposure on neurodevelopment in the first three years of life among inner-city children. Pediatrics 118:e1845–e1859.

Rauh VA, Whyatt RM, Garfinkel R, Andrews H, Hoepner L, Reyes A, et al. 2004. Developmental effects of exposure to environmental tobacco smoke and material hardship among inner-city children. Neurotoxicol Teratol 26:373–385.

Richardson DB, Ciampi A. 2003. Effects of exposure measurement error when an exposure variable is constrained by a lower limit. Am J Epidemiol 57(4):355–363.

Richardson RJ. 1995. Assessment of the neurotoxic potential of chlorpyrifos relative to other organophosphorus compounds: a critical review of the literature. J Toxicol Environ Health 44:135–165.

Rothenberg SJ, Rothenberg JC. 2005. Testing the dose-response specification in epidemiology: public health and policy consequences for lead. Environ Health Perspect 113:1190–1195.

Slotkin TA. 2004. Cholinergic systems in brain development and disruption by neurotoxicants: nicotine, environmental tobacco smoke, organophosphates. Toxicol Appl Pharmacol 198:132–151.

Slotkin TA. 2005. Developmental neurotoxicity of organophosphates: a case study of chlorpyrifos. In: Toxicity of Organophosphates and Carbamate Pesticides (Gupta RC, ed). San Diego:Academic Press, 293–314.

Slotkin TA, Seidler FJ. 2005. The alterations in CNS serotonergic mechanisms caused by neonatal chlorpyrifos exposure are permanent. Dev Brain Res 158:115–119.

Smith EE, Jonides J. 1997. Working memory: a view from neuroimaging. Cogn Psychol 33:5–42.

Sobel ME. 1982. Asymptotic confidence intervals for indirect effects in structural equation models. Sociol Methodol 13:290–312.

Tibshirani R. 1996. Regression shrinkage and selection via the lasso. J R Stat Soc Series B Stat Methodol 58(1):267–288.

U.S. EPA (U.S. Environmental Protection Agency). 2000. Chlorpyrifos Revised Risk Assessment and Agreement with Registrants. Washington, DC:U.S. EPA.

U.S. EPA (U.S. Environmental Protection Agency). 2002. Chlorpyrifos End-Use Products Cancellation Order. Washington, DC:U.S. EPA.

Vallar G, Papano C. 2002. Neuropsychological impairments of verbal short-term memory. In: Handbook of Memory Disorders (Baddeley AD, Kopelman MD, Wilson BA, eds). Chichester, UK:Wiley, 249–270.

Wechsler D. 2003. Wechsler Intelligence Scale for Children. 4th ed. San Antonio, TX:Psychological Corporation.

Whyatt RM, Barr DB, Camann DE, Kinney PL, Barr JR, Andrews HF, et al. 2003. Contemporary-use pesticides in personal air samples during pregnancy and blood samples at delivery among urban minority mothers and newborns. Environ Health Perspect 111:749–756.

Whyatt RM, Camann D, Perera FP, Rauh VA, Tang D, Kinney PL, et al. 2005. Biomarkers in assessing residential insecticide exposures during pregnancy and effects on fetal growth. Toxicol Appl Pharmacol 206:246–254.

Whyatt RM, Camann DE, Kinney PL, Reyes A, Ramirez J, Dietrich J, et al. 2002. Residential pesticide use during pregnancy among a cohort of urban minority women. Environ Health Perspect 110:507–514.

Whyatt RM, Garfinkel R, Hoepner LA, Holmes D, Rorjas M, Perera FP, et al. 2007. Within and between home variability in indoor-air insecticide levels during pregnancy among an inner-city cohort from New York City. Environ Health Perspect 115:383–390.

Whyatt RM, Rauh VA, Barr DB, Camann DE, Andrews HF, Garfinkel R, et al. 2004. Prenatal insecticide exposure and birth weight and length among an urban minority cohort. Environ Health Perspect 112:1125–1132.

Young JG, Eskenazi B, Gladstone EA, Bradman A, Pedersen L, Johnson C, et al. 2005. Association between in utero organophosphate exposure and abnormal reflexes in neonates. Neurotoxicology 26:199–209.

Zhao P, Yu B. 2006. On model selection consistency of Lasso. J Machine Learn Res 7:2541–2563.

Senator MERKLEY. You have been paid to assess the safety of this chemical. Who paid you or TERA to assess the safety of this chemical?

Mr. DOURSON. In 2006, in 2005, we did two manuscripts——

Senator MERKLEY. Who paid you? That is the question.

Mr. DOURSON. It was Dow AgroScience.

Senator MERKLEY. Thank you. So, my understanding of your organization is that you ultimately recommended a safe level of 10 micrograms per kilogram per day. That standard is quite different from the EPA floor for safety for children ages 1 to 2 of .0017 micrograms per kilogram per day. In fact, the safety level you proposed in your study, paid for by Dow Chemical, the very same company that makes this chemical, is 5,822 times less protective than the level proposed by the EPA.

I would like to turn to alachlor and acetochlor, two herbicides that are widely used. Simple yes or no, have they been linked to cancer?

Mr. DOURSON. We did the study for a collection of industries——

Senator MERKLEY. Have they been linked? This is a yes or no question. Your knowledge, your background, your life's work, are you aware of these studies linking these chemicals to cancer?

Mr. DOURSON. I am aware of studies with neurological disturbances with acetochlor.

Senator MERKLEY. But not cancer?

Mr. DOURSON. I am not so sure I recall those data.

Senator MERKLEY. Mr. Chairman, I would like to submit for the record the following peer reviewed study linking alachlor and acetochlor to cancer.

Senator BARRASSO. Without objection.

Senator MERKLEY. Thank you very much.

[The referenced information follows:]

American Journal of Epidemiology
Copyright © 2004 by the Johns Hopkins Bloomberg School of Public Health
All rights reserved
Vol. 159, No. 4
Printed in U.S.A.
DOI: 10.1093/aje/kwh040

Cancer Incidence among Pesticide Applicators Exposed to Alachlor in the Agricultural Health Study

Won Jin Lee[1], Jane A. Hoppin[2], Aaron Blair[1], Jay H. Lubin[3], Mustafa Dosemeci[1], Dale P. Sandler[2], and Michael C. R. Alavanja[1]

[1] Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, Rockville, MD.
[2] Epidemiology Branch, National Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, Research Triangle Park, NC.
[3] Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, National Institutes of Health, Department of Health and Human Services, Rockville, MD.

Received for publication May 9, 2003; accepted for publication July 31, 2003.

The authors evaluated the incidence of cancer among pesticide applicators with exposure to alachlor in the Agricultural Health Study, a prospective cohort study of licensed pesticide applicators in Iowa and North Carolina. A total of 49,980 pesticide applicators are included in this analysis; 26,510 applicators (53%) reported use of alachlor on the enrollment questionnaire. Detailed pesticide exposure and other information were obtained from a self-administered questionnaire completed at the time of enrollment (1993–1997). Poisson regression analysis was used to evaluate the exposure-response relations between alachlor and cancer incidence controlled for the effects of potential confounding factors. A total of 1,466 incident malignant neoplasms were diagnosed during the study period, 1993–2000. Among alachlor-exposed applicators, the authors found a significant increasing trend for incidence of all lymphohematopoietic cancers associated with lifetime exposure-days (p for trend = 0.02) and intensity-weighted exposure-days (p for trend = 0.03) to alachlor. The risks of leukemia (rate ratio = 2.83, 95% confidence interval: 0.74, 10.9) and multiple myeloma (rate ratio = 5.66, 95% confidence interval: 0.70, 45.7) were increased among applicators in the highest alachlor exposure category. Our findings suggest a possible association between alachlor application and incidence of lymphohematopoietic cancers among applicators in the Agricultural Health Study.

agriculture; cohort studies; herbicides; leukemia; multiple myeloma; neoplasms; occupational exposure; pesticides

Abbreviations: CI, confidence interval; OR, odds ratio; SIR, standardized incidence ratio.

Alachlor (2-chloro-2′,6′-diethyl-*N*-(methoxymethyl)acetanilide) is a pre- and early post-emergent herbicide used mainly in the production of corn, soybeans, and peanuts (1). Alachlor has been marketed since 1969 under the trade name Lasso (Monsanto Company, St. Louis, Missouri). According to US Environmental Protection Agency estimates, alachlor had an annual usage of 7–10 million pounds (1 pound = 0.45 kg) in 1999, making it one of the most widely used herbicides in the United States (2).

Alachlor produced thyroid (3), nasal (4), and stomach cancers (5) in rats presumedly by a nongenotoxic, threshold-sensitive process (6). In 1985, the US Environmental Protection Agency categorized alachlor as a probable human carcinogen (7). There is little epidemiologic information on cancer in alachlor-exposed populations. Two retrospective cohort studies showed elevated risks for colorectal cancer and leukemia among alachlor-manufacturing workers (8, 9). However, interpretation of these findings is difficult because of the small number of observed cancer cases (n = 23 (8) and n = 18 (9)) and the lack of control for potentially confounding exposures.

Reprint requests to Dr. Michael C. R. Alavanja, 6120 Executive Boulevard, EPS 8000, Occupational Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Rockville, MD 20852 (e-mail: alavanjm@mail.nih.gov).

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

The Agricultural Health Study cohort (10) will be used to comprehensively examine the hypothesized link between a wide variety of occupational exposures among farmers and commercial applicators and the risk of cancer and other chronic diseases. Our overall approach is to evaluate risk factors for specific diseases of interest once sufficient numbers of exposed cases have been observed in the cohort (e.g., prostate cancer (11)) and also to evaluate cancer risks among selected exposure groups of a priori interest. For the latter, we first focus on major-use pesticides of biologic interest. In this context, we have chosen to examine the cancer experience of alachlor applicators because alachlor is widely used in US agriculture and it has animal bioassay data, which suggest that it may be a human carcinogen.

MATERIALS AND METHODS

Cohort enrollment and follow-up

The Agricultural Health Study is a prospective cohort study composed of 57,311 applicators licensed to apply restricted use pesticides and the 32,347 spouses of private applicators from Iowa and North Carolina (10). Recruitment of applicators began in December 1993 and continued until December 1997. Cohort members were matched to cancer registry files in Iowa and North Carolina for case identification and to the state death registries and to the National Death Index to ascertain vital status. Incident cancers were identified from the date of enrollment (i.e., 1993–1997) through December 31, 2000, and coded according to the *International Classification of Diseases*, Ninth Revision (12). Cohort members alive but no longer residing in Iowa or North Carolina ($n = 857$) were identified through the current address records of the Internal Revenue Service, motor vehicle registration offices, and pesticide license registries of the state agriculture departments, and they were censored in the year they left the state. The average number of years of follow-up is 5.5 years.

Exposure assessment

A self-administered enrollment questionnaire collected comprehensive exposure data on 22 pesticides and ever/never use information for 28 more pesticides, as well as information on use of personal protective equipment, pesticide application methods, pesticide mixing, equipment repair, smoking, alcohol consumption, cancer history of first-degree relatives, and basic demographic data. (The questionnaire may be found at http://www.aghealth.org). Questionnaire data from the enrollment and measurement data from the published pesticide exposure literature were used to calculate the estimated intensity of exposure to individual pesticides using the formula: intensity level = (mixing status + application method + equipment repair status) × personal protective equipment use (13). We constructed two lifetime alachlor exposure variables, each categorized into quartiles for this analysis: 1) lifetime exposure-days based on the number of years applied and the frequency of application using the midpoints of the questionnaire category (i.e., years of use × days per year: <19.9, 20.0–56.0, 56.1–116.0, ≥116.1) and 2) intensity-weighted exposure-days multiplying lifetime exposure-days by exposure intensity level (i.e., years of use × days per year × intensity level: <101.9, 102.0–253.1, 253.2–710.4, ≥710.5).

Data analysis

Prevalent cancer cases ($n = 1,064$) and applicators who did not provide any information on alachlor use ($n = 6,267$) were excluded from this analysis, leaving 26,510 exposed and 23,470 nonexposed applicators. Those excluded were mainly from North Carolina (69 percent) and were likely to have missing data for other variables.

A standardized incidence ratio for all cancers was calculated as the ratio of observed to expected number of cancer cases using standard methods (14, 15). Expected numbers for the standardized incidence ratio were estimated from 5-year age and calendar-time, race-specific cancer incidence rates from the population-based cancer registries in Iowa and North Carolina. We also conducted site-specific analysis for cancers with five or more exposed cases.

Poisson regression analysis using the Stata program (version 7.0) (16) was conducted while controlling for the effect of potential confounding factors to examine internal exposure-response relations. Rate ratios derived from the analysis were adjusted for age at enrollment (<40, 40–49, 50–59, ≥60 years), sex, education (high school graduate or less, greater than high school), smoking (by pack-years: never/low/high), alcohol drinking during the past 12 months (yes/no), family history of cancer in first-degree relatives (yes/no), state (Iowa/North Carolina), and enrollment year. The median value of pack-years among smokers (12 pack-years) was used to classify the "low" and "high" categories of smokers. The reference group for each rate ratio was the lowest level of lifetime exposure-days or intensity-weighted exposure-days; applicators who reported not using alachlor were excluded from the Poisson regression analyses. Since there was potential confounding from other pesticide exposures, we also adjusted rate ratios for the five most highly correlated pesticides (atrazine, cyanazine, metolachlor, trifluralin, 2,4-dichlorophenoxyacetic acid (2,4-D)), with intensity-weighted exposure-days of alachlor ($r \geq 0.4$). The exposure levels of these five pesticides were categorized as never, low, and high. The low group and the high group of each pesticide were classified by the median intensity-weighted exposure-days of each pesticide. Tests for linear trend were performed to assess exposure-response patterns in each cancer outcome using the method described by Breslow and Day (17). All significance tests were two sided.

RESULTS

Table 1 shows selected characteristics of applicators by alachlor exposure. The majority of the cohort are male private applicators. Among subjects with complete exposure information, 25,532 applicators have used alachlor and have information on lifetime alachlor exposure-days. This group was divided into two parts, that is, the lowest exposed quartile ($n = 5,539$) and the three remaining exposed quartiles ($n = 19,993$). The group with no alachlor use consisted of

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

TABLE 1. Selected characteristics of applicators, by alachlor exposure, based on 1993–1997 enrollment data in the Agricultural Health Study

Characteristics	The lowest exposed* (*n* = 5,539)		Other exposed† (*n* = 19,993)		Nonexposed (*n* = 23,470)	
	No.	%	No.	%	No.	%
Age (years)						
<40	1,647	29.7	5,709	28.6	9,168	39.1
40–49	1,650	29.8	6,341	31.7	6,062	25.8
50–59	1,210	21.9	4,478	22.4	4,255	18.1
≥60	1,032	18.6	3,465	17.3	3,984	17.0
Gender						
Male	5,450	98.4	19,866	99.4	22,432	95.6
Female	89	1.6	127	0.6	1,038	4.4
State of residence						
Iowa	4,140	74.7	14,387	72.0	15,138	64.5
North Carolina	1,399	25.3	5,606	28.0	8,332	35.5
Applicator type‡						
Private	5,304	95.8	18,241	91.2	20,893	89.0
Commercial	235	4.2	1,752	8.8	2,577	11.0
Smoking history						
Never	3,045	56.5	10,574	54.4	12,678	55.7
Low (<12 pack-years)	1,239	23.0	4,339	22.3	5,117	22.5
High (≥12 pack-years)	1,102	20.5	4,542	23.3	4,950	21.8
Alcohol drinking history§						
No	1,632	29.7	5,546	28.0	7,699	33.4
Yes	3,855	70.3	14,262	72.0	15,371	66.6
Education						
High school or less	2,859	52.8	10,842	55.3	12,827	56.0
Greater than high school	2,555	47.2	8,756	44.7	10,087	44.0
Family history of cancer						
No	2,950	56.1	10,751	56.8	14,005	63.1
Yes	2,305	43.9	8,184	43.2	8,190	36.9
Corn production						
No	1,117	20.2	3,623	18.1	9,504	40.5
Yes	4,422	79.8	16,370	81.9	13,966	59.5
Five pesticides most highly correlated with alachlor						
Atrazine	4,390	80.1	17,647	89.1	11,382	49.2
Cyanazine	2,818	51.3	11,514	58.0	5,314	22.8
Metolachlor	2,975	54.3	12,397	62.5	6,610	28.4
Trifluralin	3,353	61.2	12,686	64.1	8,356	36.1
2,4-D¶	4,569	83.7	17,273	87.5	13,993	60.9

* First quartile of lifetime exposure-days (years of use × days per year).

† Second, third, and fourth quartiles of lifetime exposure-days (years of use × days per year).

‡ The term "private applicators" refers primarily to individual farmers, and "commercial" refers to professional pesticide applicators.

§ Based on the question, "Did you ever drink any kind of alcoholic beverage during the past 12 months?".

¶ 2,4-D, 2,4-dichlorophenoxyacetic acid.

23,470 applicators. The lowest exposed quartile is observed to be more similar to the remaining three exposed quartiles than to the nonexposed group of applicators on a number of important variables. These include age, sex, state of residence, family history of cancer, type of farm (corn production), and the number of different pesticides used in a

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77127/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

TABLE 2. Standardized incidence ratios and rate ratios for selected cancers* by alachlor exposure status of the Agricultural Health Study applicators, 1993–2000

Cause of cancer (ICD-9† classification)	Exposed			Nonexposed			Exposed/nonexposed	
	Observed (no.)	SIR†	95% CI†	Observed (no.)	SIR	95% CI	RR†,‡	95% CI
All malignant neoplasms (codes 140–208)	805	0.80	0.74, 0.85	661	0.81	0.75, 0.87	1.01	0.88, 1.15
Buccal cavity, pharynx (codes 140–149)	22	0.60	0.37, 0.91	23	0.81	0.52, 1.22	0.71	0.34, 1.49
Esophagus (code 150)	12	0.79	0.41, 1.39	4	0.35	0.09, 0.89	1.77	0.46, 6.74
Stomach (code 151)	8	0.51	0.22, 1.01	10	0.82	0.39, 1.50	0.37	0.12, 1.15
Colorectal (codes 153 and 154)	87	0.72	0.58, 0.89	72	0.76	0.59, 0.95	0.82	0.55, 1.21
Colon (code 153)	61	0.76	0.58, 0.98	49	0.77	0.57, 1.01	0.86	0.54, 1.37
Rectum (code 154)	26	0.64	0.42, 0.94	23	0.74	0.47, 1.11	0.74	0.36, 1.51
Liver (codes 155 and 156)	7	1.09	0.44, 2.25	5	0.96	0.31, 2.25	1.36	0.32, 5.78
Pancreas (code 157)	13	0.61	0.33, 1.05	14	0.83	0.45, 1.39	0.49	0.20, 1.24
Larynx (code 161)	7	0.36	0.14, 0.74	4	0.26	0.07, 0.67	3.33	0.62, 17.78
Lung (code 162)	83	0.44	0.35, 0.54	63	0.41	0.31, 0.52	1.11	0.70, 1.77
Melanoma (code 172)	38	1.00	0.70, 1.37	20	0.64	0.39, 0.99	1.59	0.83, 3.05
Prostate (code 185)	325	1.16	1.04, 1.30	246	1.13	0.99, 1.28	1.13	0.91, 1.41
Testis (code 186)	8	0.89	0.38, 1.75	11	1.23	0.61, 2.21	0.75	0.25, 2.23
Bladder (code 188)	30	0.49	0.33, 0.71	25	0.51	0.33, 0.75	1.07	0.54, 2.12
Kidney (code 189)	23	0.74	0.47, 1.11	24	0.99	0.63, 1.47	0.63	0.28, 1.42
Brain (codes 191 and 192)	13	0.84	0.44, 1.43	11	0.87	0.43, 1.55	0.99	0.34, 2.90
Thyroid (code 193)	10	1.27	0.61, 2.33	6	0.90	0.33, 1.97	1.63	0.42, 6.37
All lymphohematopoietic cancers (codes 200–208)	70	0.85	0.66, 1.07	65	0.98	0.76, 1.25	0.83	0.54, 1.26
Non-Hodgkin's lymphoma (codes 200 and 202)	29	0.73	0.49, 1.05	32	1.00	0.69, 1.41	0.50	0.26, 0.94
Multiple myeloma (code 203)	11	1.04	0.52, 1.87	11	1.30	0.65, 2.33	0.93	0.30, 2.84
Leukemia (codes 204–208)	26	0.94	0.61, 1.38	19	0.88	0.53, 1.38	1.53	0.72, 3.25

* Cancer subtypes with fewer than five exposed cases are not shown.

† ICD-9, *International Classification of Diseases*, Ninth Revision; SIR, standardized incidence ratio; CI, confidence interval; RR, rate ratio.

‡ Rate ratio adjusted for age, sex, alcohol, smoking, education, family history of cancer, enrollment year, state of residence, and the five pesticides most highly correlated with alachlor (atrazine, cyanazine, metolachlor, trifluralin, 2,4-D (2,4-dichlorophenoxyacetic acid)). The reference category was applicators who were not exposed to alachlor.

lifetime—variables that could be surrogates of important occupational and environmental exposures not explicitly identified by our study questionnaire but potential confounders in our analysis.

A total of 805 and 661 incident cancers were observed among alachlor-exposed and alachlor-nonexposed applicators, respectively (table 2). The standardized incidence ratio analysis indicates that both the alachlor-exposed (standardized incidence ratio (SIR) = 0.80, 95 percent confidence interval (CI): 0.74, 0.85) and the alachlor-nonexposed (SIR = 0.81, 95 percent CI: 0.75, 0.87) groups show a significant reduced risk of cancer overall compared with those expected based on incidence rates in Iowa and North Carolina. This is particularly true for smoking-related cancers, for example, lung cancer, for we observed a standardized incidence ratio of 0.44 (95 percent CI: 0.35, 0.54) among those exposed to alachlor and a standardized incidence ratio of 0.41 (95 percent CI: 0.31, 0.52) among those nonexposed. Findings for bladder cancer were similar with a significantly reduced risk among those exposed (SIR = 0.49) and those nonexposed (SIR = 0.51). For colorectal cancer and cancers not typically associated with smoking, a significantly reduced risk was observed for both the alachlor-exposed group (SIR = 0.72) and the nonexposed group (SIR = 0.76). For prostate cancer, a small but similar excess was seen in both the exposed (SIR = 1.16) and nonexposed (SIR = 1.13) groups. A marginally lower risk for melanoma was observed among the nonexposed alachlor group (SIR = 0.64) but not among those exposed to alachlor (SIR = 1.00).

The non-Hodgkin's lymphoma risk (rate ratio = 0.50) was significantly lower than expected when we directly compared those exposed to alachlor versus those nonexposed by the mean of relative risks controlled for age, sex, alcohol, smoking, education, family history of cancer, enrollment year, state of residence, and the five pesticides most highly correlated with alachlor (table 2). All other relative risks are in the expected range. The results from state-specific analyses were similar (not shown).

The rate ratios for selected cancers, including those of a priori interest (nasal cavity, stomach, thyroid), are reported in table 3 by quartiles of lifetime exposure-days and intensity-weighted alachlor exposure-days. For all cancers

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

TABLE 3. Rate ratios for selected cancers by lifetime exposure-days and intensity-weighted exposure-days to alachlor among Agricultural Health Study applicators, 1993–2000

	All neoplasms			All lymphohematopoietic cancers			Leukemia			Multiple myeloma			Non-Hodgkin's lymphoma		
	No. of cases	RR*,†	95% CI*	No. of cases	RR	95% CI	No. of cases	RR	95% CI	No. of cases	RR	95% CI	No. of cases	RR	95% CI
Lifetime alachlor exposure-days‡															
0.1–19.9§	148	1.0		14	1.0		6	1.0		3	1.0		5	1.0	
20.0–56.0	221	1.22	0.96, 1.55	12	0.67	0.27, 1.66	6	0.76	0.19, 3.07	1	0.48	0.04, 5.47	4	0.55	0.12, 2.48
56.1–116.0	180	1.34	1.04, 1.73	16	1.59	0.70, 3.63	4	1.16	0.28, 4.82	2	1.53	0.20, 11.8	8	1.50	0.42, 5.40
≥116.1	206	1.27	0.97, 1.65	26	2.04	0.89, 4.65	10	3.01	0.82, 11.0	5	2.99	0.47, 19.0	10	1.14	0.30, 4.36
Trend¶		0.08			0.02			0.05			0.14			0.53	
Intensity-weighted alachlor exposure-days#															
0.1–101.9§	189	1.0		15	1.0		7	1.0		3	1.0		5	1.0	
102.0–253.1	188	1.37	1.09, 1.74	12	0.99	0.40, 2.44	7	0.99	0.27, 3.58	2	2.22	0.29, 16.9	3	0.62	0.11, 3.44
253.2–710.4	188	1.42	1.11, 1.82	18	2.14	0.95, 4.83	3	0.85	0.19, 3.73	1	1.12	0.09, 14.4	10	2.40	0.65, 8.82
≥710.5	189	1.11	0.84, 1.46	23	2.42	1.00, 5.89	9	2.83	0.74, 10.9	5	5.66	0.70, 45.7	9	1.40	0.32, 6.11
Trend		0.39			0.03			0.17			0.13			0.42	

	Bladder cancer			Colon cancer			Rectal cancer			Stomach cancer			Thyroid cancer		
	No. of cases	RR	95% CI	No. of cases	RR	95% CI	No. of cases	RR	95% CI	No. of cases	RR	95% CI	No. of cases	RR	95% CI
Lifetime alachlor exposure-days															
0.1–19.9§	4	1.0		11	1.0		6	1.0		3	1.0		3	1.0	
20.0–56.0	7	1.25	0.30, 5.27	17	1.68	0.69, 4.14	3	0.32	0.06, 1.78	1	0.27	0.02, 3.35	3	1.17	0.10, 13.2
56.1–116.0	5	1.72	0.40, 7.45	18	2.00	0.79, 5.09	8	1.68	0.48, 5.83	1	0.25	0.02, 3.47	2	1.53	0.13, 17.8
≥116.1	13	3.65	0.92, 14.5	13	0.62	0.20, 1.99	7	0.71	0.16, 3.11	2	0.49	0.05, 4.78	2	1.27	0.10, 16.4
Trend		0.03			0.53			0.77			0.53			0.82	
Intensity-weighted alachlor exposure-days															
0.1–101.9§	4	1.0		14	1.0		6	1.0		4	1.0		3	1.0	
102.0–253.1	8	3.11	0.79, 12.3	12	1.36	0.56, 3.34	7	1.68	0.46, 6.17	0			2	2.17	0.19, 24.9
253.2–710.4	10	3.64	0.89, 14.8	16	1.85	0.76, 4.50	3	0.75	0.15, 3.73	1	0.20	0.02, 2.52	2	0.93	0.05, 16.5
≥710.5	7	2.03	0.41, 10.0	17	1.14	0.40, 3.23	8	1.07	0.23, 5.07	2	0.22	0.02, 2.26	3	2.89	0.22, 38.7
Trend		0.44			0.64			0.83			0.31			0.54	

* RR, rate ratio; CI, confidence interval.

† Rate ratio adjusted for age, sex, alcohol, smoking, education, family history of cancer, enrollment year, state of residence, and the five pesticides most highly correlated with alachlor (atrazine, cyanazine, metolachlor, trifluralin, 2,4-D (2,4-dichlorophenoxyacetic acid)).

‡ Lifetime exposure-days = years of use × days per year.

§ Reference group.

¶ *p* value for trend test.

Intensity-weighted exposure-days = years of use × days per year × intensity index.

combined, there was no trend of increasing risk with increasing exposure. A significant exposure-response trend was observed for all lymphohematopoietic cancers combined using either the lifetime exposure-days or intensity-weighted exposure-days, rising to an over twofold increased risk in the highest category. The risks of leukemia and multiple myeloma were markedly increased in the highest exposure category, although they had wide confidence intervals. These results were not changed when we added "total years of pesticide application" to the multivariate analysis as a surrogate measure of other potential farming exposures (data not shown). A significant trend for bladder cancer was observed for the lifetime exposure-days but not the intensity-weighted exposure-days. Similar analyses for other cancers did not suggest associations. An analysis that was restricted to private applicators living in Iowa

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

yielded results similar to those reported in table 3. The results for North Carolina applicators were unstable as a result of smaller numbers of cases.

DISCUSSION

We found significant positive exposure-response trends among pesticide applicators exposed to alachlor for all lymphohematopoietic cancers combined, using two exposure measures (i.e., lifetime exposure-days and intensity-weighted exposure-days). Among the lymphohematopoietic cancers, leukemia and multiple myeloma showed this pattern independently, but the numbers were small. The findings were similar when we repeated the exposure-response analyses restricting the study population to Iowa or to private applicators.

Elevated risks for all lymphohematopoietic cancers (SIR = 3.6, 95 percent CI: 1.2, 8.5) and chronic myeloid leukemia (SIR = 25.0, 95 percent CI: 3.0, 90.3) have been reported for alachlor-manufacturing workers (9). A subsequent analysis of these manufacturing workers also showed an increased risk for chronic myeloid leukemia (8). However, population-based case-control studies have shown no significant association between alachlor exposure and leukemia (odds ratio (OR) = 1.0, 95 percent CI: 0.7, 1.5) (18), non-Hodgkin's lymphoma (OR = 1.2, 95 percent CI: 0.8, 1.7) (19), or multiple myeloma (OR = 0.9, 95 percent CI: 0.5, 1.7) (20). As with many population-based case-control studies, these were limited by the relatively small numbers of exposed cases and the fact that exposure assessment was conducted after disease diagnosis.

There is some evidence of a genotoxic effect of alachlor in experimental systems. In mammals, alachlor induced chromosomal aberrations in bone marrow cells of Wistar rats treated in vivo (21) and in cultured Chinese hamster ovary cells (22). Increased thyroid, stomach, and nasal tumors were observed in Long-Evans and Sprague-Dawley rats associated with alachlor exposure (3–6). Alachlor also has been found to cause chromosomal damage in human lymphocytes (21, 23) exposed in vitro.

Our standardized incidence ratio analysis of those exposed and those nonexposed to alachlor indicates that the two groups are both at significantly reduced risk of cancer overall and particularly to smoking-related cancers of the lung and bladder. A similar reduced risk is observed among both groups for colorectal cancer, which may in part be due to the more physically active work of farmers and commercial pesticide applicators compared with other residents of Iowa and North Carolina. The fact that melanoma is marginally lower than expected among the nonexposed group and not among the exposed group may indicate that nonexposed cohort members are less frequently exposed to excess sunlight exposure. Although comparing all those ever exposed with those never exposed to alachlor in a standardized incidence ratio analysis can establish whether the two groups have similar cancer risk profiles, standardized incidence ratios are a relatively insensitive indicator of occupational risk because they cannot adequately control for significant confounding factors and have well-established "healthy worker" problems. The significantly lower risk of non-Hodgkin's lymphoma observed among those exposed to alachlor compared with those not exposed while controlling for age, sex, alcohol, smoking, education, family history of cancer, enrollment year, state of residence, and the five most highly correlated pesticides with alachlor is unexpected. This "protective effect" of alachlor is not observed in the subsequent dose-response analysis described in table 3, and it is likely therefore to be a statistical artifact due to either chance or residual confounding resulting from exposure not explicitly identified by our questionnaire.

Although a significant 1.3-fold risk for all cancers combined was found among applicators in the second highest category of lifetime exposure to alachlor, the lack of a monotonic exposure-response relation suggests that this increase may be due to chance. Moreover, we did not find increased cancer risks for several sites of a priori interest that were positive in animal bioassays including the nose, stomach, and thyroid gland. Since the number of observed cases at these sites was small during our short follow-up study, continued follow-up is warranted. Although the use of positive animal bioassays to indicate the potentially important biologic activity of a chemical is standard practice, extrapolating organ site-specific experimental results to humans is problematic because of differences in human metabolism, physiology, and environmental conditions (24).

A previous cohort study (9) reported increased risk (SIR) for colorectal cancer among alachlor-manufacturing workers. However, Acquavella et al. (8) suggested that the association between alachlor and colorectal cancer was noncausal because they did not observe any cases in a highly exposed department and because the colon plays only a minor role in alachlor metabolism and excretion. We saw no excess for colorectal cancer in the standardized incidence ratio analysis nor any trend by level of exposure.

Our observation of a slightly increased standardized incidence ratio for prostate cancer among both alachlor-exposed and alachlor-nonexposed applicators is consistent with a previous report from this study and with results from other studies of farmers (25–30). Recently, Alavanja et al. (11) reported that chlorinated pesticides and methyl bromide (but not alachlor) were significantly associated with an excess risk of prostate cancer in this cohort. We did not see any association between alachlor and prostate cancer in the Poisson analyses.

An increasing trend for bladder cancer associated with lifetime exposure-days was observed. The lack of a corresponding increase with the intensity-weighted exposure-days is difficult to explain but argues against a causal relation.

Overall, 17 percent of applicators in this cohort are current smokers, which rate is lower than for the United States as a whole (28 percent for males and 23 percent for females) (31). The observed deficits for smoking-related cancers, such as cancers of the lung, bladder, larynx, and buccal cavity, compared with rates for the general population in Iowa and North Carolina are consistent with the low prevalence of smoking in the Agricultural Health Study cohort. Our exposure-response analyses are adjusted for tobacco use and other potentially important confounders.

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

Although the period of cohort follow-up is still relatively short (5.5 years on average), this study has several important strengths. The Agricultural Health Study is the largest study of pesticide applicators exposed to alachlor conducted to date. All exposure information was collected prior to the diagnosis of cancer, which obviates case-recall bias. This study included comprehensive questionnaire data that were used to quantitatively estimate alachlor exposure levels and to control for potential confounding (10, 13).

A limitation of this study and almost all studies of pesticide users is that persons who apply pesticides are seldom exposed to just a single agent and that potential confounding is, therefore, possible. Coble et al. (32) evaluated the relations among different agricultural exposures and found that substantial bias due to confounding from exposure to multiple agents was unlikely in this cohort. However, the significant difference observed between alachlor users and nonusers (table 1) for age, gender, state of residence, applicator type, family history of cancer, corn production, and other coexposure to pesticides suggests the possibility that unrecognized residual confounding may bias the dose-response relation in our analysis. To mitigate the possibility of residual confounding, we chose the lowest alachlor exposure group as the referent in our rate ratio analysis rather than the nonexposed group, and we adjusted the lymphohematopoietic risk estimates by including the five pesticides most highly correlated with alachlor in our models.

A total of 857 (less than 1 percent) cohort members left the states of Iowa and North Carolina during the period of the study from 1993 through 2000, and any cancers resulting from this group are lost to the state cancer registry. This small portion of the total cohort is younger and more educated, smokes less, and has a slightly lower frequency of family history of cancer than the total cohort (data not shown) and is therefore likely to generate proportionally fewer cancers than the rest of the cohort. To assess the magnitude of the potential bias caused by having this group of low-cancer-risk study subject leave the cohort, we recalculated our risk estimated by adding all the lost person-years generated by this group to the denominator and assumed no cancer cases in the numerator. We observed only minimal changes in our risk estimates that did not affect our conclusion.

Additionally, the formulation and use of alachlor may have changed over the years. These factors create a potential for some exposure misclassification, particularly in studies where exposure is based on subject recall. Subjects in this study were asked to recall pesticide use over their lifetime. Recall of pesticide use by the Agricultural Health Study cohort has been shown to be similarly reliable to that for other factors routinely evaluated by questionnaire in epidemiology studies, such as smoking and alcohol use, and to be better than others, such as consumption of fruits and vegetables and physical activity (33). Hoppin et al. (34) also demonstrated that participants in our cohort provided plausible information regarding the duration of use of specific pesticides.

Our study had relatively low statistical power to detect excess risks for less common cancers. The statistical power to detect a 1.5-fold increase in the incidence of cancers of a priori interest varied by site, from 75 percent for lymphohematopoietic tissue to 63 percent for colon, 17 percent for stomach, and 12 percent for thyroid cancer.

Although the interpretation of our results is limited by a small number of cases, our findings suggest a possible association between alachlor application and the incidence of lymphohematopoietic cancers—in particular leukemia and multiple myeloma—among applicators in the Agricultural Health Study. Additional follow-up of this cohort will shed further light on the risks for these and other cancers as the number of cancer cases increases over time.

REFERENCES

1. Hayes WJ Jr, Laws ER Jr, eds. Handbook of pesticide toxicology. Vol 3. Classes of pesticides. New York, NY: Academic Press, Inc, 1991:1341–3.
2. Donaldson D, Kiely T, Grube A. Pesticide industry sales and usage: 1998 and 1999 market estimates. Washington, DC: Environmental Protection Agency, 2002. (http://www.epa.gov/oppbead1/pestsales/99pestsales/market_estimates1999.pdf).
3. Wilson AG, Thake DC, Heydens WE, et al. Mode of action of thyroid tumor formation in the male Long-Evans rat administered high doses of alachlor. Fundam Appl Toxicol 1996;33:16–23.
4. Genter MB, Burman DM, Dingeldein MW, et al. Evolution of alachlor-induced nasal neoplasms in the Long-Evans rat. Toxicol Pathol 2000;28:770–81.
5. Thake DC, Iatropoulos MJ, Hard GC, et al. A study of the mechanism of butachlor-associated gastric neoplasms in Sprague-Dawley rats. Exp Toxicol Pathol 1995;47:107–16.
6. Heydens WF, Wilson AG, Kier LD, et al. An evaluation of the carcinogenic potential of the herbicide alachlor to man. Hum Exp Toxicol 1999;18:363–91.
7. Special review of certain pesticide products—alachlor. Springfield, VA: Office of Pesticide Programs, Environmental Protection Agency, 1985. (Document no. PB85-175503).
8. Acquavella JF, Riordan SG, Anne M, et al. Evaluation of mortality and cancer incidence among alachlor manufacturing workers. Environ Health Perspect 1996;104:728–33.
9. Leet T, Acquavella J, Lynch C, et al. Cancer incidence among alachlor manufacturing workers. Am J Ind Med 1996;30:300–6.
10. Alavanja MC, Sandler DP, McMaster SB, et al. The Agricultural Health Study. Environ Health Perspect 1996;104:362–9.
11. Alavanja MC, Samanic C, Dosemeci M, et al. Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study cohort. Am J Epidemiol 2003;157:800–14.
12. World Health Organization. International classification of diseases. Manual of the international statistical classification of diseases, injuries, and causes of death. Ninth Revision. Geneva, Switzerland: World Health Organization, 1979.
13. Dosemeci M, Alavanja MC, Rowland AS, et al. A quantitative approach for estimating exposure to pesticides in the Agricultural Health Study. Ann Occup Hyg 2002;46:245–60.
14. Lidell F. Simple exact analysis of the standardized mortality ratio. J Epidemiol Community Health 1984;38:85–8.
15. Monson RR. Occupational epidemiology. 2nd ed. Boca Raton, FL: CRC Press, 1990:105–31.
16. StataCorp. Stata reference manual: release 7. College Station, TX: Stata Press, 2001.
17. Breslow NE, Day NE. Statistical methods in cancer research. Vol II. The design and analysis of cohort studies. Lyon, France:

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

International Agency for Research on Cancer, 1987:91–103. (IARC scientific publication no. 82).
18. Brown LM, Blair A, Gibson R, et al. Pesticide exposures and other agricultural risk factors for leukemia among men in Iowa and Minnesota. Cancer Res 1990;50:6585–91.
19. Cantor KP, Blair A, Everett G, et al. Pesticides and other agricultural risk factors for non-Hodgkin's lymphoma among men in Iowa and Minnesota. Cancer Res 1992;52:2447–55.
20. Brown LM, Burmeister LF, Everett GD, et al. Pesticide exposures and multiple myeloma in Iowa men. Cancer Causes Control 1993;4:153–6.
21. Georgian L, Moraru I, Draghicescu T, et al. Cytogenetic effects of alachlor and mancozeb. Mutat Res 1983;116:341–8.
22. Lin MF, Wu CL, Wang TC. Pesticide clastogenicity in Chinese hamster ovary cells. Mutat Res 1987;188:241–50.
23. Meisner LF, Belluck DA, Roloff BD. Cytogenetic effects of alachlor and/or atrazine in vivo and in vitro. Environ Mol Mutagen 1992;19:77–82.
24. Madle S, Obe G. Methods for analysis of the mutagenicity of indirect mutagens/carcinogens in eukaryotic cells. Hum Genet 1980;56:7–20.
25. Blair A, Zahm SH. Cancer among farmers. Occup Med 1991;6:335–54.
26. Blair A, Zahm SH. Agricultural exposures and cancer. Environ Health Perspect 1995;103(suppl 8):205–8.
27. Morrison H, Savitz D, Semenciw R, et al. Farming and prostate cancer mortality. Am J Epidemiol 1993;137:270–80.
28. Aronson KJ, Siemiatycki J, Dewar R, et al. Occupational risk factors for prostate cancer: results from a case-control study in Montreal, Quebec, Canada. Am J Epidemiol 1996;143:363–73.
29. Keller-Byrne JE, Khuder SA, Schaub EA. Meta-analyses of prostate cancer and farming. Am J Ind Med 1997;31:580–6.
30. Acquavella J, Olsen G, Cole P, et al. Cancer among farmers: a meta-analysis. Ann Epidemiol 1998;8:64–74.
31. Centers for Disease Control and Prevention. Smoking and health: United States National Health Interview surveys, selected years 1965–1991. Atlanta, GA: Centers for Disease Control and Prevention, 1995.
32. Coble J, Hoppin JA, Engel L, et al. Prevalence of exposure to solvents, metals, grain dust, and other hazards among farmers in the Agricultural Health Study. J Expo Anal Environ Epidemiol 2002;12:418–26.
33. Blair A, Tarone R, Sandler D, et al. Reliability of reporting on life-style and agricultural factors by a sample of participants in the Agricultural Health Study from Iowa. Epidemiology 2002;13:94–9.
34. Hoppin JA, Yucel F, Dosemeci M, et al. Accuracy of self-reported pesticide use duration information from licensed pesticide applicators in the Agricultural Health Study. J Expo Anal Environ Epidemiol 2002;12:313–18.

Downloaded from https://academic.oup.com/aje/article-abstract/159/4/373/77227/Cancer-Incidence-among-Pesticide-Applicators
by guest
on 04 October 2017

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

HHS Public Access
Author manuscript
Int J Cancer. Author manuscript; available in PMC 2016 September 01.

Published in final edited form as:
Int J Cancer. 2015 September 1; 137(5): 1167–1175. doi:10.1002/ijc.29416.

Use of acetochlor and cancer incidence in the Agricultural Health Study

Catherine C. Lerro[1,2], **Stella Koutros**[1], **Gabriella Andreotti**[1], **Cynthia J. Hines**[3], **Aaron Blair**[1], **Jay Lubin**[4], **Xiaomei Ma**[2], **Yawei Zhang**[2], and **Laura E. Beane Freeman**[1]

[1]Occupational and Environmental Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD

[2]Yale University School of Public Health, New Haven, CT

[3]Division of Surveillance, Hazard Evaluations and Field Studies, National Institute for Occupational Safety and Heath, Cincinnati, OH

[4]Biostatistics Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD

Abstract

Since its registration in 1994 acetochlor has become a commonly used herbicide in the US, yet no epidemiologic study has evaluated its carcinogenicity in humans. We evaluated use of acetochlor and cancer incidence among licensed pesticide applicators in the Agricultural Health Study. In telephone interviews administered 1999-2005, participants provided information on acetochlor use, use of other pesticides, and additional potential confounders. We used Poisson regression to estimate relative risks (RR) and 95% confidence intervals (95% CI) for cancers that occurred from the time of interview through 2011 in Iowa and 2010 in North Carolina. Among 33,484 men, there were 4,026 applicators who used acetochlor and 3,234 incident cancers, with 304 acetochlor-exposed cases. Increased risk of lung cancer was observed among acetochlor users (RR = 1.74; 95% CI: 1.07-2.84) compared to nonusers, and among individuals who reported using acetochlor/atrazine product mixtures (RR = 2.33; 95% CI: 1.30-4.17), compared to nonusers of acetochlor. Colorectal cancer risk was significantly elevated among the highest category of acetochlor users (RR = 1.75; 95% CI: 1.08-2.83) compared to never users. Additionally, borderline significantly increased risk of melanoma (RR = 1.61; 95% CI: 0.98-2.66) and pancreatic cancer (RR = 2.36; 95% CI: 0.98-5.65) were observed among acetochlor users. The associations between acetochlor use and lung cancer, colorectal cancer, melanoma, and pancreatic cancer are suggestive, however the lack of exposure-response trends, small number of exposed cases, and relatively short time between acetochlor use and cancer development, prohibit definitive conclusions.

Address for correspondence and reprints: Catherine Lerro, Occupational and Environmental Epidemiology Branch, National Cancer Institute, 9609 Medical Center Drive, 6E620, MSC 7991, Bethesda, MD 20892-7991, (t) 240-276-7813, (f) 240-276-7835, lerrocc@mail.nih.gov.

DISCLAIMER

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Keywords

Acetochlor; Agricultural Health Study; Pesticides; Cancer

INTRODUCTION

Acetochlor is a broad leaf herbicide and a member of the chloracetanilide class[1], which also includes alachlor, hutachlor, propachlor, and metolachlor.[1, 2] In 1994, the US Environmental Protection Agency (EPA) approved acetochlor for use on corn, with continued registration dependent upon a reduction in the use of several other corn herbicides of known health concern, including alachlor, metolachlor, atrazine, 2,4-dichlorophenoxyacetic acid (2,4-D), butylate, and S-Ethyl dipropylthiocarbamate (EPTC).[3] Re-registration was not contingent upon reduction of use for any particular herbicide, but rather an overall reduction in the use of these six herbicides.[3] EPA re-affirmed acetochlor registration for use on field corn and popcorn in 2006.[4] Over 32 million pounds of acetochlor were applied during 1997-2001 on approximately 25% of corn crops in the US; [5] similar amounts continue to be applied in recent years.[6]

The EPA considers acetochlor to have "suggestive evidence of carcinogenic potential" based on increased incidence of certain tumors in laboratory animals;[7] other agencies have not reviewed the carcinogenicity of this chemical. Acetochlor is not considered mutagenic or genotoxic at relevant doses,[8] however, evidence suggests potential for acetochlor-induced chromosomal aberration at cytotoxic doses.[1] In animal studies, lung tumors and histiocytic sarcomas have been reported in mice, while nasal olfactory tumors and thyroid follicular cell tumors have been reported in Sprague-Dawley rats.[1] Liver adenomas and carcinomas, renal adenomas and sarcomas, and benign ovarian tumors have been reported in rats and mice, however, generally only at excessively toxic doses or demonstrated weak associations with acetochlor exposure.[1] Bioassays of other chloroacetanilide herbicides have overlapping but not identical tumor profiles.[1]

Epidemiologic research examining the relationship between acetochlor exposure and non-cancer human health outcomes is limited. Acetochlor levels in umbilical cord blood of full-term infants were associated with risk of low birth weight in a pilot study from a Chinese birth cohort.[9] Conversely, acetochlor levels in maternal urine during pregnancy were not associated with any adverse birth outcomes in a French birth cohort.[10] A study of various pesticides found an inverse association between acetochlor exposure and semen quality, although this relationship was non-significant after excluding men with other risk factors for reduced semen quality.[11] Though there have been no epidemiologic studies of acetochlor and cancer risk to date, studies have evaluated other chloroacetanilide chemicals. Previous findings from the Agricultural Health Study (AHS) noted associations between alachlor exposure and lymphohematopoietic cancers,[12] and between metolachor exposure and lung cancer.[13, 14]

Because of the limited information on cancer risk with acetochlor exposure, we examined occupational exposure to acetochlor and subsequent cancer outcomes among pesticide applicators in the Agricultural Health Study (AHS).

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

MATERIALS & METHODS

Study Population

The AHS cohort has been described elsewhere in detail.[15] Briefly, the AHS is a prospective cohort that includes 57,310 licensed pesticide applicators enrolled during 1993-1997 in Iowa and North Carolina. A follow-up interview was conducted during 1999-2003 for private applicators and 2003-2005 for commercial applicators, with 36,342 total respondents. Incident cancer cases were obtained via linkage with Iowa and North Carolina state cancer registries. Cancer site was classified according to the International Classification of Diseases for Oncology (third revision).[16] Due to its recent introduction in 1994, we ascertained acetochlor use only at follow-up interview. Thus, we analyzed first primary cancers diagnosed from the date of follow-up interview through last date of study follow-up (December 31, 2011 for Iowa, December 31, 2010 for North Carolina). The study protocol was approved by the institutional review boards of the National Institutes of Health, University of Iowa, and all other contractors in compliance with applicable requirements of the US.

Exposure Assessment

Computer assisted telephone interviews assessed use of acetochlor and other factors, the texts of which are available at http://aghealth.nih.gov/background/questionnaires.html. Participants were asked to list all pesticides used on each crop during the last year they farmed. Additionally, they were probed to specify if they personally mixed, handled, or applied each pesticide, and how many days per year they applied the pesticide. Where trade names were reported, individual active ingredients were abstracted from the product trade names.

Whether or not an applicator reported any application of acetochlor (yes/no) was examined in order to broadly classify personal use. Total years of acetochlor use for each applicator was assumed to be number of years between the year the applicator last farmed (follow-up interview reference year) and the enrollment year; we used 1994 (year of acetochlor registration) for applicators enrolled prior to this date. The number of lifetime days of acetochlor use was calculated by multiplying the number of days per year using acetochlor by total years of use. Intensity-weighted lifetime exposure days were computed by multiplying an intensity weighting factor by lifetime exposure days. The intensity weighting factor is a function of pesticide handling practices and personal protective equipment used.[17] Exposure days and intensity-weighted exposure days were classified as low (less than the median among all exposed cancer cases) or high (greater than or equal to the median among all exposed cancer cases). Additionally, because acetochlor is frequently applied as a mixture with atrazine (53% of acetochlor applicators reported use of such a mixture), we classified use as 1) never applied acetochlor or atrazine, 2) applied acetochlor but not atrazine, 3) applied atrazine but not acetochlor, or 4) applied both acetochlor and atrazine. Application of both acetochlor and atrazine were further separated into those who reported use of acetochlor/atrazine mixtures (based on trade names of product mixtures including acetochlor and atrazine) and those who reported use of acetochlor and atrazine separately.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Statistical Analysis

Analyses were limited to individuals who responded to the follow-up interview (n = 36,342), and we further restricted to male pesticide applicators due to the small number of female applicators (n = 1006) and few exposed cancer cases (n = 4). We excluded men with cancer diagnoses prior to completion of the follow-up interview (n = 1675) and men with missing or zero person-years of follow-up (n = 177), leaving 33,484 applicators available for analysis. Analyses examining lifetime days and intensity-weighted days of acetochlor use further excluded those missing days of use (n = 456) or intensity (n = 11), leaving 33,028 and 33,017 applicators, respectively.

We report results for all cancer sites with at least 15 exposed cases for days and intensity-weighted days of use, and results for ever use for sites with more than five exposed cases. Colon and rectal tumors were combined as were lymphohematopoietic cancers. Aggressive prostate cancer, as defined by Koutros et al, was examined separately.[18] Relative risks (RR) and 95% confidence intervals (CIs) were estimated using Poisson regression in SAS version 9.3 (SAS Institute, Inc., Cary, NC). Subjects contributed person-time from date of follow-up interview through date of first cancer diagnosis, date moved out of state, date of death, or last follow-up, whichever occurred first.

All models were adjusted for potential confounders including age at follow-up interview (continuous), state of residence (Iowa or North Carolina), applicator type (private or commercial), duration of cigarette smoking as reported at enrollment (never, <10 years, 10-19 years, 20-29 years, 30+ years, missing), race (white, other, missing), alcohol use (yes/no in preceding 12 months, missing), educational attainment (less than a high school degree, high school degree, more than a high school degree, missing), use of an enclosed tractor cab (yes, no, missing), and family history of cancer in first degree relatives (yes, no, missing; specific cancer site where available). We also adjusted for ever-use of pesticides most highly associated with acetochlor use (lifetime use: imazethapyr, dicamba, atrazine, EPTC, cyanazine, pendimethalin, trifluralin; follow-up only: flumetsulam, clopyralid, isoxaflutole), pesticides mentioned in the acetochlor EPA registration (alachlor, metolachlor, atrazine, EPTC, 2,4-D, butylate), and pesticides previously found to be associated with specific cancer outcomes in the AHS.[19] Tests for trend used the midpoint of each exposure category treated as a continuous variable. Sensitivity analyses were conducted in which the cohort was restricted to cases diagnosed more than two years after completion of follow-up interview. All tests were two-sided with $\alpha = 0.05$. Data in this analysis are based on the AHS data releases *P2REL201209.00* and *P1REL201209.00*.

RESULTS

Table 1 displays selected demographic, behavioral, health, and farming characteristics of the cohort, stratified by acetochlor use. Acetochlor was used almost exclusively by applicators in Iowa (99%). A larger proportion of commercial applicators used acetochlor compared to private applicators (28.9% and 9.3%, respectively). Applicators who used acetochlor were more likely to be younger, more educated, and white compared to non-users. Applicators in Iowa similarly tend to be younger, more educated, and white compared to applicators in North Carolina, so these differences may be regional and not directly related to acetochlor

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

use. Additionally, acetochlor users were more likely than non-users to be never-smokers and ever-drinkers in the last 12 months, have no family history of cancer, and report that the tractor regularly used to apply pesticides had an enclosed cab.

We evaluated the use of acetochlor in association with a variety of cancer sites controlling the covariates described above (Table 2). We observed an association with ever-use of acetochlor and increased risk of lung cancer (RR = 1.74; 95% CI: 1.07-2.84), melanoma (RR = 1.61; 95% CI: 0.98-2.66), and pancreatic cancer (RR = 2.36; 95% CI: 0.98-5.65), although the associations for melanoma and pancreatic cancer were of borderline statistical significance.

Compared to never use of acetochlor, low use of acetochlor, as measured by lifetime days used, was associated with a decreased risk of colorectal cancer (RR = 0.31; 95% CI: 0.11-0.83) while high use was associated with an increased risk of colorectal cancer (RR = 1.75; 95% CI: 1.08-2.83), with a borderline significant exposure-response trend (p-trend = 0.07, Table 3). Results were similar for colorectal cancer risk and lifetime intensity-weighted days of acetochlor use. Low use of acetochlor, as measured by lifetime days used, was associated with an increased risk of lung cancer (RR = 2.64; 95% CI: 1.47-4.74) compared to never use; no association was seen for high use and no exposure-response trend was observed (p-trend = 0.36). Similarly, low use of acetochlor, as measured by lifetime intensity-weighted days used, was associated with an increased risk of lung cancer (RR = 2.26; 95% CI: 1.24-4.14, p-trend = 0.16). High use of acetochlor, as measured by lifetime days used, was associated with borderline increased risk of melanoma (RR = 1.78; 95% CI: 0.90-3.52, p-trend = 0.08) compared to never use. However, when measured using lifetime intensity-weighted days used, low acetochlor use was associated with borderline increased risk of melanoma (RR = 1.79; 95% CI: 0.93-3.45, p-trend = 0.29).

Over 80% of acetochlor users also reported use of atrazine at follow-up interview (Table 1); 53% of applicators reporting ever use of acetochlor report using it in a product also containing atrazine. We found that applicators using both atrazine and acetochlor were at increased risk of lung cancer (RR = 2.01; 95% CI: 1.17-3.46) compared to those with no use of either (Table 4). This association was similarly strong for persons using acetochlor/atrazine product mixtures (RR = 2.33; 95% CI: 1.30-4.17), compared to use of neither atrazine nor acetochlor. Among those exposed to acetochlor as a mixture only, we saw elevated risks among both low (RR = 2.71; 95% CI: 1.14-5.78) and high (RR = 1.96; 95% CI: 0.75-5.11) categories of intensity-weighted days of exposure (results not shown). We also observed a borderline significant excess risk of pancreatic cancer among users of atrazine/acetochlor product mixtures (RR = 2.62; 95% CI: 0.95-7.20).

The findings for lung cancer, colorectal cancer, melanoma, and pancreatic cancer were similar in magnitude and direction after restricting the study population to those diagnosed with cancer at least two years after completion of the follow-up interview, though the risk estimates for ever use of lung and pancreatic cancer no longer reached statistical significance. We limited lung and pancreatic cancer analyses to never smokers to examine the results independent of smoking status. The results were in a similar direction and magnitude for low acetochlor exposure (days of use) and risk of lung cancer (RR = 3.30;

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

95% CI: 0.89-12.27), though the association was only borderline statistically significant. It is possible that the small number of exposed cases (n = 3) caused the estimates to be unstable. We saw a stronger association for ever use of acetochlor and risk of pancreatic cancer when restricting to never smokers (RR = 5.61; 95% CI: 1.58-19.97). We also restricted our analyses to Iowa applicators, as the majority of acetochlor was applied there (98.8%); the results were overall very similar. Approximately half of our study population had complete information regarding potential confounders for colorectal cancer (physical activity, fruit and vegetable consumption) and melanoma (sun sensitivity and sun protection). When we limited our analyses to these men, the relationship for high days of acetochlor use and colorectal cancer was similar in magnitude and direction (RR = 1.71; 95% CI: 0.88-3.33) after controlling for physical activity and dietary factors, and the relationship between ever use of acetochlor and melanoma risk was strengthened (RR = 2.55; 95% CI: 1.45-4.48) after controlling for sun sensitivity and exposure factors. We also examined days and intensity-weighted days of acetochlor use per year, classified as high or low based on the median among cancer cases, in order to determine if number of years between enrollment and follow-up was skewing our results. The results were consistent with findings for days and intensity-weighted days, and we additionally observed a significant exposure-response trend for intensity-weighted days per year of acetochlor use and lung cancer risk (p-trend = 0.05).

DISCUSSION

In this analysis of reported use of acetochlor among AHS applicators, we found elevated risk for several cancer sites. To our knowledge, this is the first epidemiologic study attempting to evaluate cancer risk from occupational use of acetochlor. Specifically, we observed an increased risk of colorectal cancer among pesticide applicators with high lifetime use of acetochlor, and increased risk of lung cancer among ever users and low lifetime users of acetochlor. Additionally, ever use and increasing days of acetochlor use were associated with borderline significantly increased risk of melanoma. Though the number of exposed cases was small, there was a borderline significant increased risk of pancreatic cancer among ever users of acetochlor.

The finding that use of acetochlor is associated with increased risk of lung cancer is complicated because it was observed among those with below median use, but not among those with higher exposure. However, this finding was robust in sensitivity analyses restricting the cohort to persons diagnosed two or five years after interview. This suggests that reporting of acetochlor use was not likely to be influenced by early disease. A previous AHS analysis found that high use of metolachlor, another chloracetanilide herbicide, was associated with an increased risk of lung cancer.[14] The observed association in our study did not appear to be related to previous metolachlor use, as there was very little correlation between metolachlor and acetochlor use ($\rho = 0.11$). Concerned about the possibility of residual confounding, we adjusted for smoking using several metrics, including duration (years smoked), total cigarette exposure (pack-years), and current/former/never smoking status; all produced similar results and duration was chosen based on model fit. We saw results of a similar direction and magnitude for low acetochlor exposure and risk of lung cancer when we restricted our sample to never smokers. Because we did not see an excess of

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

lung cancer among the more highly exposed individuals and there was no significant exposure-response trend, the association may be spurious. Though we were underpowered to do so, future studies should attempt to examine lung cancer risk by histologic subtype; we noted slight differences in lung cancer histologic subtype by acetochlor exposure in descriptive analyses.

Colorectal cancer is not often associated with occupational exposures;[20] however, we observed an increased risk between reported acetochlor use and risk of colorectal cancer, with some indication of an exposure-response trend. In the AHS, several pesticides have been associated with colon and rectal cancers; aldicarb, dicamba, EPTC, imazethapyr, and trifluralin were associated with colon cancer, and chlordane, chlorpyrifos, pendimethalin, and toxaphene were associated with rectal cancer.[19] A small study of manufacturing workers exposed to alachlor, a chemical structurally related to acetochlor, found elevated risks of colorectal cancer.[21] A limitation in our study is that while we could control for body mass index, an established risk factor for colorectal cancer,[22] we were not able to control for other known risk factors such as dietary habits or physical activity,[20] which were only collected for a portion of the cohort. When restricted to individuals who provided information on leisure time physical activity and average fruit and vegetable consumption, our results remained relatively unchanged.

We observed an association between melanoma and ever use of acetochlor, though the exposure-response relationship was not consistent for days and intensity-weighted days of use. The relationship between pesticides and melanoma is complicated by other occupational exposures, particularly extended exposure to natural ultraviolet radiation,[23] however several pesticides have been associated with melanoma in previous AHS analyses.[24, 25] Sun sensitivity and exposure characteristics were only available for about half of our cohort; however when we limited our analyses to men with valid response and controlled for these factors, the relationship between ever use of acetochlor and melanoma risk was strengthened.

Occupationally, pancreatic cancer has been associated with chlorinated hydrocarbon solvents,[26] though findings for chlorinated pesticides and pancreatic cancer have been less clear.[27-30] In the AHS, EPTC and pendimethalin were associated with increased risk of pancreatic cancer, possibly via the formation of N-nitroso-compounds.[31] Smoking, an established risk factor for pancreatic cancer, was controlled for in our analyses and we observed a significantly increased risk of pancreatic cancer among never smokers. While we did not present the results due to small number of exposed cases, we did see a significant exposure-response trend for intensity-weighted days of acetochlor use and pancreatic cancer (p-trend = 0.01). Future studies should evaluate these findings.

We evaluated atrazine and acetochlor product mixtures because these active ingredients are often applied as a mixture in our cohort. Previous studies in the AHS have not been able to explicitly examine product mixtures because of how pesticide use was assessed at enrollment.[14, 32, 33] At follow-up interview, participants self-reported specific pesticide product names, and based on this information we determined if acetochlor was being applied alone or as a mixture with atrazine. These analyses did not account for applicators who

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

mixed individual ingredients or products on their own (as opposed to using pre-mixed formulations); this information was not collected. Little is known about the toxicology and potential carcinogenicity of pesticide mixtures. Epidemiologic studies usually examine pesticides either independently, or more often by chemical class. Findings here suggest that future epidemiologic studies should consider the effects of pesticide mixtures, particularly acetochlor and atrazine, and future toxicological studies should attempt to understand whether exposure as a mixture influences genotoxicity and mutagenicity.

Acetochlor, like most pesticides licensed for use today, does not appear to be mutagenic or genotoxic in laboratory studies.[1] Therefore, other mechanisms of carcinogenesis should be considered. Occupational use of other chloracetanilide herbicides alachlor and metolachlor was significantly associated with shortened telomere length in a recent AHS study,[34] acetochlor was not examined. Telomere length has been implicated in cancer etiology.[35] Another proposed mechanism of carcinogenicity for chloracetanilide herbicides involves bioactivation through several steps to DNA-reactive metabolites (2-methyl-6-ethylbenzoquinone imine for acetochlor and metolachlor and 2,6-diethylbenzoquinone imine for alachlor).[7] These chloracetanilide metabolites, 2-methyl-6-ethylbenzoquinone imine and 2,6-diethylbenzoquinone imine, may lead to formation of DNA adducts or single-strand DNA breaks.[7, 36, 37] Studies suggest that triazine herbicides, such as atrazine, stimulate cytochrome P450 (CYP450) system activity.[38] Acetochlor is metabolized and potentially bioactivated by members of the CYP450 family of enzymes, CYP2B6 and CYP34A, in the liver.[7] Thus, when atrazine and acetochlor are applied together, it is possible that there is increased acetochlor bioactivation as a result of atrazine-induced CYP450 activity.

Our analysis is the first epidemiologic study to examine the effect of acetochlor on cancer outcomes in humans. Strengths include longitudinal study design with regular follow-up of participants for cancer and mortality outcomes, as well as detailed and validated self-reported pesticide exposure and intensity information.[39] An important limitation for our analysis was sample size; although AHS is a large cohort, only about 12% (n = 4026) of our sample reported any acetochlor use. Additionally because acetochlor was introduced after AHS enrollment and therefore assessed only in follow-up interviews, the follow-up period is shorter than analyses of other chemicals, and thus fewer cancer cases were accrued. Because acetochlor was registered for use relatively recently, the observed associations for acetochlor and solid tumors may be due to earlier exposures and reflect long latency periods for these cancers. However, we restricted our cohort to those diagnosed at least two and five years after the start date of the study, and did not see marked differences in the magnitude and direction of the effects for lung cancer, colorectal cancer, pancreatic cancer, and melanoma. Applicators in our cohort were typically applying other pesticides prior to acetochlor registration and concurrently at follow-up interview. We controlled for use of pesticides that were highly correlated with acetochlor, as well as herbicides that were specified in the acetochlor EPA registration, in order to minimize these possible sources of confounding. Due to limited numbers of cases, we were unable to evaluate rarer cancer sites, as well as histologic subtypes of more common cancers. Due to few exposed women, we were unable to evaluate cancer sites more common in females such as breast or thyroid cancer.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

In conclusion, we observed associations between acetochlor use and lung cancer, colorectal cancer, pancreatic cancer, and melanoma. However, due to minimal evidence for exposure-response relationships, the observed associations could reflect chance findings. Findings regarding the carcinogenicity of acetochlor need further evaluation in populations with sufficient numbers of exposed subjects. Additionally, future studies should attempt to evaluate potential mechanisms of carcinogenesis for acetochlor and other chloroacetanilide herbicides by examining genetic markers of susceptibility, as well as markers of cellular and DNA damage.

ACKNOWLEDGEMENTS

This work was supported by the intramural research program of the National Institutes of Health, the National Cancer Institute (Z01-CP010119), and the National Institute of Environmental Health Sciences (Z01-ES049030).

Abbreviations

EPA	Environmental Protection Agency
2,4-D	2,4-dichlorophenoxyacetic acid
EPTC	S-Ethyl dipropylthiocarbamate
AHS	Agricultural Health Study
DNA	Deoxyribonucleic acid
CYP450	Cytochrome P450
NHL	Non-Hodgkin Lymphoma
BMI	Body Mass Index

REFERENCES

1. Evaluation of the Carcinogenic Potential of Acetochlor (Fifth Assessment) (121601). Environmental Protection Agency, Cancer Assessment Review Committee, Health Effects Division, Office of Pesticide Programs; 2007. p. 1-66.
2. Green T, Lee R, Moore RB, Ashby J, Willis GA, Lund VJ, Clapp MJ. Acetochlor-induced rat nasal tumors: further studies on the mode of action and relevance to humans. Regul Toxicol Pharmacol. 2000; 32:127–33. [PubMed: 11029275]
3. Acetochlor (EPA-HQ-OPP-2007-0725-0002). Environmental Protection Agency; 2007.
4. Acetochlor; Tolerance Reassessment Decision (EPA-HQ-OPP-2005-0227). Vol. 71. Environmental Protection Agency; 2006. p. 15730-1.
5. Usage Report in Support of Registration for the Herbicide Acetochlor (121601). Environmental Protection Agency, Office of Prevention, Pesticides, and Toxic Substances; Washington, DC: 2004.
6. Pesticide Industry Sales and Usage: 2006 and 2007. Market Estimates Office of Pesticide Programs, US Environmental Protection Agency; Washington, DC: 2011.
7. Coleman S, Linderman R, Hodgson E, Rose RL. Comparative metabolism of chloroacetamide herbicides and selected metabolites in human and rat liver microsomes. Environ Health Perspect. 2000; 108:1151–7. [PubMed: 11133395]
8. Ashby J, Kier L, Wilson AG, Green T, Lefevre PA, Tinwell H, Willis GA, Heydens WF, Clapp MJ. Evaluation of the potential carcinogenicity and genetic toxicity to humans of the herbicide acetochlor. Hum Exp Toxicol. 1996; 15:702–35. [PubMed: 8880207]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

9. Wickerham EL, Lozoff B, Shao J, Kaciroti N, Xia Y, Meeker JD. Reduced birth weight in relation to pesticide mixtures detected in cord blood of full-term infants. Environ Int. 2012; 47:80–5. [PubMed: 22796478]
10. Chevrier C, Limon G, Monfort C, Rouget F, Garlantezec R, Petit C, Durand G, Cordier S. Urinary biomarkers of prenatal atrazine exposure and adverse birth outcomes in the PELAGIE birth cohort. Environ Health Perspect. 2011; 119:1034–41. [PubMed: 21367690]
11. Swan SH, Kruse RL, Liu F, Barr DB, Drobnis EZ, Redmon JB, Wang C, Brazil C, Overstreet JW. Semen quality in relation to biomarkers of pesticide exposure. Environ Health Perspect. 2003; 111:1478–84. [PubMed: 12948887]
12. Lee WJ, Hoppin JA, Blair A, Lubin JH, Dosemeci M, Sandler DP, Alavanja MC. Cancer incidence among pesticide applicators exposed to alachlor in the Agricultural Health Study. Am J Epidemiol. 2004; 159:373–80. [PubMed: 14769641]
13. Rusiecki JA, Hou L, Lee WJ, Blair A, Dosemeci M, Lubin JH, Bonner M, Samanic C, Hoppin JA, Sandler DP, Alavanja MC. Cancer incidence among pesticide applicators exposed to metolachlor in the Agricultural Health Study. Int J Cancer. 2006; 118:3118–23. [PubMed: 16425265]
14. Alavanja MC, Dosemeci M, Samanic C, Lubin J, Lynch CF, Knott C, Barker J, Hoppin JA, Sandler DP, Coble J, Thomas K, Blair A. Pesticides and lung cancer risk in the agricultural health study cohort. Am J Epidemiol. 2004; 160:876–85. [PubMed: 15496540]
15. Alavanja MC, Sandler DP, McMaster SB, Zahm SH, McDonnell CJ, Lynch CF, Pennybacker M, Rothman N, Dosemeci M, Bond AE, Blair A. The Agricultural Health Study. Environ Health Perspect. 1996; 104:362–9. [PubMed: 8732939]
16. Fritz, AG. International Classification of Diseases for Oncology: ICD-O. World Health Organization; 2000.
17. Coble J, Thomas KW, Hines CJ, Hoppin JA, Dosemeci M, Curwin B, Lubin JH, Beane Freeman LE, Blair A, Sandler DP, Alavanja MC. An updated algorithm for estimation of pesticide exposure intensity in the agricultural health study. Int J Environ Res Public Health. 2011; 8:4608–22. [PubMed: 22408592]
18. Koutros S, Beane Freeman LE, Lubin JH, Heltshe SL, Andreotti G, Barry KH, DellaValle CT, Hoppin JA, Sandler DP, Lynch CF, Blair A, Alavanja MC. Risk of total and aggressive prostate cancer and pesticide use in the Agricultural Health Study. Am J Epidemiol. 2013; 177:59–74. [PubMed: 23171882]
19. Weichenthal S, Moase C, Chan P. A review of pesticide exposure and cancer incidence in the Agricultural Health Study cohort. Environ Health Perspect. 2010; 118:1117–25. [PubMed: 20444670]
20. Schottenfeld, D.; Fraumeni, JF. Cancer Epidemiology and Prevention. Oxford University Press; USA: 2006.
21. Acquavella JF, Delzell E, Cheng H, Lynch CF, Johnson G. Mortality and cancer incidence among alachlor manufacturing workers 1968-99. Occup Environ Med. 2004; 61:680–5. [PubMed: 15258274]
22. Siegel R, Ma J, Zou Z, Jemal A. Cancer statistics, 2014. CA: A Cancer Journal for Clinicians. 2014; 64:9–29. [PubMed: 24399786]
23. MacKie RM, Hauschild A, Eggermont AM. Epidemiology of invasive cutaneous melanoma. Annals of oncology: official journal of the European Society for Medical Oncology / ESMO. 2009; 20(Suppl 6):vi1–7. [PubMed: 19617292]
24. Dennis LK, Lynch CF, Sandler DP, Alavanja MC. Pesticide use and cutaneous melanoma in pesticide applicators in the agricultural heath study. Environ Health Perspect. 2010; 118:812–7. [PubMed: 20164001]
25. Purdue MP, Hoppin JA, Blair A, Dosemeci M, Alavanja MC. Occupational exposure to organochlorine insecticides and cancer incidence in the Agricultural Health Study. Int J Cancer. 2007; 120:642–9. [PubMed: 17096337]
26. Ojajarvi A, Partanen T, Ahlbom A, Boffetta P, Hakulinen T, Jourenkova N, Kauppinen T, Kogevinas M, Vainio H, Weiderpass E, Wesseling C. Risk of pancreatic cancer in workers exposed to chlorinated hydrocarbon solvents and related compounds: a meta-analysis. Am J Epidemiol. 2001; 153:841–50. [PubMed: 11323314]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

27. Ji BT, Silverman DT, Stewart PA, Blair A, Swanson GM, Baris D, Greenberg RS, Hayes RB, Brown LM, Lillemoe KD, Schoenberg JB, Pottern LM, et al. Occupational exposure to pesticides and pancreatic cancer. American journal of industrial medicine. 2001; 39:92–9. [PubMed: 11148019]
28. Fryzek JP, Garabrant DH, Harlow SD, Severson RK, Gillespie BW, Schenk M, Schottenfeld D. A case-control study of self-reported exposures to pesticides and pancreas cancer in southeastern Michigan. Int J Cancer. 1997; 72:62–7. [PubMed: 9212224]
29. Garabrant DH, Held J, Langholz B, Peters JM, Mack TM. DDT and related compounds and risk of pancreatic cancer. Journal of the National Cancer Institute. 1992; 84:764–71. [PubMed: 1573662]
30. Hoppin JA, Tolbert PE, Holly EA, Brock JW, Korrick SA, Altshul LM, Zhang RH, Bracci PM, Burse VW, Needham LL. Pancreatic cancer and serum organochlorine levels. Cancer Epidemiol Biomarkers Prev. 2000; 9:199–205. [PubMed: 10698482]
31. Andreotti G, Freeman LE, Hou L, Coble J, Rusiecki J, Hoppin JA, Silverman DT, Alavanja MC. Agricultural pesticide use and pancreatic cancer risk in the Agricultural Health Study Cohort. Int J Cancer. 2009; 124:2495–500. [PubMed: 19142867]
32. Freeman LE, Rusiecki JA, Hoppin JA, Lubin JH, Koutros S, Andreotti G, Zahm SH, Hines CJ, Coble JB, Barone-Adesi F, Sloan J, Sandler DP, et al. Atrazine and cancer incidence among pesticide applicators in the agricultural health study (1994-2007). Environ Health Perspect. 2011; 119:1253–9. [PubMed: 21622085]
33. Rusiecki JA, De Roos A, Lee WJ, Dosemeci M, Lubin JH, Hoppin JA, Blair A, Alavanja MC. Cancer incidence among pesticide applicators exposed to atrazine in the Agricultural Health Study. Journal of the National Cancer Institute. 2004; 96:1375–82. [PubMed: 15367570]
34. Hou L, Andreotti G, Baccarelli AA, Savage S, Hoppin JA, Sandler DP, Barker J, Zhu ZZ, Hoxha M, Dioni L, Zhang X, Koutros S, et al. Lifetime Pesticide Use and Telomere Shortening among Male Pesticide Applicators in the Agricultural Health Study. Environ Health Perspect. 2013; 121:919–24. [PubMed: 23774483]
35. Ma H, Zhou Z, Wei S, Liu Z, Pooley KA, Dunning AM, Svenson U, Roos G, Hosgood HD 3rd, Shen M, Wei Q. Shortened telomere length is associated with increased risk of cancer: a meta-analysis. PLoS One. 2011; 6:e20466. [PubMed: 21695195]
36. Bonfanti M, Taverna P, Chiappetta L, Villa P, D'Incalci M, Bagnati R, Fanelli R. DNA damage induced by alachlor after in vitro activation by rat hepatocytes. Toxicology. 1992; 72:207–19. [PubMed: 1566280]
37. Brown MA, Kimmel EC, Casida JE. DNA adduct formation by alachlor metabolites. Life sciences. 1988; 43:2087–94. [PubMed: 3210901]
38. Hernandez AF, Parron T, Tsatsakis AM, Requena M, Alarcon R, Lopez-Guarnido O. Toxic effects of pesticide mixtures at a molecular level: their relevance to human health. Toxicology. 2013; 307:136–45. [PubMed: 22728724]
39. Thomas KW, Dosemeci M, Coble JB, Hoppin JA, Sheldon LS, Chapa G, Croghan CW, Jones PA, Knott CE, Lynch CF, Sandler DP, Blair AE, et al. Assessment of a pesticide exposure intensity algorithm in the agricultural health study. J Expo Sci Environ Epidemiol. 2010; 20:559–69. [PubMed: 19888312]

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Novelty and Impact

This study is the first to examine the relationship between occupational exposure to acetochlor, a commonly used herbicide registered for use on corn, and human cancer risk in a large prospective cohort. Acetochlor use was associated with increased risk of lung cancer, colorectal cancer, pancreatic cancer, and melanoma. Use of mixtures of acetochlor and atrazine, another widely used herbicide often applied concurrently with acetochlor, was associated with increased risk of lung cancer.

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 1

Selected characteristics of AHS pesticide applicators[1] who completed follow-up questionnaire (n=33,017), stratified by lifetime intensity-weighted days of acetochlor use (none, low, high)[2]

		Acetochlor use			
	Total N=33,017 N (%)	**Never N=29,458 N (%)**	**Low Use N= 1,621 N (%)**	**High Use N=1,938 N (%)**	**p-value[3]**
State					
Iowa	21810 (66.06)	18297 (62.11)	1601 (98.77)	1912 (98.66)	p < 0.0001
North Carolina	11207 (33.94)	11161 (37.89)	20 (1.23)	26 (1.34)	
Type of applicator					
Commercial	2527 (7.65)	1797 (6.10)	141 (8.70)	589 (30.39)	p < 0.0001
Private	30490 (92.35)	27661 (93.9)	1480 (91.30)	1349 (69.61)	
Age at follow-up					
Quartile 1: <43.4	8319 (25.20)	7058 (23.96)	543 (33.50)	718 (37.05)	p < 0.0001
Quartile 2: 43.4-51.2	8260 (25.02)	7234 (24.56)	430 (26.53)	596 (30.75)	
Quartile 3: 51.3-61.4	8227 (24.92)	7431 (25.23)	362 (22.33)	434 (22.39)	
Quartile 4: ≥61.5	8211 (24.87)	7735 (26.26)	286 (17.64)	190 (9.80)	
Educational Attainment[4]					
< High School	2624 (7.95)	2532 (8.60)	46 (2.84)	46 (2.37)	p < 0.0001
High School Graduate	14774 (44.75)	13168 (44.70)	734 (45.28)	872 (44.99)	
> High School	14383 (43.56)	12596 (42.76)	813 (50.15)	974 (50.26)	
Other/Missing	1236 (3.74)	1162 (3.94)	28 (1.73)	46 (2.37)	
Race					
White	31685 (95.97)	28166 (95.61)	1602 (98.83)	1917 (98.92)	p < 0.0001
Non-white	728 (2.20)	718 (2.44)	7 (0.43)	3 (0.15)	
Other/Missing	604 (1.83)	574 (1.95)	12 (0.74)	18 (0.93)	
Tobacco use[4]					
Never Smoker	17302 (52.40)	15069 (51.15)	1015 (62.62)	1218 (62.85)	p < 0.0001
Former Smoker, ≤10 yrs	4896 (14.83)	4380 (14.87)	255 (15.73)	261 (13.47)	
Former Smoker, >10 yrs	4548 (13.77)	4225 (14.34)	159 (9.81)	164 (8.46)	
Current Smoker, ≤10 yrs	917 (2.78)	813 (2.76)	41 (2.53)	63 (3.25)	
Current Smoker, >10 yrs	3885 (11.77)	3574 (12.13)	114 (7.03)	197 (10.17)	
Missing	1469 (4.45)	1397 (4.74)	37 (2.28)	35 (1.81)	
Alcohol consumption					
No	17702 (53.61)	16291 (55.30)	711 (43.86)	700 (36.12)	p < 0.0001
Yes	15025 (45.51)	12886 (43.74)	905 (55.83)	1234 (63.67)	
Missing	290 (0.88)	281 (0.95)	5 (0.31)	4 (0.21)	
Family History of Cancer[4]					
No	17390 (52.67)	15347 (52.10)	876 (54.04)	1167 (60.22)	p < 0.0001
Yes	12971 (39.29)	11579 (39.31)	678 (41.83)	714 (36.84)	

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

	Total N=33,017 N (%)	Acetochlor use			p-value[3]
		Never N=29,458 N (%)	Low Use N= 1,621 N (%)	High Use N=1,938 N (%)	
Missing	2656 (8.04)	2532 (8.60)	67 (4.13)	57 (2.94)	
Use of Enclosed Cab					
No	20063 (60.77)	19048 (64.66)	434 (26.77)	581 (29.98)	p < 0.0001
Yes	12954 (39.23)	10410 (35.34)	1187 (73.23)	1357 (70.02)	
Atrazine use					
No	22579 (68.39)	21932 (74.45)	329 (20.30)	318 (16.41)	p < 0.0001
Yes	10438 (31.61)	7526 (25.55)	1292 (79.7)	1620 (83.59)	

[1] Reported on follow-up questionnaire

[2] Low: 72-879 intensity-weighted days, High: 880- 47520 intensity-weighted days

[3] Chi-square test for homogeneity

[4] Reported on enrollment questionnaire

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 2

Relative risks (RR) and 95% confidence intervals (95% CI)[1] for ever-use of acetochlor, relative to never-use, and risk for various cancers among AHS applicators (n=33,484).

	$N_{unexposed}$	$N_{exposed}$	RR (95% CI)
All Sites	2930	304	1.06 (0.94-1.21)
Bladder	167	15	1.08 (0.61-1.91)
Lymphohematopoietic	293	23	0.77 (0.49-1.20)
Colon	206	21	1.07 (0.66-1.73)
Colorectal	300	31	1.03 (0.69-1.53)
Esophagus	42	6	1.28 (0.47-3.44)
Kidney	98	13	1.14 (0.61-2.11)
Leukemia	93	9	0.89 (0.43-1.84)
Lung	251	23	1.74 (1.07-2.84)**
Melanoma	124	23	1.61 (0.98-2.66)*
NHL	249	18	0.70 (0.43-1.16)
Pancreas	55	7	2.36 (0.98-5.65)*
Prostate	1232	130	0.99 (0.82-1.20)
Prostate, Aggressive	644	69	0.98 (0.75-1.28)
Rectum	94	10	0.97 (0.48-1.95)

*Significant at p<0.1;

**Significant at p<0.05

[1]Adjusted for age, race, state, applicator type, smoking, family history of cancer, alcohol consumption, BMI, use of an enclosed cab, education, and correlated /associated pesticide use

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 3

Relative risks (RR) and 95% confidence intervals (95% CI)[1] by days (n= 33,028) and intensity-weighted days (n= 33,017) of acetochlor use, compared to never-use, for various cancers.

		Acetochlor days use[2]		Acetochlor intensity-weighted days use[3]	
		N	RR (95% CI)	N	RR (95% CI)
All Sites	Never	2930	1.00 (REF)	2930	1.00 (REF)
	Low	119	0.99 (0.82-1.20)	127	1.00 (0.83-1.20)
	High	139	1.19 (1.00-1.43)*	131	1.20 (1.00-1.45)*
	p-trend		0.07*		0.06*
Bladder	Never	167	1.00 (REF)	167	1.00 (REF)
	Low	7	1.11 (0.51-2.44)	6	0.91 (0.39-2.10)
	High	4	0.74 (0.26-2.09)	5	1.01 (0.40-2.57)
	p-trend		0.63		0.98
Lymphohematopoietic	Never	293	1.00 (REF)	293	1.00 (REF)
	Low	12	0.93 (0.51-1.68)	10	0.76 (0.40-1.44)
	High	9	0.80 (0.40-1.59)	11	1.02 (0.55-1.91)
	p-trend		0.51		0.91
Colon	Never	206	1.00 (REF)	206	1.00 (REF)
	Low	4	0.46 (0.17-1.27)	4	0.44 (0.16-1.20)
	High	12	1.56 (0.83-2.91)	12	1.67 (0.90-3.11)
	p-trend		0.28		0.20
Colorectal	Never	300	1.00 (REF)	300	1.00 (REF)
	Low	4	0.31 (0.11-0.83)**	7	0.51 (0.24-1.09)*
	High	21	1.75 (1.08-2.83)**	18	1.59 (0.95-2.64)*
	p-trend		0.07*		0.16
Kidney	Never	98	1.00 (REF)	98	1.00 (REF)
	Low	4	0.81 (0.29-2.25)	3	0.57 (0.18-1.86)
	High	7	1.53 (0.67-3.47)	8	1.87 (0.86-4.03)
	p-trend		0.36		0.16
Lung	Never	251	1.00 (REF)	251	1.00 (REF)
	Low	14	2.64 (1.47-4.74)**	13	2.26 (1.24-4.14)**
	High	7	1.14 (0.51-2.57)	8	1.47 (0.68-3.16)
	p-trend		0.36		0.16
Melanoma	Never	124	1.00 (REF)	124	1.00 (REF)
	Low	8	1.41 (0.67-2.97)	11	1.79 (0.93-3.45)*
	High	11	1.78 (0.90-3.52)*	8	1.38 (0.64-2.99)
	p-trend		0.08*		0.29
NHL	Never	249	1.00 (REF)	249	1.00 (REF)
	Low	11	1.01 (0.54-1.87)	10	0.89 (0.47-1.71)

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

		Acetochlor days use[2]		Acetochlor intensity-weighted days use[3]	
		N	RR (95% CI)	N	RR (95% CI)
Prostate	High	5	0.50 (0.20-1.25)	6	0.63 (0.28-1.46)
	p-trend		0.16		0.27
	Never	1232	1.00 (REF)	1232	1.00 (REF)
	Low	52	0.95 (0.72-1.27)	57	0.99 (0.75-1.30)
	High	59	1.10 (0.84-1.46)	54	1.08 (0.81-1.44)
	p-trend		0.54		0.63
Prostate, Aggressive	Never	644	1.00 (REF)	644	1.00 (REF)
	Low	27	0.92 (0.62-1.36)	30	0.97 (0.67-1.42)
	High	33	1.20 (0.83-1.74)	30	1.16 (0.78-1.70)
	p-trend		0.40		0.50

*Significant at p<0.1

**Significant at p<0.05

[1]Adjusted for age, race, state, applicator type, smoking, family history of cancer, alcohol consumption, BMI, use of an enclosed cab, education, and correlated /associated pesticide use

[2]Low: 2-19 days, High: 20-1080 days

[3]Low: 72-879 intensity-weighted days, High: 880- 47,520 intensity-weighted days

Author Manuscript Author Manuscript Author Manuscript Author Manuscript

Table 4

Relative risk (RR) and 95% confidence intervals (95% CI)[1] for ever applying acetochlor and atrazine alone or as a mixture, compared to never use, for selected cancers.

		N	RR (95% CI)
All Sites	Neither acetochlor or atrazine	2282	1.00 (REF)
	Acetochlor	59	0.99 (0.76-1.29)
	Atrazine	648	1.07 (0.97-1.17)
	Both acetochlor and atrazine	245	1.12 (0.97-1.29)
	Applied separately	83	1.20 (0.95-1.50)
	Applied as a mixture	162	1.08 (0.91-1.28)
Colorectal	Neither acetochlor or atrazine	240	1.00 (REF)
	Acetochlor	6	0.87 (0.38-1.99)
	Atrazine	60	0.91 (0.67-1.23)
	Both acetochlor and atrazine	25	1.03 (0.66-1.61)
	Applied separately	8	1.01 (0.49-2.11)
	Applied as a mixture	17	1.04 (0.62-1.75)
Lung	Neither acetochlor or atrazine	204	1.00 (REF)
	Acetochlor	4	1.96 (0.70-5.45)
	Atrazine	47	1.32 (0.93-1.88)
	Both acetochlor and atrazine	19	2.01 (1.17-3.46)**
	Applied separately	4	1.29 (0.45-3.68)
	Applied as a mixture	15	2.33 (1.30-4.17)**
Melanoma	Neither acetochlor or atrazine	89	1.00 (REF)
	Acetochlor	6	2.24 (0.94-5.33)*
	Atrazine	35	1.39 (0.91-2.14)
	Both acetochlor and atrazine	17	1.75 (0.97-3.14)*
	Applied separately	6	1.87 (0.77-4.51)
	Applied as a mixture	11	1.69 (0.86-3.34)
Pancreas	Neither acetochlor or atrazine	49	1.00 (REF)
	Acetochlor	2	2.62 (0.6-11.44)
	Atrazine	6	0.63 (0.26-1.55)
	Both acetochlor and atrazine	5	1.84 (0.67-5.08)
	Applied separately	0	--
	Applied as a mixture	5	2.62 (0.95-7.20)*

*Significant at p<0.1;

**Significant at p<0.05

[1]Adjusted for age, race, state, applicator type, smoking, family history of cancer, alcohol consumption, BMI, use of an enclosed cab, education, and correlated /associated pesticide use

Senator MERKLEY. Mr. Dourson, I understand you have been paid to assess the safety of both of these chemicals; therefore, your familiarity with them I anticipate to be significantly more. What organization paid you to assess the safety of these two chemicals? Just the name, please.

Mr. DOURSON. Dow AgroSciences. And we also had Monsanto. I believe both of them contributed to a collaborative project that included a group of people, including government scientists, that helped with the assessment.

Senator MERKLEY. Thank you. That is my understanding, those two companies.

Mr. DOURSON. Right.

Senator MERKLEY. Your organization ultimately recommended reference dose for the degradates or breakdown products that would translate to a safety level of 5,600 parts per billion. That is a significantly weaker standard than the standard set by the State of Wisconsin of 20 parts per billion, of Minnesota at 60 parts per billion. In fact, the safety standard proposed is 280 times weaker than standards set by Wisconsin and 70 times weaker than that of Minnesota.

The same trend is true for acetochlor. Your standards were 15 times weaker than standards set by Minnesota. This is a disturbing pattern for someone charged with representing the safety of our citizens from these chemicals.

Mr. Chairman, I would like unanimous consent to submit for the record a letter from a wide range of worker advocacy organizations, including many farm worker advocacy organizations.

Senator BARRASSO. Without objection.

[The referenced information follows:]

October 2, 2017

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators:

We, the undersigned organizations, serve and represent farmworkers, rural, immigrant, indigenous and Latino communities at the local, state and national level. We write to you on behalf of over two million farmworkers in the United States and the Commonwealth of Puerto Rico. Agriculture is one of the most dangerous industries in the nation, with higher worker death rates than in the transportation, mining and construction industry sectors.[1] Daily exposure to a range of harmful agricultural chemicals is among one of the many hazards that farmworkers encounter on the job. Farmworkers urgently need and deserve the strongest safeguards to prevent illness, injuries, and fatalities, and to protect the healthy development of their children and families from toxic chemicals. **As organizations that represent some of the workers and communities most exposed to toxic pesticides, we urge you to oppose the confirmation of Dr. Michael Dourson to head the Office of Chemical Safety and Pollution Prevention at the EPA.**

The impacts of occupational exposures to pesticides on men, women and children are a reality of everyday life that we see on a regular basis in the course of our work in and among the people in these communities. Farmworkers tell us about their experiences in the field – their health concerns for themselves and their children or symptoms they may be experiencing, such as headache, nausea, vomiting and dizziness. Most farmworkers do not have health insurance, so many of their symptoms go untreated. Sometimes these symptoms go away without treatment. Other times, the symptoms may lead to further health complications that impact the entire family, especially if a family member loses work and income due to an untreated illness. Long-term exposure can lead to debilitating chronic illnesses for an already disadvantaged community.

Alarmingly, what we know about Dr. Dourson and his company, Toxicology Excellence for Risk Assessment (TERA), is that they have served as toxicologists-for-hire, paid by chemical companies and their trade associations to cast doubt on the science and to undermine health-protective standards for dozens of toxic chemicals, including the neurotoxic chemical chlorpyrifos.[2]

Chlorpyrifos is a widely used agricultural pesticide that poses serious risks to children, farmworkers, rural communities and all consumers. Prenatal exposures to chlorpyrifos have been linked to neurodevelopmental impairment in children and in many states, this chemical is most often identified as the culprit in acute pesticide poisoning incidents of workers and bystanders.[3] The health, safety and wellbeing of our members and our communities are directly threated by the continued use of this nerve agent pesticide, a chemical that EPA Administrator Scott Pruitt has refused to ban in our food.

The nomination of Dr. Dourson to be in charge of chemical safety at the EPA is a threat to our nation's children, farmworkers and communities at the frontlines of exposure to chlorpyrifos:

- In 2006, Dr. Dourson and his colleagues at TERA published a paper, funded by Dow AgroSciences, making recommendations that would be far less protective than what EPA found was necessary to protect children its 2001 human health risk assessment.[4] The 2006 paper relied heavily on the findings of another paper[5] the authors published a year prior, also funded by Dow AgroSciences.

- Since Dr. Dourson's publications, several peer-reviewed studies have found harm to children's brains from much lower doses of chlorpyrifos than previously accounted for in EPA's risk assessments.
- Following these findings, in 2016, Dr. Dourson was among a group hired by the pesticide trade association Croplife America to present at a meeting of EPA's FIFRA Scientific Advisory Panel.[6] Dr. Dourson's group attempted to undercut one of the Columbia University studies that showed impaired mental development for children who were exposed to chlorpyrifos in the womb, and his group recommended that EPA do nothing to incorporate the findings of neurodevelopmental harm to children in future risk assessments.

Dr. Dourson's work on chlorpyrifos shows either a fundamental lack of understanding or a callous disregard for EPA's duty and mandate to protect children from pesticides. It is critically important to understand that this amounts to a national public health issue that affects us all. While we represent and defend farmworkers, the health of our nation's children is jeopardized by continued use of chlorpyrifos, due in part to EPA's own findings of unsafe levels on food and in drinking water. In addition, our country cannot afford the health consequences of the weakening of any protections of the public against exposure to toxic agricultural chemicals. By protecting farmworkers, we protect our food supply and, ultimately, we protect ourselves and the health of our children.

We urge the Senate to wholeheartedly object to this unconscionable nomination.

Respectfully,

Alianza Nacional de Campesinas (National Alliance of Farmworker Women)
CRLA Foundation
Earthjustice
El Comité de Apoyo a los Trabajadores Agrícolas (The Farmworker Support Committee)
Fair World Project
Farmworker Association of Florida
Farmworker Justice
Farmworker Self-Help
Food Chain Workers Alliance
Labor Council for Latin American Advancement (LCLAA)
League of United Latin American Citizens (LULAC)
Mi Familia Vota
Migrant Legal Aid
Mixteco Indigena Community Organizing Project
National Hispanic Medical Association (NHMA)
New Mexico Center on Law and Poverty (NMCLP)
New York Environmental Law and Justice Project (NYELJP)
Northwest Forest Worker Center
Organización en California de Líderes Campesinas, Inc.
PCUN-Pineros y Campesinos Unidos del Noroeste (Northwest Treeplanters and Farm Workers United)
United Automobile, Aerospace and Agricultural Implement Workers of America (UAW), International Union
United Farm Workers (UFW)
Warehouse Worker Resource Center
Worker Justice Center of New York, Inc. (WJCNY)

CC: Members of the Committee on Environment and Public Works

[1] American Federation of Labor and Congress of Industrial Organizations (AFL-CIO). (2017). *Death on the Job: The Toll of Neglect, 2017.* (26th edition). Retrieved from AFL-CIO website: https://aflcio.org/sites/default/files/2017-04/2017Death-on-the-Job_0.pdf

[2] *See: Lerner, S.,* The Intercept, *July 21, 2017 "Trump's EPA Chemical Safety Nominee Was In The 'Business Of Blessing' Pollution"* and *Adams, R. and Song, L.,* Inside Climate News, *December 19, 2014 "One-Stop Science Shop Has Become a Favorite of Industry—and Texas"*

[3] Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Apr. 30, 2015), in EPA-HQ-OPP-2008-0850, available at http://earthjustice.org/sites/default/files/files/FarmworkerandConservationCommentsonChlorpyrifosRHHRA.pdf

[4] *Zhao, Q., Dourson, M., and Gadagbui, B., "A review of the reference dose for chlorpyrifos," Regulatory Toxicology and Pharmacology Volume 44, Issue 2, March 2006; EPA Chlorpyrifos Human Health Risk Assessment (2000); and EPA Chlorpyrifos Revised Human Health Risk Assessment (2016)*

[5] *Zhao, Q., Gadagbui, B., and Dourson, M., "Lower birth weight as a critical effect of chlorpyrifos: A comparison of human and animal data," Regulatory Toxicology and Pharmacology Volume 42, Issue 1, June 2005*

[6] See pp. 384-5 of the transcript of the FIFRA SAP Panel meeting, available at https://www.epa.gov/sites/production/files/2016-05/documents/fifra_sap_04_19_16_to_04_21_16_final_transcript.pdf

Senator MERKLEY. Thank you.

This letter states, "The nomination of Mr. Dourson to be in charge of chemical safety at the EPA is a threat to our nation's children, farm workers, communities at the front lines of exposure to chlorpyrifos."

Flame retardants are chemicals that are used in everything from car seats to couches. EPA has placed many of these chemicals on its list of chemicals it wishes to examine first under TSCA. Ten years ago the biggest companies that made these chemicals formed an organization, Citizens for Fire Safety, to promote their use.

In 2012 the group was found to have paid doctors to testify against proposed legislation to ban the chemicals. These doctors described heartbreaking stories about burned children who died in their arms, but might have been saved if only flame retardants had been used on their burning sheets and pillow cases.

Just one problem—those children did not exist. These stories were fabricated. Citizens for Fire Safety folded in 2012, right after this shameful scam was exposed. And I note this because the very same flame retardant manufacturers that backed Citizens for Fire Safety then announced they would continue their advocacy efforts through the North American Flame Retardant Alliance, which was part of the American Chemistry Council. That Alliance consistently promotes the use of flame retardants, downplays the risk to health, lobbies against proposals to regulate them.

Mr. Dourson, according to documents you provided the Committee, you were a member of the North American Flame Retardant Alliance Scientific Advisory Council from early 2012 until just a couple months ago. You list being paid $10,000 in consulting fees. You have led research funded by the same flame retardant companies that were backing the Citizens for Fire Safety and the Alliance.

Having taken this employment, this advocacy, it is simply hard to conclude how you can be an objective and impartial regulator when it comes to these flame retardants. If confirmed, do you commit to recuse yourself from working on any chemical safety matter related to flame retardants?

Mr. DOURSON. Senator, we have—TERA and the University of Cincinnati, has worked with a number of organizations for flame retardants, including Consumer Product Safety Commission, Health Canada, the National——

Senator MERKLEY. That is not the question I am asking.

Senator BARRASSO. Senator, your time has expired.

Senator MERKLEY. It is a simple yes or no question.

Senator BARRASSO. And there is a second round. We will have plenty of time for a second round of questions.

Senator MERKLEY. Yes or no, Mr. Dourson? Can you answer the question?

Senator BARRASSO. I ask all members to keep this in their 5 minute rounds.

Senator MERKLEY. Well, we would be done if he would answer the question, Mr. Chairman. It is a simple yes or no question.

Mr. DOURSON. I will rely on the guidance from the EPA ethics——

Senator MERKLEY. That is not sufficient. Thank you.

Mr. DOURSON [continuing]. To determine any issues——

Senator BARRASSO. You will have time for a second round of questions to further pursue.

I would like to introduce for the record a letter from Dr. James Klaunig, who served as Indiana's State Toxicologist for over a decade, is now Professor of Indiana University School of Public Health, who wrote, "Dr. Dourson is an exceptional scientist and leader in the fields of risk assessment and toxicology. As the Assistant Administrator of the EPA Office of Chemical Safety and Pollution, he would bring over a generation of experience in chemical safety and human risk assessment" to submit for the record.

[The referenced information follows:]

SCHOOL OF PUBLIC HEALTH
INDIANA UNIVERSITY
Department of Environmental Health
Bloomington

July 12, 2017

The Honorable Senator John Barrasso,
Chairman, Environment and Public Works Committee
United State Senate
413 Dirksen Senate Office Building
Washington, DC 20510

Attn: Matt_Leggett@epw.senate.gov

RE: Nomination of Dr. Michael L Dourson for Assistant Administrator of the EPA Office of Chemical Safety and Pollution Prevention

Dear Senator Barrasso:

I am writing in support of the nomination of Dr. Michael L Dourson for Assistant Administrator of the EPA Office of Chemical Safety and Pollution Prevention. My name is James E Klaunig. I am currently Professor of Environmental Health and Toxicology at Indiana University. I have been involved in the basic research and applied research of the possible effects of agro chemicals and pharmaceuticals on humans for the past 40 years. I have served on US EPA and USFDA review panels and have chaired review panels for the USEPA for its human health strategy and environmental carcinogenesis programs. I have also served as a member of the US National Toxicology Board of science advisors. My research has been support by the USEPA, NIH, State of Indiana and corporate entities. Prior to joining the Indiana University School of Public Health I served as the Professor and Director of Toxicology at Indiana University School of Medicine. In this position I also served as the State Toxicologist for the State of Indiana as well as the Associate Director of the IU Cancer Center. I have also served Indiana on its pesticide review board, Governor's council on impaired and dangerous driving, and the controlled substances advisory Board. For this service to the State of Indiana I was honored by the Governor of Indiana with the Sagamore of the Wabash award (highest award to a citizen of Indiana for service to the State). I have published over 250 peer reviewed manuscripts and book chapters. My research has been highly cited as evident by my designation of one of 135 highly cited researchers in toxicology and pharmacology worldwide by the web of science (http://hcr.stateofinnovation.com/). A copy of my curriculum vitae can be found on the webpage, Klauniglab.com.

I have known and been familiar with the work of Dr. Dourson for over 30 years. Dr. Dourson is a leader in the field of risk assessment, predominantly with

the application of peer reviewed science to the human risk assessment. He has been instrumental in bringing scientists of difference disciplines and representing different constituents together to address current and future approaches to the risk of humans to exogenous chemicals. He is currently a Professor in the Risk Science Center in the University of Cincinnati, College of Medicine. Before joining the University Dr. Dourson was the founder of the Toxicology Excellence for Risk Assessment Center (TERA). Prior to forming and directing TERA, he worked for 15 years in the U.S. Environmental Protection Agency in numerous leadership positions. He has been elected to multiple officer positions in the American Board of Toxicology (including its President), the Society of Toxicology (including the presidency of 3 specialty sections), the Society for Risk Analysis (including its Secretary), and is the President of the Toxicology Education Foundation, a nonprofit organization with a vision to help our public understand the essentials of toxicology. In addition to numerous appointments on government panels, such as EPA's Science Advisory Board, he is also a member on the editorial board of Regulatory Toxicology and Pharmacology, Human and Experimental Toxicology and Toxicology Sciences.

He extensive service to the disciplines of toxicology and risk assessment has resulted in numerous awards including 4 bronze medals at EPA, the Arnold J. Lehman award from the Society of Toxicology, and the International Achievement Award by the International Society of Regulatory Toxicology and Pharmacology. Dr. Dourson has also been elected as a Fellow of the Academy of Toxicological Sciences and as a Fellow for the Society for Risk Analysis.

Besides his leadership in toxicology and risk assessment Dr. Dourson has published over 150 peer review manuscripts as well as over 100 government regulatory risk assessment documents dedicated to risk assessment methods and toxicology. He is also frequently called upon to chair symposium and workshop sessions at national and international scientific meetings.

Dr. Dourson is an exceptional scientist and leader in the fields of risk assessment and toxicology. As the Assistant Administrator of the EPA Office of Chemical Safety and Pollution Prevention he would bring over a generation of experience in chemical safety and human risk assessment. I enthusiastically support the nomination of Dr. Michael Dourson for USEPA Assistant Administrator. Please contact me if you have any questions regarding this support letter.

Sincerely,

James E. Klaunig, PH.D., Fellow ATS, Fellow IATP
Professor
Environmental Health
Indiana University
1025 E 7th St
Bloomington , IN 47405
812 856 3957
jklauni@indiana.edu
klauniglab.com

Senator CARPER. Mr. Chairman, I would like to ask unanimous consent, if I could, to submit for the record an October 3rd letter from the International Association of Fire Fighters to members of this Committee. This letter expresses the Association's strong opposition to the nomination of Dr. Dourson.

Senator BARRASSO. Without objection.

[The referenced information follows:]

INTERNATIONAL ASSOCIATION OF FIRE FIGHTERS ®
HAROLD A. SCHAITBERGER
General President
EDWARD A. KELLY
General Secretary-Treasurer

October 3, 2017

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
Washington, DC 20510

Dear Chairman Barrasso and Ranking Member Carper,

On behalf of the nation's 305,000 professional fire fighters and emergency medical personnel, we urge you to oppose the nomination of Michael Dourson to be Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention. Michael Dourson's long career as a toxicologist paid by industry to work on the same chemicals he will be in charge of at EPA, including flame retardants, is a recipe for disaster for fire fighters.

The scientific evidence demonstrates fire fighters have higher incidences of cancer compared to other occupations, and that these cancers are specifically related to the job of fire-fighting. For example, the National Institute for Occupational Safety and Health (NIOSH) found the chance of fire fighter lung cancer diagnosis or death and the chance of fire fighter leukemia death increased with time spent fighting fire and the number of fire runs, respectively.

In the course of duty, fire fighters are exposed to toxic chemicals including flame retardants applied to upholstered furniture and many other household products. In work paid by NAFRA, Dourson concluded that the flame retardant tetrabromobisphenol A (TBBPA)—an EPA work plan chemical—is not likely to be a reproductive or developmental toxicant. Numerous other studies indicate just the opposite. Dourson's consistent record of reaching conclusions not supported by other scientific experts including those in state and federal regulatory agencies raises serious concerns.

The IAFF is committed to protecting the health and safety of the public as well as its members. We need real facts about the safety of the chemicals our members come in contact with.

The IAFF is deeply concerned and is committed to protecting the health and safety of its members, and preventing toxic occupational exposures that put their health at significant risk. Michael Dourson's long record undermining efforts to shed light on the toxicity of flame retardants leaves us little doubt that he is the wrong man to lead EPA's Office of Chemical Safety and Pollution Prevention. Again, we urge you to oppose his nomination.

Sincerely,

Harold A. Schaitberger

Harold A. Schaitberger
General President

Senator BARRASSO. Senator Fischer.

Senator FISCHER. Thank you, Mr. Chairman.

Mr. Wehrum, last week the EPA proposed to dramatically change the RFS in a proposal that is typically just a request for additional data. Moreover, there are press reports that EPA wants to attach a compliance credit to exported biofuels, an act that would completely undermine the integrity of the program, not to mention, I believe, harm the reputation of the United States as a fair trading partner.

I have some real concerns with the approach that the Agency has recently taken on the RFS, especially after Administrator Pruitt committed to me, in this room, as he did to Senator Ernst, he also committed to me in two private meetings to uphold the law as intended.

As you are aware, the RFS is the law until 2022. Are you aware of that?

Mr. WEHRUM. And beyond, Senator, yes.

Senator FISCHER. And beyond. The EPA could look at it after 2022, is that correct?

Mr. WEHRUM. That is correct, Senator.

Senator FISCHER. What are your thoughts on the EPA's, I believe, attacks on the RFS that we have been seeing lately?

Mr. WEHRUM. Senator, as I responded to Senator Ernst earlier, the RFS is a very complicated program, and I am not apprised of all of the recent actions and all of the recent activity under the RFS, but it certainly will be one of my primary responsibilities, if confirmed to this position; and as I committed to Senator Ernst, I will commit to you that I will work very closely with you and with your staff and with your constituents to understand your concerns, and my goal would be to implement the RFS as faithfully and completely as I could, Senator.

Senator FISCHER. And as Senator Ernst asked, would you commit that the RFS is the law, and it is in law until 2022?

Mr. WEHRUM. Senator, there is no doubt the RFS is in law. It is included in the Clean Air Act; it was an amendment to the Clean Air Act.

Senator FISCHER. Until 2022, at the earliest, when the EPA could look at it?

Mr. WEHRUM. Yes, Senator. So the statute specifies renewable volume obligation goals through 2022, and then leaves it to the discretion of the Administrator, in consultation with others, to determine what those goals might be beyond 2022.

Senator FISCHER. The Assistant Administrator of the Office of Air and Radiation plays a key role in ensuring the RFS functions according to congressional intent. And with the President's commitment to the RFS and the biofuel production that we see, would you commit to upholding the President's commitment?

Mr. WEHRUM. The President, Senator, would be my ultimate boss, so our job is to implement the policy as the President specifies.

Senator FISCHER. According to the law.

Mr. WEHRUM. According to the law, that is absolutely correct.

Senator FISCHER. Do you think that the EPA has the authority to artificially reduce biofuel blending that runs counter to the intent and the literal reading of the RFS law?

Mr. WEHRUM. Well, Senator, I have said a couple times the statute is pretty extensive, the statutory provisions; they go on for many pages in the Clean Air Act, and the regulations are even more extensive than that. What I do know is that there is discretion built into the law for the Agency and others to use in making sure that the law can be implemented according to the law, but also be effective as a practical matter.

So I understand much of the concern is with regard to how that discretion has been implemented, and again, I will fully commit to you that, if confirmed to this position, that I would work very closely with you to understand your concerns, to understand the concerns of your constituents, and to try to implement the law as best we can.

Senator FISCHER. Do you believe it is the intent of the RFS to increase the production of American made renewable fuels and also to decrease our country's reliance on foreign oil?

Mr. WEHRUM. I believe there is no doubt that that is the case, Senator.

Senator FISCHER. And is it in the best interest of our national security that we have a reliable, stable fuel supply?

Mr. WEHRUM. I believe that to be true, and energy security clearly was one of the motivating factors behind the enactment of the RFS, Senator.

Senator FISCHER. And do you believe it was also the intent of the legislation to have a balanced portfolio when it comes to our energy sources in this country?

Mr. WEHRUM. Senator, I am not exactly sure what you mean by that. I would be happy to respond; I am just not sure what you are getting at.

Senator FISCHER. Well, I look forward to furthering our understanding of the situation in future conversations.

Mr. WEHRUM. As do I, Senator.

Senator FISCHER. Thank you.

Thank you, Mr. Chairman.

Senator BARRASSO. Thank you, Senator Fischer.

Senator Markey.

Senator MARKEY. Thank you, Mr. Chairman.

Mr. Dourson, you and the organization you have led, known as Toxicology Excellence for Risk Assessment, have been routinely paid and funded by chemical companies and polluters defending the need for weakened chemical safety standard. For example, in 2014 and 2017 you led two industry funded studies that defended a safe level of exposure to the carcinogen 1,4-dioxin that is 1,000 times greater than EPA's health based safety level; 350 parts per billion versus EPA's .35 parts per billion. One thousand times greater exposure to dioxin.

Dioxin is an industrial chemical found in a wide range of products and known to frequently contaminate water systems. According to water sampling studies conducted by the environmental working group Water Surprise, for more than 7 million Americans in 27 States are contaminated with the chemical at a level higher

than EPA's health based standard. Just last year the EPA announced dioxin to be one of the first chemicals to be evaluated by the office to which you were nominated under the new Toxic Substances Control Act, which I helped to write.

Given your recent work defending a 1,000 times weaker safety standard for dioxin than what the EPA determined will cause cancer, will you recuse yourself from working on this chemical if you receive confirmation for this position?

Mr. DOURSON. Senator, I worked with a team of groups, including five different U.S. States, three different international organizations——

Senator MARKEY. Will you recuse yourself from the consideration of dioxin?

Mr. DOURSON [continuing]. Several consulting firms, and several industries to advance the science that EPA put out in its 2013 document——

Senator MARKEY. Will you recuse yourself? Will you promise not to weaken the standard the EPA has set to protect the public's health against the carcinogen dioxin? Will you not weaken that standard?

Mr. DOURSON. If confirmed, I would bring new science and thinking into the Agency and——

Senator MARKEY. Your science says that dioxin can be exposed to by human beings at 1,000 times greater rate than the EPA has determined is safe for human beings. Will you recuse yourself?

Mr. DOURSON. This new information is new information and new science since the time of the EPA document——

Senator MARKEY. I hear you. You are not going to give us a commitment, Mr. Dourson. And what is going to happen is, when you arrive at the EPA, you are going to have been the defendant's chemical lawyer, who then becomes the judge over the very science, bogus science which you have been propounding. You are not just an outlier on this science; you are outrageous in how far from the mainstream of science you actually are.

They are giving out the Nobel Prizes in chemistry this week. If there was a Nobel Prize in chemistry in reverse, you would be the clear winner this week in the United States and the world. This is an absolute atrocity.

Let me move on, then, to TCE, a volatile organic compound and common industrial solvent that has been linked to cancer, congenital heart defects, other health issues. It is a route by which humans actually contract cancer. Because of the wide range of health concerns that can occur through even short-term exposure to TCE, the EPA has proposed banning TCE in commercial vapor degreasing and dry cleaning. Other uses of the chemical have been prioritized by the EPA for assessment under the updated TSCA law.

A study you led and funded, Mr. Dourson, in 2016 proposed a safety range for TCE that is 1.5 to 15 times less protective than the EPA's own drinking water standard. Given that the EPA will soon be finalizing its proposals on TCE for certain uses, and assessing the remaining uses for regulation, will you commit to not working to weaken the standards the EPA has already proposed?

Mr. DOURSON. Again, Senator, based on existing science, EPA came out with an assessment. Subsequent to that science, I worked with a consortium of individuals and groups of various sectors to bring additional science to EPA's good questions. It is inappropriate for me to prejudge an issue, but if confirmed, I will ensure that the issue is fully and fairly considered in a publicly transparent manner.

Senator MARKEY. Mr. Dourson, it is pretty clear that you have never met a chemical you didn't like, and your previous studies have already prejudged the exposure. You are a scientist who already did work on this subject, and you have come to conclusions which are fundamental threats to the public health and safety of this country. You should commit here to recusal on the issues where you have already reached conclusions.

Mr. DOURSON. The published paper we used, Senator, was using U.S. EPA safe doses and also EPA's method for estimating ranges.

Senator MARKEY. EPA found 1.5 to 15 times higher risk than you did, and that is not consistent with the conclusion——

Senator BARRASSO. There will be a second round of questions, Senator, for your opportunity.

Senator Boozman.

Senator BOOZMAN. Thank you, Mr. Chairman. I am about to lose my voice, but I did want to ask a couple questions.

Mr. Ross, in recent years EPA has made it increasingly difficult for Arkansas to manage its delegated national pollutant discharge elimination program and responsibilities under the Clean Water Act.

Too often, permits, rulemakings, or other actions sent to EPA for review were returned with demands for more restrictive requirements, additional expensive data collection, or other costly, onerous requirements. New leadership at EPA has an opportunity to correct this coercive federalism and instead restore cooperative federalism, as intended.

The States have the expertise and local knowledge necessary to administer our environmental programs. The EPA has been proud to say that the States are essentially in charge and that they will defer to them, and that is true, as long as they agree with what the States come up with.

I guess the question is EPA has the opportunity to play a significant role in supporting a move back to cooperative federalism. Can you please explain how you plan to change the EPA's State dynamic?

Mr. ROSS. Thank you for the question, Senator. I do believe strongly in cooperative federalism. One of the things that I have heard in the run up to this hearing, and also working for two different States over the last several years, is the frustration in the relationship between the Federal Government and the State government, and I commit to taking that head on. And one of the ways that I have heard is to make sure we get outside the Beltway; to go out, work with States, figure out the relationships, and listen and develop a common relationship on how best to manage our nation's resources.

Senator BOOZMAN. Very good.

Mr. Wehrum, more than 1,000 U.S. companies and organizations sent a letter to Congress and the Administration calling for lawmakers to preserve the voluntary Energy Star program that was recently proposed for elimination. This program, founded in 1992 during the Bush administration, is an extremely successful public-private partnership model. Consumers enjoy the benefits of the program, which encourages innovation and has saved taxpayers over $430 billion since 1992.

Do you view the Energy Star program as a successful public-private partnership?

Mr. WEHRUM. Senator, Energy Star is a unique program, and products that are allowed to carry the Energy Star label must be shown to be cost effective, energy efficiency technologies, which means they pay for themselves over time, so a very strict criteria are applied to deciding where the Energy Star label can be applied. So it is a different kind of program because it is a voluntary program and not a mandatory regulatory program, and it is a program that has been widely used in many different industries.

Senator BOOZMAN. So you think it has been successful?

Mr. WEHRUM. Personally, I do believe it has been successful, Senator, yes.

Senator BOOZMAN. Thank you.

Dr. Dourson, for the past 8 years EPA has acted as a political arm of the Obama administration. Time and time again we have seen rules developed not based on sound science, but on political ideology. When rules have been released, States, the private sector, and even Congress have had trouble getting EPA to show the science that helped develop these rules. As an Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, can we expect EPA to be more transparent as to how rules are developed?

Mr. DOURSON. Yes, Senator. My career has been based on transparency and collaboration, and I intend to do so if confirmed.

Senator BOOZMAN. Good. That is very, very important, to have access. It is one thing to come out with a finding, but certainly that needs to be transparent. We need to have the ability to see the science behind it.

Thank you, Mr. Chairman.

Senator BARRASSO. Thank you, Senator Boozman.

Senator Booker.

Senator BOOKER. Thank you, Mr. Chairman.

Mr. Dourson, I have to say, and you have heard from my colleagues, that I have only been in the Senate for 4 years. But your nomination is one of the more shocking that I have seen, and your job that you are being nominated to, as my colleague just said, is to the Chemical Safety and Pollution Prevention Office, and the mission, as I hope you have memorized, frankly, is to protect families and the environment from the potential risks from pesticides and toxic chemicals.

You heard already from some of my colleagues; Senator Duckworth talking about the south side of Chicago. I live in a community that has seen the effects of corporate villainy to the point now that our soil is poisoned; we can't plant many places in our city. The air is poisoned, asthma rates, lead poisoning rates, the

water is poisoned because corporations, pressing their hand and their power and their money, have been able to poison communities to the extent that you have autism rates, birth defects, cancers in our children in places in this country that are unconscionable.

And I really hope, as you sit there on your perch right now, that you have the capacity to have empathy for those people, many of whom are sitting behind you right now, who view your nomination with fear, with anguish. And that fear and anguish is not partisan; it is not coming from the thin air. As you have heard from my colleagues, it is coming from looking at your record.

I would imagine that somebody would be nominated that has a track record of standing up for those vulnerable people in our nation. But my colleague after colleague has now pointed out what you have been doing with your professional career. And I will just go through, because it almost seems like a bit of a scene out of some Disney movie where there are corporate villains that do harm to our environment, or at least seek to if it weren't for the heroic actions of others.

So, this is the process. First, a company or industry identifies a problem, and you have already talked to Dow and Monsanto and chemical companies like this, and they want to exercise influence to stop safety measures being done by governments. So, what happens is that the corporation hires your organization, TERA, to come up with a recommendation, a safety standard so that they can try to defend their desire to put more poisons into the atmosphere, into the soil, and into our water. So, what happens is that you come up with the science to back up these corporations.

But I try to give this a fair measure. I mean, the surface information I received was so astonishing that you would be sitting where you are as a nominee that I wanted to dig into some of the stuff, and came up with the same things that other folks came up with. You have heard these chemicals now mentioned by my colleagues—alachlor and acetochlor. They are banned in the European Union. Literally banned. You all advocated for limits in the water based on your science that ended up being 280 times higher than the State of Wisconsin believed was safe for their kids.

So, I know that you can pick your chemical here. The pattern I have seen from just looking at your record, sir, goes again and again and again. Corporations fund studies from TERA and have science on here is chlorpyrifos that literally comes out. Your studies, this one, in the case of that chemical, that affects farm workers and children, was 1,000 time higher than the ultimate EPA standard. A thousand times higher.

So clearly, to me, we have a situation where you are about to be the person that is a head of an office that has the mission of protecting children, and you have a pattern of working with corporations to advocate for a position that is hundreds, if not thousands, of times more dangerous than the standards we set and that we see other nations who are moving to ban the very chemicals that you have been advocating for as safe at higher levels.

The Chairman said that you have been a leader, read a letter that calls you a leader in human risk assessment. I don't see this as leadership when you are advocating for levels that will literally poison people. It doesn't make you seem like a leader in your ca-

reer; it seems like you are a lackey, a corporate lackey doing the bidding of people that are trying to create in communities like the one I live in, where my niece was born, to create environments that are chemically toxic.

So, I have heard you not answer this question over and over again, but I am appealing to you to recuse yourself. It seems logical and legal that you would recuse yourself from making decisions on chemicals from companies that have paid you. And I don't understand any defense to that. If these corporations were going to be advocating for standards that you set at levels that poison human beings, it seems logical that you should not be now the judge of whether those chemicals should be released, or changing standards that now will reflect what those corporations wanted.

So, I doubt I am going to get it, but will you recuse yourself, sir?

Mr. DOURSON. Senator, I will follow the EPA ethics officials' determination for any recusal.

Senator BOOKER. And that is the point I will conclude with, sir, because you are going to follow the ethics that you think that the EPA is going to give you, and I am talking to you not just about ethics and law, but I am talking to you about conscience and moral values.

And it seems like you have been willing to bend those ideals, because I don't know if you have children, I don't know if you have grandchildren, I don't know if you have nieces or nephews like me, but I doubt you would let them live next to the companies that are spewing this stuff in the air. You would not let them live there and accept standards in their atmosphere that you have been claiming for your entire career are safe. You would not do it. But you are advocating for positions, and there are people here right now, you are advocating for positions that are going to endanger those children that are in those communities.

Thank you very much.

Senator BARRASSO. And there will be time for a second round of questioning.

I would like to submit for the record a letter by Dr. Jennifer Seed, who has worked for 23 years in various positions at the Office of Pollution Prevention and Toxics at the EPA, who wrote that Dr. Dourson has a long history of supporting regulatory agencies both at the State and Federal level. As an EPA employee, he played a paramount role in the development of risk assessment practices that are now used internationally.

Unanimous consent that the letter be admitted.

[The referenced information follows:]

From: Jennifer Seed [mailto:jseed89770@aol.com]
Sent: Saturday, July 22, 2017 2:02 PM
To: Leggett, Matt (EPW) <Matt_Leggett@epw.senate.gov>
Cc: palich.christian@epa.gov
Subject: A note in support of Dr. Michael Dourson as AA of OCSPP

Senator John Barrasso,

I am writing in support of the nomination of Michael Dourson as AA of the Office of Chemical Safety and Pollution Prevention (OCSPP). I retired from the EPA in 2014. I worked in the Office of Pollution Prevention and Toxics (one of the Offices in OCSPP) for 23 years in various positions including Biologist, Senior Science Advisor, Branch Chief, and Deputy Director of the Risk Assessment Division. During that time, I had interactions with Dr. Dourson, both when he was an employee of EPA and later when he founded TERA. I know you are aware of his extensive toxicology and risk assessment background so I will not dwell upon that here. I am also aware that some objections have been raised due to his work with industry. I would just like to take this opportunity to point out that Dr. Dourson has a long history of supporting regulatory agencies, both at the State level and the Federal level. As an EPA employee, he played a paramount role in the development of risk assessment practices that are now used internationally. He has worked with states to develop assessments. He has worked to harmonize risk numbers internationally. I would also point out that he had a 5 year cooperative agreement with my prior Division and Office in EPA to develop a peer consultation process and to use the assessments that were being done under OPPT's Voluntary Childrens' Chemical Evaluation Program (VCCEP) as examples. This was done with the utmost professionalism.

Sincerely,
Jennifer Seed, Ph.D.
Retired from EPA

Senator CARPER. Mr. Chairman, I would also like to ask unanimous consent to submit for the record a September 19th letter from several environmental organizations to members of our Committee, and on behalf of their millions of members, these organizations write to oppose the nominations of Dr. Dourson and Mr. Wehrum. It has raised serious concerns regarding the nominations of Mr. Ross and Mr. Leopold to their respective positions at the Environmental Protection Agency.

Senator BARRASSO. Without objection.

Senator CARPER. Thank you.

[The referenced information follows:]

Sierra Club * Earthjustice * League of Conservation Voters
Rachel Carson Council * American Sustainable Business Council
Oil Change International * Waterkeeper Alliance * Center for Biological Diversity
NextGen America * Safe Climate Campaign

September 19, 2017

Dear Senator,

On behalf of our millions of members, the undersigned organizations write to raise serious concerns regarding the nominations of Bill Wehrum for Assistant Administrator for the Office of Air and Radiation, Dr. Michael Dourson for Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, David Ross for Assistant Administrator for the Office of Water, and Matt Leopold to serve as General Counsel for the Environmental Protection Agency.

A closer inspection of the careers and writings of each of these candidates will reveal many instances where their views and actions are in opposition to policies and safeguards that would protect our air and water, our health, and our communities from toxic pollution and that they have pursued these ends through work inside and outside of government.

Bill Wehrum, nominee for Assistant Administrator for the Office of Air and Radiation, both during his tenure at EPA and as an industry lobbyist, actively worked to undermine the air pollution safeguards and public health protections guaranteed under the Clean Air Act. From 2001 to 2007, Wehrum worked in EPA's Office of Air and Radiation, serving as Acting Assistant Administrator from 2005 to 2007 when his nomination for Assistant Administrator was withdrawn, having failed to secure the 60 votes needed for confirmation. While at EPA, Wehrum led efforts to weaken standards to reduce mercury emissions from coal fired power plants. In addition to mercury, Wehrum sought to weaken and roll back safeguards against lead, fine particulate pollution, and ozone smog. Rules proposed during Wehrum's EPA tenure included language copied verbatim from Latham & Watkins memorandums, the firm where Wehrum was previously employed and worked on behalf of utilities and polluting energy companies to influence rules issued under the authority of the Clean Air Act. Wehrum's tenure at EPA also marked a series of high profile legal cases brought against the Agency for efforts to roll back, weaken, or avoid action on protections under the Clean Air Act. EPA lost 27 cases during this time and was repeatedly admonished by federal courts for its violation of the plain language of the law--the DC Circuit Court of Appeals went so far as to say EPA arguments "deploy[ed] the logic of the Queen of Hearts, substituting EPA's desires for the plain text of" the law. These cases, brought on by EPA's favor of industry, delayed or blocked pollution safeguards, resulting in grievous harm to public health and air and water quality. Wehrum's opposition to the fundamental health protections guaranteed under the Clean Air Act and his disturbing record of work to roll back, delay, and weaken pollution safeguards illustrate that he is grossly unfit to serve in a position charged with ensuring clean air and protecting public health.

Dr. Michael Dourson, nominee for Assistant Administrator at EPA's Office of Chemical Safety and Pollution Prevention, has made a career of supporting industry polluters and distorting the

facts of the toxic effects of substances like chlorpyrifos, TCE, PFOA, and 1,4 dioxane. Dourson was a chief defender of tobacco, distorting the health effects to benefit the industry at the expense of public health. Through his work as a toxicologist, and through his firm, Toxicology Excellence for Risk Assessment (TERA), Dourson has cultivated a close relationship with chemicals manufacturers and associations, working under the false aegis of "independence" to obscure the public health hazard posed by chemicals, pesticides, and other toxic substances. Dourson's TERA received "financial and in-kind support" from these same companies and chemicals manufacturers, at times receiving payment to review studies favored by the industry for inclusion in its database -- these ties call into serious question Dourson's ability to be an effective and impartial regulator of industry. Dourson's risk assessment firm, TERA, was responsible for the "Kids + Chemical Safety" website which has been alleged to advance industry positions and downplay health and exposure risks, particularly for children, of toxics present in household items, including toys. Dourson's record of inaccurately representing the health risks of toxic chemical exposure and downplaying the potential for harm, particularly to children, make clear that Dourson should not be charged with protecting the health of children and families from toxic chemicals.

David Ross, nominee for Assistant Administrator at EPA's Office of Water, is an environmental attorney and state government official. Ross has been an attorney in private practice and in 2014 was named Director of the Environmental Protection Unit at Wisconsin's Department of Justice. Ross' practice has focused on the Clean Water Act, RCRA, and CERCLA and both his record, and the circumstances of his tenure at Wisconsin's Department of Justice are concerning. Under his leadership, Wisconsin's Environmental Protection Unit both saw significant decreases in staff capacity, "[shrinking] to its smallest size in 25 years," and a significant decrease in the fines it sought from polluters. Ross is alleged to have taken a light hand in pursuing pollution violations, declining to assess fines and instead deferring to polluters and relying on compliance schemes, as opposed to assessing penalties in the course of settlement. This has weakened the Unit's enforcement priorities, shifting the office into a more partisan role. Ross' disinclination to take meaningful action to address pollution violations and the decrease in both the vigor of, and capacity for, enforcement action during his tenure at the Wisconsin Department of Justice Environmental Protection Unit are concerning given that the responsibilities of the Office of Water are to ensure protections for water and to safeguard families against toxic runoff, pollution, and discharges.

Matt Leopold, nominee for General Counsel at EPA has been an outspoken critic of the Agency and its efforts to regulate pollution and issue safeguards. Leopold's legal career has focused on the environment, both in private practice and as general counsel with the Florida Department of Environmental Protection. In a speech to the Federalist Society in Florida, Leopold argued against greater involvement by federal regulators in air, water, and land protections; he suggested that state governments should fill this role and questioned the authority of the EPA to exercise its regulatory powers. While with the Florida DEP, Leopold's role in the firing of two environmental lawyers was questioned over concerns that the terminations were made on partisan grounds. At the same time, Leopold presided over a steep decline in enforcement action brought by the Department. This raised concerns about a 'cozy' relationship with developers and polluters. Leopold's position on the Clean Power Plan is also concerning, and while he has said the EPA's authority to regulate greenhouse gases is settled law, he has questioned if the EPA is

exceeding its authority by looking outside emissions from power plants. As General Counsel, Leopold would play a key role in Administrator Pruitt's plan to roll back the Clean Power Plan, and in the ongoing efforts to roll back, weaken, or rescind safeguards issued by the Agency. Given his poor record of enforcement and his position on EPA's authority to regulate pollution, entrusting Leopold with the responsibility of General Counsel raises troubling concerns.

We urge your consideration of the above and request your careful evaluation of Ross and Leopold. The nominations of Bill Wehrum and Dr. Michael Dourson undermine public confidence in the Agency and paint a grim picture for the future of enforcement of our bedrock environmental laws, like the Clean Air Act and Clean Water Act. Each of these individuals have demonstrated a willingness to advance the agenda of polluters and industry before health protections and safeguards for clean air and clean water. Their close ties to industry, including the very companies and industries they would be charged with regulating, are alarming and would only add to the disturbing alignment of political staff at EPA under Administrator Pruitt with outside interests, instead of the American people. We urge you to oppose their nominations.

Sincerely,

Sierra Club
Rachel Carson Council
Earthjustice
League of Conservation Voters
American Sustainable Business Council
Oil Change International
Waterkeeper Alliance
Center for Biological Diversity
NextGen America
Safe Climate Campaign

Senator BARRASSO. Senator Rounds.

Senator ROUNDS. Thank you, Mr. Chairman.

Dr. Dourson, if you are confirmed to lead the Office of Chemical Safety, you will be responsible for implementing the TSCA reforms passed by Congress last year. This Committee has a strong interest in making certain that TSCA reforms are implemented properly and in a timely fashion.

Can you commit to us that you will keep Congress apprised of the status of TSCA implementation and answer congressional requests for information about the program?

Mr. DOURSON. Yes, Senator. As I said in my opening statement, the Lautenberg Chemical Safety Act was a significant milestone, celebrated broadly by scientists in my sector, so I will commit to working with this Committee and Congress to make sure it is implemented correctly.

Senator ROUNDS. Dr. Dourson, in the prior administration we heard reports of the EPA not using up to date or the most relevant science when making chemical safety decisions. Can you explain to me your views on the importance of science at the Agency, particularly in the decisions being made by the Office of Chemical Safety?

Mr. DOURSON. Senator, good science and use of good science is a touchstone of everything that U.S. EPA does, and other Federal agencies, I am sure, as well. Bringing good science and doing it in a collaborative and transparent manner has been my life's passion. Collaboration is important, and if confirmed, I will work with the talented people of the Office of Chemical Safety and Pollution Prevention and make sure that the best science is looked at and reviewed, and used to protect the public health, including the most vulnerable members of our population.

Senator ROUNDS. Let me get into this a little bit more, because when we talk about sound science, and we talk about good science, the science community has a unique way of looking at the way that it is reviewed, the way that we go about establishing the processes, and so forth. You are a scientist. Can you share with the Committee your analysis of what makes good science and sound science, and what the expectations should be of this Committee of the EPA in the way that they set up work with the science community to develop recommendations based on sound science? What goes into it?

Mr. DOURSON. Well, the sound science, if you would take a particular chemical, it doesn't matter which one for an example, you would look at all the available information on that particular chemical.

Senator ROUNDS. Who looks at it? Who looks at the information?

Mr. DOURSON. Well, it would be the scientists within the Office of Chemical Safety and Pollution Prevention, and it could be exposure science, it could be toxicology, it could be epidemiology. But you bring all this together, and you work with teams within the organization to review all this data. The next step is to look and winnow out and use the most significant or credible science on which to make the basis, your assessment of chemical safety or exposure. And once that determination is made, you do this in an open fashion, you ask for information, then you have an independent peer review.

Senator ROUNDS. Talk about that a little bit. I think that is the important part here that sometimes gets missed.

Mr. DOURSON. Well, the independent peer review, U.S. EPA has several ways to do this, and they have several very good organizations within U.S. EPA. The Science Advisory Board, of which I have served as a member until just a couple days ago when my 6-year term was up, is an example of very good independent peer review. They are independent of the Agency, the group within EPA that does this, and they bring scientists from the outside sector that are multiple disciplines and also multiple sectors in to review the information that EPA puts out. That is very important.

Another important thing is access to all of the available data. There are sometimes studies you don't have access to the raw data. Sometimes that is difficult to make decisions in that case.

Senator ROUNDS. OK.

Mr. Ross, in the last Administration we uncovered several instances in which regulations were promulgated by the EPA without taking into consideration the opinions of the Science Advisory Board or not properly submitting information to the Science Advisory Board to review prior regulating.

If confirmed, will you commit to relying on the best available science when regulating?

Mr. ROSS. Absolutely, Senator. I think sound science, together with the proper application of law, are the twin pillars of sound Government policy decisionmaking, so absolutely.

Senator ROUNDS. Thank you.

Thank you, Mr. Chairman.

Senator BARRASSO. Thank you very much, Senator Rounds.

Senator Harris.

Senator HARRIS. Thank you.

Mr. Wehrum, section 209(b) of the Clean Air Act recognizes California's authority to increase air pollution standards for new motor vehicles. I am sure you are familiar with that.

Mr. WEHRUM. I am, Senator.

Senator HARRIS. And I have an e-mail that is dated March 15th, 2006, from you to the EPA staff, where you told staff that you thought the EPA should preempt California and deny the waiver.

And Mr. Chairman, I would like to enter that into the record.

Senator BARRASSO. Without objection.

[The referenced information follows:]

EPA Email

From:	Bill Wehrum
To:	Staff at EPA Office of Transportation and Air Quality and EPA Office of Air and Radiation
CC:	Staff at EPA Office of General Counsel
Date:	3/15/2006 4:45 PM
Subject:	CA Vehicle GHG Regulations

... -- I took another look at the briefing materials from late January. I think we should assert the existence of preemption and propose to deny the waiver based on the absence of compelling and extraordinary conditions. This determination would be specific to the GHG standard and should not generally apply to the other aspects of their LEV rule. I think it makes sense to ask for comment on some of the other key questions presented in the briefing, but not present them as our proposed alternative.

Having said that, I also think that this issue goes far beyond OAR. ..., will you please set up a briefing with Marcus ASAP to give him the background and seek his concurrence. ..., I'd like to adjust the January briefing package to include the recommended approach described above. We can talk about it more before going to Marcus if you or others have concern with this approach. Lastly, we will need to consult with our interagency breatheren before going forward with a Fed. Reg. notice. I'll get this started once we've touched base with Marcus.

Thanks.

Senator HARRIS. Also, in 2008 there was a House Committee on Oversight and Government Reform investigation showing that the EPA career staff and lawyers unanimously and uniformly thought the waiver should be granted.

And I have that document as well, Mr. Chairman, that I would like entered.

Senator BARRASSO. Without objection.

[The referenced information follows:]

HENRY A. WAXMAN, CALIFORNIA,
CHAIRMAN

TOM LANTOS, CALIFORNIA
EDOLPHUS TOWNS, NEW YORK
PAUL E. KANJORSKI, PENNSYLVANIA
CAROLYN B. MALONEY, NEW YORK
ELIJAH E. CUMMINGS, MARYLAND
DENNIS J. KUCINICH, OHIO
DANNY K. DAVIS, ILLINOIS
JOHN F. TIERNEY, MASSACHUSETTS
WM. LACY CLAY, MISSOURI
DIANE E. WATSON, CALIFORNIA
STEPHEN F. LYNCH, MASSACHUSETTS
BRIAN HIGGINS, NEW YORK
JOHN A. YARMUTH, KENTUCKY
BRUCE L. BRALEY, IOWA
ELEANOR HOLMES NORTON,
DISTRICT OF COLUMBIA
BETTY MCCOLLUM, MINNESOTA
JIM COOPER, TENNESSEE
CHRIS VAN HOLLEN, MARYLAND
PAUL W. HODES, NEW HAMPSHIRE
CHRISTOPHER S. MURPHY, CONNECTICUT
JOHN P. SARBANES, MARYLAND
PETER WELCH, VERMONT

ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515–6143

MAJORITY (202) 225–5051
FACSIMILE (202) 225–4784
MINORITY (202) 225–5074

www.oversight.house.gov

TOM DAVIS, VIRGINIA,
RANKING MINORITY MEMBER

DAN BURTON, INDIANA
CHRISTOPHER SHAYS, CONNECTICUT
JOHN M. MCHUGH, NEW YORK
JOHN L. MICA, FLORIDA
MARK E. SOUDER, INDIANA
TODD RUSSELL PLATTS, PENNSYLVANIA
CHRIS CANNON, UTAH
JOHN J. DUNCAN, JR., TENNESSEE
MICHAEL R. TURNER, OHIO
DARRELL E. ISSA, CALIFORNIA
KENNY MARCHANT, TEXAS
LYNN A. WESTMORELAND, GEORGIA
PATRICK T. MCHENRY, NORTH CAROLINA
VIRGINIA FOXX, NORTH CAROLINA
BRIAN P. BILBRAY, CALIFORNIA
BILL SALI, IDAHO
JIM JORDAN, OHIO

MEMORANDUM

May 19, 2008

To: Members of the Committee on Oversight and Government Reform

Fr: Committee on Oversight and Government Reform, Majority Staff

Re: EPA's Denial of the California Waiver

For the past five months, the Oversight Committee has been investigating the decision by the Environmental Protection Agency to reject California's petition to regulate greenhouse gas emissions from cars and trucks. During the course of the investigation, the Committee obtained over 27,000 pages of documents from the Environmental Protection Agency (EPA) and deposed or interviewed eight key officials. This memorandum summarizes some of the significant evidence the Committee has received.

The record before the Committee shows: (1) the career staff at EPA unanimously supported granting California's petition; (2) Stephen Johnson, the Administrator of EPA, also supported granting California's petition at least in part; and (3) Administrator Johnson reversed his position after communications with officials in the White House.

The Position of EPA Staff. Internal EPA documents and transcribed interviews with EPA staff show that the agency career staff all supported granting the California petition. This recommendation and the reasons for it were communicated to the Administrator in several meetings. A September 21, 2007, meeting was significant. As one EPA staffer described it, "Administrator Johnson essentially polled the room on what people's final opinions were about granting or not granting a waiver." According to five EPA staff who were in the meeting, not a single staffer argued that the California waiver should be denied.

A briefing prepared by the lead staff lawyer for EPA's General Counsel stated: "After review of the docket and precedent, we don't believe there are any good arguments against granting the waiver. All of the arguments ... are likely to lose in court if we are sued." Similarly, a briefing from the Office of Transportation and Air Quality and the Office of General Counsel stated:

> OTAQ and OGC are reviewing these options from a legal, technical, and waiver precedent perspective and other options may fall in or out of our review. The clearest and most defensible option is to grant the waiver. The other options have high to very high vulnerability to legal challenge.

The EPA staff interviewed by the Committee were unable to identify any agency documents that argued in favor of denial prior to December 19, 2007, the day California's petition was denied.

The Position of Administrator Johnson. EPA Associate Deputy Administrator Jason Burnett told the Committee that Administrator Johnson supported granting California's petition for a waiver of preemption under the Clean Air Act. In a deposition, he testified that Administrator Johnson "was very interested in a full grant of the waiver" in August and September 2007 and then thought that a partial grant of the waiver "was the best course of action." Mr. Burnett explained: "the Administrator was interested in initially a full grant, and became interested in a partial grant, asked for me and others to explore ways of making a partial grant work."

According to Mr. Burnett's deposition testimony, Administrator Johnson's preference for a full or partial grant of the waiver did not change until after he communicated with the White House. When asked by Committee staff "whether the Administrator communicated with the White House in between his preference to do a partial grant and the ultimate decision" to deny the waiver, Mr. Burnett responded: "I believe the answer is yes." When asked "after his communications with the White House, did he still support granting the waiver in part," Mr. Burnett answered: "He ultimately decided to deny the waiver." Mr. Burnett also affirmed that there was "White House input into the rationale in the December 19th letter" announcing the denial of the waiver and in the formal decision document issued in March 2008.

The Position of the White House. The record before the Committee suggests that the White House played a pivotal role in the decision to reject the California petition, but it does not explain the basis for the White House intervention. During his deposition, Mr. Burnett was asked to identify the White House officials who spoke with Administrator Johnson and to describe the substance of their communications with Administrator Johnson. Mr. Burnett informed the Committee that he had been directed not to answer any questions about the involvement of the White House in the decision to reject California's petition.

The President has an obligation under the Constitution to take care that the laws of the United States are faithfully executed. In this case, the applicable law is the Clean Air Act, which requires that California's petition to regulate greenhouse gas emissions from motor vehicles be decided on the merits based on specific statutory criteria. It would be a serious breach if the President or other White House officials directed Administrator Johnson to ignore the record before the agency and deny California's petition for political or other inappropriate reasons. Further investigation will be required to assess the legality of the White House role in the rejection of the California motor vehicle standards.

I. INTRODUCTION

A. California's Waiver Request

The Clean Air Act authorizes two sets of standards to control tailpipe pollution from motor vehicles: (1) federal standards and (2) state standards established by California, which can also be adopted by other states. Section 209(b) of the Clean Air Act requires EPA to waive federal preemption for California motor vehicle standards if the agency determines that California's standards in the aggregate will be at least as protective of public health and welfare as federal standards. EPA may reject a waiver request only if the Administrator finds: (1) California's determination regarding protectiveness is "arbitrary and capricious;" (2) California does not need state standards "to meet compelling and extraordinary conditions;" or (3) California's standards are not consistent with statutory requirements for adequate lead-time and technological feasibility.[1]

The special authority for California to set its own motor vehicle standards was part of the Air Quality Act of 1967 and was retained when Congress adopted the original 1970 Clean Air Act.[2] This authority was expanded in the 1977 amendments, with Congress recognizing that "the underlying intent" of section 209 is "to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare."[3]

In internal documents, EPA has recognized that the language of section 209, its legislative history, court decisions, and consistent EPA interpretation of the provision over several decades all indicate that California has the "broadest possible discretion in developing [its] program, and EPA has only narrow and circumscribed discretion to deny a waiver to California."[4] According to these internal documents, the "[b]urden of proof is on parties opposing a waiver," and "EPA traditionally looks broadly at whether [California] has conditions such that it still needs its own motor vehicle emission program. [EPA has] not examined the need and conditions for specific standards or specific air pollution problem[s]."[5]

---

[1] Clean Air Act §209(b).

[2] See Motor & Equipment Mfrs. Ass'n v. EPA ("MEMA I"), 627 F.2d 1095, 1108-1111 (D.C. Cir. 1979); Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. New York State Dept. of Environmental Conservation, 17 F.3d 521, 525 (2nd Cir. 1994).

[3] H.R. Rep. No. 294, 95th Cong., 1st Sess. 301-02 (1977).

[4] Environmental Protection Agency, *California Request for a Waiver of Preemption of GHG Standards*, at 5 (Apr. 30, 2007) (briefing slides for Administrator Johnson). *See also Motor & Equipment Mfrs. Ass'n v. EPA ("MEMA I")*, 627 F.2d 1095, 1108-1111 (D.C. Cir. 1979).

[5] Environmental Protection Agency, *California Request for a Waiver of Preemption of GHG Standards*, at 7, 10 (Apr. 30, 2007) (briefing slides for Administrator Johnson).

In September 2004, California amended its existing motor vehicle regulations to include standards requiring cars and light-duty trucks to limit emissions of greenhouse gases.[6] The standards begin with the 2009 model year and phase-in gradually over eight years.[7] By the 2016 model year, they would cut global warming pollution from new vehicles by almost 30%.[8] Thirteen other states — Arizona, Connecticut, Maine, Maryland, Massachusetts, New Mexico, New Jersey, New York, Oregon, Pennsylvania, Rhode Island, Vermont, and Washington — have already adopted the California standards. Together, these 14 states' consumers buy over 40% of the new vehicles sold nationwide each year.[9]

On December 21, 2005, California requested that EPA grant a waiver of preemption under section 209(b) for the California greenhouse gas emissions standards.[10] EPA took no public action on the waiver request until the Supreme Court ruled in *Massachusetts v. EPA* on April 2, 2007, that greenhouse gases are air pollutants under the Clean Air Act.[11] EPA then published a notice on April 30, 2007, announcing a public hearing and a comment period on the waiver request.[12] The public comment period closed on June 15, 2007.[13]

---

[6] California Environmental Protection Agency Air Resources Board, Final Regulation Order — Amendments to Sections 1900 and 1961 and Adoption of New Sections 1961.1, Title 13, California Code of Regulations as Approved by OAL, California Exhaust Emission Standards and Test Procedures for 2001 and Subsequent Model Passenger Cars, Light Trucks and Medium-Duty Vehicles as Approved by OAL (Sept. 24, 2004 hearing date) (online at www.arb.ca.gov/regact/grnhsgas/grnhsgas.htm).

[7] California Environmental Protection Agency Air Resources Board, Request for a Clean Air Act Section 209(b) Waiver of Preemption for California's Adopted and Amended New Motor Vehicle Regulations and Incorporated Test Procedures to Control Greenhouse Gas Emissions: Support Document, at 6 (Dec. 21, 2005).

[8] California Environmental Protection Agency Air Resources Board, *ARB Approves Greenhouse Gas Rule* (Sept. 24, 2004) (press release) (online at www.arb.ca.gov/newsrel/nr092404.htm).

[9] Union of Concerned Scientists, *Automakers v. the People* (online at www.ucsusa.org/clean_vehicles/avp/) (accessed May 8, 2008).

[10] Letter from Catherine Witherspoon, Executive Director, California Air Resources Board, to Stephen L. Johnson, Administrator, U.S. Environmental Protection Agency, Re: Regulations to Control Greenhouse Gas Emissions From Motor Vehicles; Request for Waiver of Preemption Under Clean Air Act Section 209(b) (Dec. 21, 2005).

[11] *Massachusetts v. EPA*, 127 S.Ct. 1438 (2007).

[12] Environmental Protection Agency, California State Motor Vehicle Pollution Control Standards; Request for Waiver of Federal Preemption; Opportunity for Public Hearing, 72 Fed. Reg. 21260 (Apr. 30, 2007).

[13] Environmental Protection Agency, California State Motor Vehicle Pollution Control Standards; Notice of Decision Denying a Waiver of Clean Air Act Preemption for California's 2009 and Subsequent Model Year Greenhouse Gas Emission Standards for New Motor Vehicles, 73 Fed. Reg. 12156, 12157 (Mar. 6, 2008).

On December 19, 2007, Administrator Johnson announced that he had "found that California does not have a 'need to meet compelling and extraordinary conditions'" and that he had decided to deny California's waiver request.[14] In an unusual departure from agency practice, the Administrator announced this decision without releasing a decision document explaining the legal basis for the decision. The formal legal justification for the decision was not released until March 6, 2008, when Administrator Johnson wrote in the Federal Register:

> I do not believe section 209(b)(1)(B) was intended to allow California to promulgate state standards for emissions from new motor vehicles designed to address global climate change problems; nor, in the alternative, do I believe that the effects of climate change in California are compelling and extraordinary compared to the effects in the rest of the country.[15]

B. The Committee's Investigation

Upon learning of Administrator Johnson's decision to deny the waiver, Chairman Waxman announced that the Committee would be investigating "how and why this decision was made."[16] On December 20, 2007, Chairman Waxman wrote to Administrator Johnson requesting documents relating to the California waiver request.[17]

EPA initially resisted producing many documents to the Committee. As a result, Chairman Waxman issued subpoenas to compel production of documents on three occasions. Chairman Waxman issued two subpoenas to require production of documents that the Committee staff had reviewed but that EPA had refused to produce.[18] After the issuance of the subpoenas, these documents were provided to the Committee.

---

[14] Letter to Arnold Schwarzenegger, Governor of California, from Stephen L. Johnson, Administrator, U.S. EPA (Dec. 19, 2007).

[15] Environmental Protection Agency, California State Motor Vehicle Pollution Control Standards; Notice of Decision Denying a Waiver of Clean Air Act Preemption for California's 2009 and Subsequent Model Year Greenhouse Gas Emission Standards for New Motor Vehicles, 73 Fed. Reg. 12156, 12157 (Mar. 6, 2008).

[16] Committee on Oversight and Government Reform, Chairman Waxman's Statement on EPA Denial of California Waiver Request (Dec. 19, 2007) (online at www.oversight.house.gov/story.asp?ID=1672).

[17] Letter from Chairman Henry A. Waxman to Stephen Johnson, Administrator, U.S. EPA (Dec. 20, 2007).

[18] Committee on Oversight and Government Reform, Subpoena to Stephen L. Johnson (Feb. 8, 2008) (compelling production of five sets of briefing slides for the Administrator). Committee on Oversight and Government Reform, Subpoena to Stephen L. Johnson (Mar. 13, 2008) (compelling production of 196 internal EPA documents).

On April 8, 2008, Chairman Waxman issued a third subpoena for the production of communications between EPA and persons in the White House.[19] EPA continues to withhold some documents from the Committee that are responsive to this subpoena. The White House Counsel's office has informed Committee staff that EPA possesses 32 documents that evidence telephone calls or meetings in the White House involving at least one high-ranking EPA official and at least one Assistant to the President or the President himself. The White House Counsel's office has described these documents as "indicative of deliberations at the very highest level of government."[20]

In total, the Committee has received over 27,000 pages of documents from EPA. The Committee staff has also conducted transcribed interviews and a deposition of eight EPA officials.[21]

II. CHRONOLOGY OF EVENTS

Previously undisclosed internal EPA documents and the Committee's interviews and deposition with key EPA staff provide new insights into the decisionmaking process inside EPA. These documents, interviews, and deposition show that EPA's career staff who worked on the California waiver petition all supported granting the request; that Administrator Johnson supported the position of his career staff at least in part; and that there was an unexpected reversal in the Administrator's position after he communicated with White House officials. This section of the memorandum describes key milestones in the administrative process.

A. The June 15, 2007, Briefing

Over a period of several months, EPA staff held a series of briefings for the Administrator on the California waiver request. One of the earlier briefings occurred on June 15, 2007.

---

[19] Committee on Oversight and Government Reform, Subpoena to Stephen L. Johnson (Apr. 8, 2008).

[20] Meeting between Committee on Oversight and Government Reform staff, EPA staff, and White House staff (Apr. 22, 2008).

[21] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon (Jan. 30, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Dina Washburn Kruger (Jan. 31, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Brian McLean (Feb. 5, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Robert David Brenner (Feb. 6, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge (Feb. 7, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney (Feb. 11, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo (Feb. 12, 2008); Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett (May 15, 2008).

At the June 15 briefing, Administrator Johnson reviewed a series of "briefing slides" prepared by the staff. One briefing slide presented a review of the public comments submitted to EPA. The slide included the May 2007 "initial assessment" of the Office of Transportation and Air Quality (OTAQ) career staff: "CA met the statutory criteria for a waiver."[22] It further noted that the staff's "interim assessment based on waiver record to date also supports this conclusion."[23]

According to an internal EPA e-mail, Bob Meyers, the Principal Deputy Assistant Administrator for the Office of Air and Radiation, was upset that this staff view was included in the briefing slides. Mr. Meyers's chief of staff wrote:

> We had a fairly significant slip up in preparing Friday's GHG briefing for the Administrator. It's the very last bullet on page 6 — "OTAQ's initial assessment." ... Bob was not happy when he read that page during the briefing. ... I wanted to let someone in OTAQ know about this so we can permanently delete the offending language and not have it arise again.[24]

B. The September 12, 2007, Briefing

By August 2007, the staff was refining its assessment of the merits of California's request and developing decision options for the Administrator. This culminated in a briefing to the Administrator on September 12, 2007.

On August 29, Karl Simon, the director of the OTAQ division primarily responsible for the waiver, advised his staff to drop the denial option from the list of options presented in draft briefing slides. Regarding the options, he wrote: "I think we should also do something to indicate that not all of these are equal and that the most defensible position remains a clean approval."[25] The draft slides included the following statement:

> OTAQ and OGC [Office of General Counsel] are reviewing these options from legal, technical, and waiver precedent perspective and other options may fall out of our review. Not all of these options are defensible and clearest option is to grant the waiver.[26]

The next day, a new draft of the slides was circulated. This draft included an explicit staff assessment:

---

[22] Environmental Protection Agency, *President's GHG Rule: Status Briefing* (June 15, 2007).

[23] *Id.*

[24] E-mail from Don Zinger to Karl Simon and Sarah Dunham (June 18, 2007; 5:36 p.m.).

[25] E-mail from Karl Simon to David Dickinson (Aug. 29, 2007; 9:51 p.m.).

[26] Attachment to e-mail from Ben DeAngelo to Rona Birnbaum, at 40 (Aug. 30, 2007; 5:50 p.m.).

> From a legal, technical and policy perspective (and waiver precedence) CA has made the requisite protectiveness determination and those opposing the waiver have not clearly demonstrated that any of the section 209(b) criteria have been met. A waiver should be granted.[27]

As the slides were being reviewed, the EPA General Counsel, Roger Martella, requested that that they "be focused on our options beyond granting."[28] The next day, the career staff attorney followed this direction by preparing a new briefing document entitled, "California GHG Waiver: Arguments Against Granting."[29] When he sent the document to Mary Ann Poirier, the Deputy General Counsel, he explained: "It is meant to be stripped-down and frank, to give Roger my best advice on the pros and cons of options short of a full grant."[30] Before describing the options other than a full grant of the waiver request, the slides included a strongly-worded "caveat" page, which stated:

> After review of the docket and precedent, we don't believe there are any good arguments against granting the waiver. All of the arguments discussed here are likely to lose in court if we are sued. The arguments here are the best of a bad lot, going from most to least plausible.[31]

The option of denying the waiver based on California's lack of compelling and extraordinary conditions is then presented as the third of six options. An apparently later version of the caveat page is phrased similarly:

> After review of the docket and precedent, we believe the arguments against granting the waiver have high to very high legal vulnerability. All of the arguments discussed here would more likely than not lose in court if they are challenged. The arguments here are presented in decreasing order of defensibility.[32]

On September 11, Karl Simon sent the latest version of the briefing slides to Bob Meyers, the acting head of the air office. Mr. Simon explained: "I modified the options discussion a bit to better reflect the current state of analysis and OGC's views."[33] The options slide did not include a denial option and began with the following statement:

---

[27] Attachment to e-mail from David Dickinson to Karl Simon, et al., at 3 (Aug. 31, 2007; 4:17 p.m.).

[28] E-mail from Michael Horowitz to Mary Ann Poirier (Sept. 4, 2007; 4:36 p.m.).

[29] Attachment to e-mail from Michael Horowitz to Mary Ann Poirier (Sept. 5, 2007; 1:36 p.m.).

[30] E-mail from Michael Horowitz to Mary Ann Poirier (Sept. 5, 2007; 1:36 p.m.).

[31] Attachment to e-mail from Michael Horowitz to Mary Ann Poirier (Sept. 5, 2007; 1:36 p.m.).

[32] Environmental Protection Agency, California GHG Waiver: Arguments Against Granting (undated).

[33] E-mail from Karl Simon to Karen Orehowsky (Sept. 11, 2007; 8:18 a.m.).

> OTAQ and OGC are reviewing these options from a legal, technical, and waiver precedent perspective and other options may fall in or out of our review. The clearest and most defensible option is to grant the waiver. The other options have high to very high vulnerability to legal challenge.[34]

At this point, the briefing slides also included a number of explicit "staff evaluations" regarding the compelling and extraordinary conditions criterion. For example, the staff found:

- "CA continues to exhibit extraordinary ozone conditions. CA conditions, such as population and density, coastline, salt-water intrusion, wildfires, agricultural economy, snow pack and melt, etc, when aggregated, represent serious conditions on their own and when compared with other states."[35]

- "The GHG standards are reasonably viewed as necessary to address both climate change and ozone conditions within the state."[36]

- "Opponents have not met their burden of demonstrating that CARB's [California Air Resources Board] GHG program will not have an incremental benefit for both climate change and ozone conditions."[37]

Evidence obtained by the Committee indicates that Mr. Meyers insisted on removing these staff evaluations from the briefing slides so that the information was only communicated to the Administrator orally. None of the staff evaluations regarding the compelling and extraordinary conditions or the legal defensibility of the various options available to the Administrator remained in the final slides that were presented to the Administrator on September 12.

The day the slides were sent to Mr. Meyers's office, Karl Simon sent an e-mail explaining that Mr. Meyers's assistant "is fixing the inclusion of staff evaluations. Note that Bob dropped two slides — the summary of the NERA report and the options summary page. I am pushing back."[38] Christopher Grundler, the Deputy Director of the Office of Transportation and Air Quality, replied: "what do you mean, 'fixing'? as in, deleting?"[39] Mr. Grundler also asked: "Did you get direction NOT to convey staff evaluations or options?"[40] Mr. Simon responded:

---

[34] Attachment to e-mail from Karl Simon to Karen Orehowsky, at 32 (Sept. 11, 2007; 8:18 a.m.).

[35] *Id.* at 26.

[36] *Id.* at 22.

[37] *Id.* at 24.

[38] E-mail from Karl Simon to Margo Oge, et al. (Sept. 11, 2007; 1:03 p.m.).

[39] E-mail from Christopher Grundler to Karl Simon (Sept. 11, 2007; 1:24 p.m.).

[40] E-mail from Christopher Grundler to Karl Simon (Sept. 11, 2007; 11:22 p.m.).

"yes, in a written form. we will be having the conversation though."[41] This understanding is reflected in Mr. Grundler's handwritten notes on the options slide presented to Mr. Meyers. Next to the OTAQ and OGC analysis, Mr. Grundler wrote: "Bob changes this."[42] And at the bottom of the page, he wrote: "Staff evaluation Bob deletes — Karl should take original to meeting with Steve verbally go over staff evaluation."[43] During her interview, Maureen Delaney, a career Program Analyst in the Office of Air and Radiation, confirmed that removing the staff evaluations from the slides was "a management-level decision" done at the "political level."[44]

Despite the removal of the staff evaluations from the briefing slides, career EPA staff clearly communicated their professional assessment to the Administrator at the September 12 briefing. Margo Oge, the Director of the Office of Transportation and Air Quality, told Committee staff: "verbally there was a staff evaluation ... that California has met that criteria."[45] When asked by Committee staff about the staff evaluations, Maureen Delaney explained: "I believe that they were spoken, even though they weren't included in the briefing, and they indicated generally that ... we did not have reason to deny the waiver."[46]

C. The September 20 and 21, 2007, Briefing

After the September 12 briefing, EPA staff began preparing slides for the next briefing with the Administrator on September 20 and 21. The purpose of this briefing was to present an in-depth analysis of the decision options available to the Administrator.

On September 18, a career staff attorney in the Office of General Counsel transmitted his first draft of the options slides. The conclusions slide included the following analysis:

- "Most defensible action is to grant waiver."
- "Denial based on lack of need for standards to meet compelling and extraordinary conditions has high legal risk and is contrary with central tenets of prior EPA procedure and likely EPA statements defending its own GHG rule."[47]

---

[41] E-mail from Karl Simon to Christopher Grundler (Sept. 12, 2007; 8:07 a.m.).

[42] Christopher Grundler's notes on draft briefing slides (undated).

[43] *Id.*

[44] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 11-12, 72-73 (Feb. 11, 2008).

[45] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 43-44 (Feb. 7, 2008).

[46] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 13 (Feb. 11, 2008).

[47] Attachment to e-mail from Michael Horowitz to John Hannon, at 16 (Sept. 18, 2007; 9:58 a.m.).

The next version of the options slides did not include this conclusions slide, but did include legal analysis of the options. The slides stated that the option of granting the waiver was "consistent with past interpretation of statute, EPA practice case law, and the record."[48] The slides also noted: "we routinely grant CA waivers for standards more stringent than EPA standards."[49] The document raised several "issues" regarding the denial option based on lack of compelling and extraordinary conditions, including the observation that denial would be "[i]nconsistent with precedent saying we look at vehicle program as a whole, not individual standards."[50] The slides also explained that such a denial "would undercut EPA arguments regarding benefits of federal [greenhouse gas emissions control] program in terms of ozone and general climate change benefits."[51] After Bob Meyers and Associate Deputy Administrator Jason Burnett edited the slides, much of this legal analysis was removed and did not appear in the final briefing slides for Administrator Johnson.[52]

Nevertheless, EPA career staff made it clear to the Administrator at the options briefing that they believed that the statutory criteria for granting the waiver request had been met. Karl Simon told the Committee the EPA career staff view "[t]hat the waiver criteria were met" was discussed at the briefing.[53] Several participants of the meeting told Committee staff that Mr. Johnson ended the briefing by going around the room and asking the staff for their individual recommendations. Ben DeAngelo, a Senior Analyst for Climate Change, explained: "Administrator Johnson essentially polled the room on what people's final options were about granting or not granting a waiver."[54]

According to the five EPA employees who attended the meeting and were interviewed by Committee staff, every EPA employee who expressed an opinion supported granting the waiver in full or in part. A partial grant of the waiver would involve granting the waiver for the first two to three model years starting with the 2009 model year. No one in the meeting advised the Administrator to deny the waiver. Karl Simon told Committee staff that "most people took the

---

[48] Attachment to e-mail from Michael Horowitz to Roger Martella, et al., at 6 (Sept. 19, 2007; 9:34 a.m.).

[49] *Id.* at 17.

[50] *Id.* at 16.

[51] *Id.* at 17.

[52] E-mail from Michael Horowitz to Allison Starmann (Sept. 19, 2007; 10:53 p.m.); E-mail from Michael Horowitz to Mary Ann Poirier (Sept. 24, 2007; 2:29 p.m.).

[53] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 33 (Jan. 30, 2008).

[54] Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 19 (Feb. 12, 2008).

opportunity" to offer a recommendation that "approval or partial approval would be the way to go."[55] Margo Oge explained:

> What I recall is that all the attendants, with the exception of Bob Meyers who was not asked to express his opinion ... were either supporting granting the full waiver or granting partial waiver.[56]

Jason Burnett told Committee staff: "all EPA recommendations that I am aware of, whether they be staff or me or someone in a similar position, were to grant the waiver."[57]

General Counsel Roger Martella also supported a partial granting of the waiver, although he said that he believed the agency could defend any of the options placed in front of the Administrator.[58] According to Mr. Burnett, Mr. Martella "stated that the legal risk was higher with denying the waiver and that the legal risk was lowest with granting the waiver."[59]

This interview testimony is supported by written notes and summaries of the meeting. Karl Simon's handwritten notes indicate that the Administrator "polled everyone but BM [Bob Meyers] for recommendation — all supported at least 2B," a partial grant of the waiver.[60] Ben DeAngelo's summary of the meeting stated: "OTAQ and OGC folks said granting the waiver straight-up is probably most defensible."[61] Christopher Grundler's handwritten notes simply stated: "all agreed on granting waiver."[62] A second note reads: "All attendees agree for full or partial granting the waiver."[63]

---

[55] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 82-83 (Jan. 30, 2008).

[56] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 21-22 (Feb. 7, 2008).

[57] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 129 (May 15, 2008).

[58] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 22 (Feb. 7, 2008).

[59] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 23 (May 15, 2008).

[60] Handwritten notes of Karl Simon on California GHG Waiver: Options Briefing for the Administrator (Sept. 21, 2007). +

[61] E-mail from Ben DeAngelo to Dina Kruger (Sept. 21, 2007; 5:07 p.m.).

[62] Handwritten notes of Christopher Grundler on *California GHG Waiver: Options* (undated).

[63] *Id.*

D. The October 30, 2007, Briefing

After the options briefing, some EPA staff expected the Administrator to reach a decision soon.[64] However, on October 9, Administrator Johnson called another meeting, during which he tasked the staff with providing additional information on a number of topics related to the waiver. The final briefing for the Administrator involving career staff was held on October 30. The October 30 briefing slides were intended to provide the Administrator with the information he had requested.

According to the career staff interviewed by the Committee, the final briefing slides represented the professional views of EPA's technical and legal staff.[65] The slides included the following conclusions:

- "Fundamental circumstances of geographic, climatic, human and motor vehicle populations remain compelling and extraordinary (including ozone and PM [particulate matter]) and fit the GHG circumstances which will not only exacerbate the ozone conditions but also such conditions are highly vulnerable to climate change."

- "The potential for climate change to exacerbate California's unique tropospheric ozone problem is one element of California's compelling and extraordinary conditions. However, it is by no means the sole foundation for the compelling and extraordinary argument. In fact, climate change impacts on California's wildfire, water resource, and agricultural situation may be the state's greatest concerns."

- "California exhibits a number of specific features that are somewhat unique and may be considered compelling and extraordinary with regard to both the need for mitigation actions and its potential vulnerability to climate change."[66]

The briefing slides also contained legal analysis regarding the agency's litigation prospects if the waiver was granted or denied. The slide entitled "If We Grant" stated that EPA would face a "Likely Suit by Manufacturers" and that "EPA is almost certain to win such a suit."[67] The slide entitled "If We Deny" stated that EPA would face an "[a]lmost certain lawsuit

---

[64] *See* Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo (Feb. 12, 2008).

[65] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 31 (Feb. 7, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 34, 39 (Feb. 12, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 72, 76, 153-154 (Jan. 30, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Dina Kruger, at 26, 31, 32 (Jan. 31, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Brian McLean, at 29, 32 (Feb. 5, 2008).

[66] Environmental Protection Agency, Briefing for the Administrator: California's GHG Waiver Request: Follow-Up on Additional Questions (Oct. 30, 2007).

[67] *Id.*

by California" and that "EPA's litigation risks are significantly higher than if a waiver is granted."[68]

In earlier drafts of the briefing slides, the "If We Deny" slide included stronger language. An October 29 draft provided the following legal prognosis: "EPA likely to lose suit."[69] According to Karl Simon, at the October 29 pre-briefing with Bob Meyers, "there was some discussion on some of — the way to characterize the legal advice."[70] Maureen Delaney told Committee staff: "the last statement on what would happen if California sued under a denial, that was changed, and I think changed the meaning somewhat."[71] When asked whether the earlier draft slides better represented the views of the career staff, she responded: "That conclusion, yes."[72] Ms. Delaney added: "It was a stronger statement in the previous — in the draft version."[73]

The evidence obtained by the Committee shows that EPA staff clearly informed Administrator Johnson that they believed the compelling and extraordinary conditions criterion was met. Margo Oge told Committee staff:

> When Ben presented this information to the Administrator and presented it to me, clearly, clearly what I am hearing is that California meets this extraordinary and compelling needs, the conditions. ...
>
> If you read this whole document ... in its totality, you would walk away with the same impression that I walk away when I talked to the experts ... that California has met the criteria of compelling and extraordinary needs based upon these facts. And that is what Ben told the Administrator.[74]

When asked by Committee staff whether there was "any question in your mind that this staff view that the waiver criteria were met was clearly communicated to Administrator

---

[68] *Id.*

[69] Attachment to e-mail from Betsy White to Jo Beth Banas, et al. (Oct. 29, 2007; 3:30 p.m.).

[70] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 68 (Jan. 30, 2008).

[71] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 25 (Feb. 11, 2008).

[72] *Id.*

[73] *Id.* at 76.

[74] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 60-61 (Feb. 7, 2008).

Johnson," Maureen Delaney replied: "Was there any doubt? No."[75] In addition, Ben DeAngelo's summary of the meeting states:

> In addition to the argument that climate change may exacerbate CA's tropospheric ozone problem — for which CA has historically demonstrated compelling and extraordinary conditions — I think Johnson now better appreciates that there are additional conditions in CA that make them vulnerable to climate change.[76]

Similarly, Jason Burnett agreed that career staff "clearly communicate[d] to the Administrator that they believed that the compelling and extraordinary conditions criterion was met."[77]

During the October 30 briefing, career EPA staff explicitly told the Administrator that granting the waiver was the most legally defensible option, while a denial of the waiver would be unlikely to survive legal challenge. When asked by Committee staff whether he thought the options of granting, partially granting, or denying the waiver request were all legally defensible, Karl Simon replied: "I think it depends on your definition of 'legally defensible.' ... It would get you in the courthouse door."[78] He explained that the Administrator was told that the available options were "legally defensible" only in the sense that they "get you past rule 11 sanctions" in federal court for raising a frivolous claim.[79] Referring to a lawsuit challenging EPA's denial of the waiver request, Mr. Simon stated: "I think the odds are that we will lose."[80]

Margo Oge also thought that the evidence before the Administrator all pointed toward granting the waiver. She told Committee staff:

> working on the waiver for the time that we had been working and looking at the legislative history, the precedent has been set by EPA approving the California waivers for the past 40 years ... my view was and continues to be, based on the Clean Air Act and all these factors, granting of the waiver was the most defensible way to proceed.[81]

---

[75] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 26 (Feb. 11, 2008).

[76] E-mail from Ben DeAngelo to Brian McLean, et al. (Oct. 31, 2007; 12:54 p.m.).

[77] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 128 (May 15, 2008).

[78] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 69 (Jan. 30, 2008).

[79] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 133 (Jan. 30, 2008) ("passed" in original transcript).

[80] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 111 (Jan. 30, 2008).

[81] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 88-89 (Feb. 7, 2008).

Maureen Delaney agreed that "the thrust of the explanation to him [Administrator Johnson] was that if he denied the waiver, EPA would likely lose any subsequent lawsuit."[82] During her interview, she said: "I think, as we pointed out, some [options] were more likely to survive a litigation risk than others."[83] Ms. Delaney added: "There are varying shades of what would be defensible. ... Most people felt that a denial would be ... a significant litigation risk."[84]

Ben DeAngelo confirmed that the legal jeopardy of a denial was fully explained to Administrator Johnson during the October 30 briefing.[85] When asked by Committee staff what conclusions about the legal defensibility of different options he drew from the October 30 briefing, Mr. DeAngelo stated: "I had heard by this stage in the process now a number of times from the legal people that granting the waiver was, in their minds, most legally defensible and that was my takeaway."[86]

According to Jason Burnett, the legal jeopardy of a denial was communicated to the Administrator on a number of occasions. He told Committee staff that the legal judgment of General Counsel Roger Martella and his office was that "denying the waiver had very significant legal risk."[87] He explained:

> I believe that it was communicated in several fora, through this slide, verbally when these slides were presented to the Administrator, and in multiple meetings that we had, that Roger Martella, I, and others had, with the Administrator.[88]

E. The December 19, 2007, Decision

On December 19, 2007, Administrator Johnson sent a two-page letter to Governor Arnold Schwarzenegger of California announcing that he intended to deny the waiver petition. The stated basis for the denial was California's lack of compelling and extraordinary conditions.

---

[82] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 28 (Feb. 11, 2008).

[83] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 93 (Feb. 11, 2008).

[84] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 94 (Feb. 11, 2008).

[85] Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 76-77 (Feb. 12, 2008).

[86] Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 77 (Feb. 12, 2008).

[87] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 127 (May 15, 2008).

[88] *Id.* at 127.

Career staff who had worked on the issue for months were surprised by the decision to deny the waiver because it did not appear to be supported by the record. When asked by Committee staff if he was surprised by the decision, Rob Brenner, the Director of Policy Analysis and Review, responded:

> Yes, I was surprised. I expected that it would probably be either a grant of the waiver or a partial waiver. ... I felt that ... the analyses that had been put together seemed to point towards either a full or a partial waiver.[89]

Maureen Delaney told Committee staff that she also was surprised by the decision: "Personally, having been at the briefings, and it was contrary to the advice that I thought that he had received from the staff, so I was surprised."[90] She explained: "it was difficult to see how he arrived at that decision, given the information that had been provided and the consensus among the staff ... It seemed like a difficult place to get to."[91]

In his deposition, Mr. Burnett told the Committee that the Administrator's December 19 decision was a reversal of the Administrator's prior position. According to Mr. Burnett, Administrator Johnson "was very interested in a full grant of the waiver" in August and September.[92] Mr. Burnett told the Committee that "at some point in the process," the Administrator then modified his view and believed that a partial grant of the waiver "was the best course of action."[93] Mr. Burnett explained: "the Administrator was interested in initially a full grant, and became interested in a partial grant, asked for me and others to explore ways of making a partial grant work."[94] Mr. Burnett added: "over the course of a period of months he certainly shifted his focus and his stated interests to me and others from a full grant to a partial grant."[95]

According to Mr. Burnett, Administrator Johnson's preference for a full or partial grant of the waiver did not change until after he communicated with the White House about the matter. When asked by Committee staff "whether the Administrator communicated with the White House in between his preference to do a partial grant and the ultimate decision" to deny the

---

[89] Committee on Oversight and Government Reform, Transcript of Interview of Rob Brenner, at 32 (Feb. 6, 2008).

[90] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 34 (Feb. 11, 2008).

[91] Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 63-64 (Feb. 11, 2008).

[92] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 118 (May 15, 2008).

[93] *Id.* at 119.

[94] *Id.* at 123.

[95] *Id.* at 139.

waiver, Mr. Burnett responded: "I believe the answer is yes."[96] When asked "after his communications with the White House, did he still support granting the waiver in part," Mr. Burnett answered: "He ultimately decided to deny the waiver."[97] Mr. Burnett also affirmed that there was "White House input into the rationale in the December 19th letter."[98]

At the time of the December 19 decision to deny the California waiver, there were apparently no EPA employees or agency documents arguing for this decision. Five EPA staff — Margo Oge, Karl Simon, Ben DeAngelo, Maureen Delaney, and Rob Brenner — told the Committee they were unaware of any EPA employees who espoused or agreed with the argument that California did not meet the compelling and extraordinary conditions criterion.[99] They also told the Committee that they were unaware of any pre-December 19 internal EPA documents recommending that the waiver be denied based upon a lack of compelling and extraordinary conditions.[100] On December 20, the day after Administrator Johnson announced his decision to deny California's waiver request, the most recent internal draft of the decision document was written as if the waiver was to be granted in full.[101]

F. The March 6, 2008, Federal Register Notice

Typically when an EPA Administrator announces a final decision, the agency releases an analysis explaining the basis for the decision on the same day. This did not happen in the case of the denial of the California waiver. EPA did not release a formal legal justification for the denial until March 6, 2008, when the official decision document was published in the Federal Register. This decision document included a more detailed discussion of the rationale for denial put forth in the Administrator's December 19, 2007, letter to Governor Schwarzenegger. The primary legal justification offered by the Administrator was that Section 209 of the Clean Air Act was not

---

[96] *Id.* at 60.

[97] *Id.* at 120.

[98] *Id.* at 140.

[99] Committee on Oversight and Government Reform, Transcript of Interview of Margo Oge, at 95 (Feb. 7, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 36 (Feb. 11, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 105 (Jan. 30, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 87 (Feb. 12, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Rob Brenner, at 36 (Feb. 6, 2008).

[100] Committee on Oversight and Government Reform, Transcript of Interview of Karl Simon, at 112 (Jan. 30, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Brian McLean, at 35 (Feb. 5, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Robert David Brenner, at 38 (Feb. 6, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Maureen Delaney, at 37 (Feb. 11, 2008); Committee on Oversight and Government Reform, Transcript of Interview of Benjamin DeAngelo, at 87 (Feb. 12, 2008).

[101] E-mail from David Dickinson to Michael Horowitz, et al. (Dec. 20, 2007; 6:53 a.m.).

"intended to allow California to promulgate state standards for emissions from new motor vehicles designed to address global climate change problems." He also rejected the view that "the effects of climate change in California are compelling and extraordinary compared to the effects in the rest of the country.[102]

III. THE POSITION OF THE WHITE HOUSE

The record before the Committee — in particular the deposition testimony of Mr. Burnett — indicates that the White House played a decisive role in the rejection of the California motor vehicle standards. Before communicating with White House officials, Administrator Johnson supported the position of career EPA staff that the waiver should be granted. He reversed himself only after these communications.

Little is known publicly about the White House position. According to press accounts, the CEOs of Ford and Chrysler met with Vice President Dick Cheney prior to the denial and urged the Administration to reject the waiver.[103] After Administrator Johnson announced that the waiver would be denied, a White House spokesman said that the White House supported this decision.[104]

During the deposition of Mr. Burnett, Committee staff repeatedly asked about the White House role. In response, Mr. Burnett told the Committee that he had been instructed by EPA not to answer these questions. Based on the instructions from EPA, Mr. Burnett refused to answer:

- With whom in the White House did Administrator Johnson communicate about the California waiver before it was denied?[105]
- "Can you tell us the time at which that communication with the White House occurred?"[106]
- "Will you tell us the substance of those communications?"[107]

---

[102] U.S. EPA, California State Motor Vehicle Pollution Control Standards; Notice of Decision Denying a Waiver of Clean Air Act Preemption for California's 2009 and Subsequent Model Year Greenhouse Gas Emission Standards for New Motor Vehicles, 73 Fed. Reg. 12156, 12157 (Mar. 6, 2008).

[103] *EPA blocks Calif. fuel rules*, Detroit News (Dec. 20, 2007).

[104] Press Gaggle by Tony Fratto, White House Office of the Press Secretary (Dec. 21, 2007) (online at www.whitehouse.gov/news/releases/2007/12/20071221-5.html).

[105] Committee on Oversight and Government Reform, Transcript of Deposition of Jason Burnett, at 58 (May 15, 2008).

[106] *Id.* at 60.

[107] *Id.* at 61.

- "Do you know if the Administrator communicated or met with the President on this matter?"[108]
- Did White House staff "ever communicate to you a preference or an expectation regarding the outcome of the California waiver?"[109]
- With whom in the White House did you communicate about the California waiver?[110]
- "Can you tell us the reason that ... [the Administrator] told you his mind changed?"[111]

In addition, as described above, EPA has withheld from the Committee documentary evidence of interactions between EPA and the White House about the California waiver before the denial decision was announced. The White House Counsel's office has informed Committee staff that EPA possesses 32 documents that evidence telephone calls or meetings in the White House involving at least one high-ranking EPA official and at least one Assistant to the President or the President himself. The White House Counsel's office has described these documents as "indicative of deliberations at the very highest level of government."[112]

IV. CONCLUSION

The record before the Committee answers many questions about what transpired within EPA prior to the denial of California's petition to regulate greenhouse gas emissions from motor vehicles. The record indicates that the California waiver had unanimous support among the career EPA staff and was backed at least in part by EPA Administrator Johnson. What the record does not answer, however, is why the California petition was denied given the strong support inside EPA.

It appears that the White House played a significant role in the reversal of the EPA position. This raises questions about the basis for the White House actions. The Clean Air Act contains specific standards for considering California's petition. It would appear to be inconsistent with the President's constitutional obligation to faithfully execute the laws of the United States if the President or his advisors pressured Administrator Johnson to ignore the record before the agency for political or other inappropriate reasons.

Additional investigation by the Committee will be required to assess the basis for the White House intervention in the decision.

---

[108] *Id.* at 61.

[109] *Id.* at 61.

[110] *Id.* at 61.

[111] *Id.* at 123.

[112] Meeting between Oversight and Government Reform Committee staff, EPA staff, and White House staff (Apr. 22, 2008).

Senator HARRIS. Will you commit, if confirmed, to follow the science and law, and heed the advice of career staff in the Department, and recognize and preserve California's authority to issue its own new motor vehicle standards as it relates to emissions?

Mr. WEHRUM. Senator, the provision that you refer to, in appropriate circumstances, certainly does allow California to implement its own motor vehicle standards, and my commitment to you would be to understand that provision as much as possible and implement it as faithfully as possible.

Senator HARRIS. And are you familiar with the several decades of practice and court decisions that make it clear that the EPA should be deferential to California and only deny the waiver if the EPA could "affirmatively demonstrate that California, or any State, was arbitrary and capricious"?

Mr. WEHRUM. Senator, EPA has an obligation to review waiver requests and make a determination if they are adequate in light of the criteria set out in that provision, yes.

Senator HARRIS. OK. And you are familiar with these decades of practice that have made that finding?

Mr. WEHRUM. I can't say I am familiar with every single waiver that has been issued, but I am familiar with the waiver process, Senator.

Senator HARRIS. OK. I would urge you to become familiar with it, if confirmed. Thank you.

Mr. Dourson, in my home State of California, the city of Santa Clarita has struggled with groundwater contamination from perchlorate. The toxic chemical is a byproduct of producing munitions and rocket fuel, and it affects the thyroid's ability to regulate metabolism and guide a child's development.

In Santa Clarita, for more than 50 years, the Whittaker Bermite Corporation contaminated the soil and groundwater across a 1,000-acre site in the heart of the city. You, sir, were hired by companies that have used perchlorate, like Lockheed Martin and Boeing, to study this toxic chemical, and you rewarded them by marking that the safe level would be eight times higher than what the EPA said would be safe.

In 2013 the EPA's own independent Science Advisory Board asked you to recuse yourself from perchlorate matters because of this conflict of interest.

Can you commit to this Committee that you will recuse yourself from any EPA decision having to do with perchlorate?

Mr. DOURSON. Again, Senator, I am going to rely on guidance from EPA ethics officials to determine any issues for which I need to be recused.

Senator HARRIS. Sir, you profess to be a professional. And you must be, then, aware that professional standards as it relates to ethics, and as my colleague has mentioned, also moral standards, would demand that we are aware of not only an appearance of conflict, but actual conflict. And if we are to be leaders, it would suggest to me that you, as a leader, as you say, in this field, would understand the importance of making the decision yourself, instead of waiting for someone else to tell you that you should recuse yourself from these matters.

Are you going to wait for permission from the ethics to exercise your discretion as it relates to other matters? Do you believe you possess discretion in this position, if confirmed?

Mr. DOURSON. Senator, as I stated in my opening statement, I commit my mind, body, and spirit to protecting the public health, if confirmed, in this organization, the Office of Chemical Safety and Pollution Prevention. The staff is very talented. I would be humbled and honored to serve with them, but ultimately protect the public health, including those sensitive members of the population.

Senator HARRIS. Are you aware that, if confirmed, you would have the discretion to recuse yourself and would not have to be ordered to do so by anyone?

Mr. DOURSON. Again, I can depend on EPA ethics officials to advise me in that capacity.

Senator HARRIS. Are you aware that you would have the discretion to make that decision, sir?

Mr. DOURSON. I would, again, defer to EPA ethics officials to advise me in that capacity.

Senator HARRIS. I have nothing else.

Senator BARRASSO. Thank you, Senator Harris.

Senator WICKER. Thank you, Mr. Chairman.

Dr. Dourson, am I pronouncing your name right?

Mr. DOURSON. Yes, sir.

Senator WICKER. My first question deals with the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. As we all know, pesticide policy in the United States is supposed to involve a balancing act between the potential hazards of a pesticide and the benefits of the product based on real world impacts. Pesticides can poison you, can hurt people. But without pesticides, we would not be able to supply the world with food and fiber as we do; hence, the balancing act with real world facts under FIFRA.

There is a feeling that, under the Obama administration, decisions were made by EPA that were beginning to resemble not what we call facts on the ground, but a precautionary approach to regulation, where regulatory action was taken to prevent theoretical risks, unproven risks. So would you please comment on that issue, and will you tell the Committee about your commitment to science based risk assessment of pesticides under FIFRA?

Mr. DOURSON. Senator, my career, including more than a decade as an EPA scientist, focused on protecting public health by developing, reviewing, and communicating risk assessment values done in an impartial and objective and transparent way. If confirmed, I commit myself to you and this Committee, and to the American people, to continue in that effort.

Senator WICKER. Well, OK. Do you have any insights to give to the members of the Committee about my concern or the concerns of people like me that there has been too far of a move toward precautionary regulation and prevention of theoretical and unproven risks, rather than facts on the ground?

Mr. DOURSON. The area that I study and work in, and the area of the Office of Chemical Safety and Pollution Protection risk assessment is preventive medicine. In some regards, it is precautionary. However, there have been tendencies in certain cases to be additionally precautionary, more protective than needed, and

you are correct, Senator, in those particular situations you might have an erosion of this balancing act within FIFRA.

If confirmed, I will go in and work with the talented staff of the Office of Pesticide Programs and bring impartiality to it, or maybe maintain that balance if it is already there, so that you can be assured and the American people can be assured that FIFRA is regulated in the way it is intended to be regulated as a balance between risk and benefit.

Senator WICKER. OK.

Well, let me move, then, to Federal procurement of wood and guidelines from the Federal Government and from EPA in that regard.

I can tell you that folks in my State of Mississippi feel that the Federal Government has unduly discriminated against domestic lumber and domestic wood production by this adherence to one form of certification from the Forest Stewardship Council, ignoring and to the detriment of other initiatives such as the Sustainable Forestry Initiative, SFI, or the American Tree Farm System, ATFS.

What do you know about that, and do you have any information to share with the Committee about guidelines issued for purchasing lumber and wood discriminating against domestically produced wood?

Mr. DOURSON. Senator, I am not familiar with that particular issue, but if confirmed, I would be more than happy to work with you individually or this Committee and appropriate Chemical Safety and Pollution Prevention staff to make sure that such discrimination is at least understood, and if not appropriate, to be removed.

Senator WICKER. And I will note, Mr. Chair, that I asked Administrator Pruitt essentially the same thing when he was here in January.

So, doctor, I would just like to make sure, will you commit to working with me and your colleagues at EPA to fix this flawed policy so that EPA promotes the use of all domestic forest products in its purchasing policy?

Mr. DOURSON. I would be happy to work with you, Senator, on that.

Senator WICKER. Now, Mr. Chairman, my time has expired. I understand we are going to have a second round. If I could squeeze in a quick question, I could be out of your hair.

Senator BARRASSO. Senator Gillibrand, you are next. Are you OK with him doing that?

Senator WICKER. I am sure she will love the question.

[Laughter.]

Senator WICKER. Because I was going to ask Dr. Dourson, Mr. Leopold, Mr. Ross, and Mr. Wehrum did they agree or disagree that Waters of the United States and the Clean Power Plan involved a reach beyond the authority granted the EPA by Congress.

And we will start with Mr. Wehrum down here.

Mr. WEHRUM. Well, I can speak to the Clean Power Plan, Senator, and I think I would just refer to the action of the U.S. Supreme Court, which, in an unprecedented move, stayed implementation of the Clean Power Plan even before the D.C. Circuit had rendered a decision on the underlying litigation. The Court has never taken an action like that in its history, and I think it says

a lot about that Court's perspective on the legal viability of the CPP.

Mr. ROSS. Senator, I can speak to the Waters of the United States litigation, and I will defer to the same thing. There are two Federal courts who have taken the extraordinary step of staying implementation of a rule both on procedural and substantive concerns. So I think the courts have sent the message as to whether or not there are some legal infirmities there.

Mr. LEOPOLD. Senator, I will echo the comments of my colleagues here and that courts have taken extraordinary steps that are unprecedented in staying both of those regulatory actions. Thank you.

Mr. DOURSON. Senator, as a scientist and not a lawyer, I think I will withhold comment about the legalities of this particular thing. As a member of EPA's Science Advisory Board, however, this rule came through us, and I had some comments on that and some scientific risk issues that were raised during the meeting. But again, I have no comments on the legality.

Senator WICKER. Are those a matter of public record?

Mr. DOURSON. Yes, Senator, they are.

Senator WICKER. OK. Could you make those available to the Committee?

Mr. DOURSON. Sure. Absolutely.

Senator WICKER. Thank you.

And let the record reflect that I owe Senator Gillibrand at least my 3 minutes.

Senator GILLIBRAND. I will hold you to that.

Senator BARRASSO. Senator Gillibrand, thank you for your patience. Thank you. Appreciate it.

Senator GILLIBRAND. Thank you, Mr. Chairman.

Mr. Dourson, today, in the audience, are New Yorkers whose lives have been personally impacted by the chemical PFOA: Michael Hickey, Laureen Hackett, Gwyneth Young, and Lee Marby. They live in the village of Hoosick Falls, New York, and the town of Petersburg, New York, two neighboring communities that together are going through a gut wrenching experience of discovering that their drinking water, the water that they drink, the water they give their children, the water they cook in, the water they bathe in, is contaminated by PFOA. Michael Hickey has lost his father to kidney cancer, and they have family members, friends, and neighbors affected by illnesses that are known to be linked to PFOA.

These families are so frightened. I live so close to where they live. I can't imagine what it would be like to live and not know if the water that your children are being bathed in is safe; if they are going to get cancer when they are 25; if they are ever going to be able to have kids. Their lives are so affected by the decisions that you have made, and I don't think you recognize when you are hired by a company, when you are hired by the DuPonts of the world, when you are hired by the Monsantos of the world, you are being asked to change how governments, how leaders look at these risks and whether they say it is safe or not.

We have lived through this. After 9/11 the EPA said the air was safe. Do you know how many people in their 40s and 50s and 60s have died of cancers you would not see in people who are younger

than 80? Because you have such a responsibility. You are no longer being paid for your opinions. You are here as a public servant. Your job is to serve the people sitting behind you. Your job is to look at their children in the same way you would look at your own children or any other person you love. And the decisions that you are going to make will affect hundreds and hundreds of more children just like them.

Now, you have refused to answer the question that my colleagues have asked you, if you would recuse yourself. If I was you, I would recuse myself over and over again if I was paid for a determination that in many instances were multiples, hundred times, thousand times more than what the EPA has recommended.

Now, I can take you through the drill. Do you believe that PFOA has been linked to cancer, including kidney cancer?

Mr. DOURSON. I believe the scientific studies associated with PFOA indicates that it is linked to some kinds of cancers.

Senator GILLIBRAND. Concerns about PFOA are not unique to upstate New York, but your organization, TERA, was hired to assess the safety of PFOA in West Virginia in 2002. We know that DuPont manufactures PFOA in Parkersburg, West Virginia, and I understand they paid you for that assessment, correct?

Mr. DOURSON. The State of West Virginia hired us to do that assessment, Senator.

Senator GILLIBRAND. Was DuPont involved at all?

Mr. DOURSON. Senator, I don't know about where the State of West Virginia got its money.

Senator GILLIBRAND. Did TERA recommend, in a risk assessment, that water with PFOA levels of up to 150 parts per billion was safe to drink?

Mr. DOURSON. No, Senator, TERA did not; that was a collection of 10 individuals, 5 of them government agents, government employees, 4 of them U.S. EPA that made a consensus decision on that.

Senator GILLIBRAND. But it was 150 parts per billion.

Mr. DOURSON. The science at the time indicated in a consensus manner of all the scientists at the table that that was the appropriate level to base it on.

Senator GILLIBRAND. Did you know that DuPont had an internal recommendation guideline of 1 part per billion at the time?

Mr. DOURSON. Our understanding at the time was the 1 part per billion was a placeholder; it wasn't based on a full reading of the science. They were waiting for the science panel to do it.

Senator GILLIBRAND. Do you know that EPA has a health advisory level of .07 parts per billion?

Mr. DOURSON. The science has progressed, significantly advanced since the time of 2004, and the new science indicates a lower level.

Senator GILLIBRAND. Do you know that in Hoosick Falls they have found contamination at .66 parts per billion, which at the level you determined would save 150 parts per billion is 228 times higher than the parts per billion that is actually occurring today in Hoosick Falls?

Mr. DOURSON. Well, again, the science has progressed since the time of the consensus decision of the 10-member panel in 2004. I am not aware of the specific——

Senator GILLIBRAND. So here is my fundamental question.

Mr. DOURSON [continuing]. Exposure in that particular location, however.

Senator GILLIBRAND. In the job you are about to take, will you commit that you will maintain the .07 parts per billion standard?

Mr. DOURSON. Senator, if confirmed, I will commit to protecting the American public and its most vulnerable members using the best science and working with the talented people of the Office of Chemical Safety and Pollution Prevention. We will bring the best science forward; we will be transparent; we will be collaborative. I commit to that.

Senator GILLIBRAND. Mr. Chairman, can I just ask unanimous consent to submit for the record two articles from West Virginia, a West Virginia news source? The first quotes a watchdog group formed to ensure companies remain liable for pollution for damages of PFOA, and the article concluded Michael Dourson spent his career helping chemical companies cover up deadly chemical contamination, and he was directly complicit in the PFOA contamination crisis that seriously harmed thousands of West Virginians and Ohioans. This nomination is a classic example of the fox guarding the hen house.

Senator BARRASSO. Without objection.

[The referenced information follows:]

News & Sentinel

BREAKING NEWS Mass shooting at Las Vegas concert

EPA nominee once helped chemical industry

Dourson says higher C8 levels are acceptable

LOCAL NEWS

SEP 28, 2017

JESS MANCINI
City Editor
jmancini@newsandsentinel.com

TWEET SHARE

PARKERSBURG — The president's nominee to run a regulatory agency of the Environmental Protection Agency is being questioned for his closeness to the chemical industry.

{"type":"headsupcheck","url":"http://www.lightstalking.com/restore-your-photos/"}

Michael Dourson was nominated by President Trump to head the Office of Chemical Safety and Pollution Prevention. Dourson has been a consultant for the chemical industry and once said the acceptable level for C8, or PFOA, should be higher than the EPA limit.

Based on that, *"he's not qualified,"* said Dr. Paul Brooks, whose company organized the collection of health data from 70,000 people in the Mid-Ohio Valley and led the C8 science panel to conclude there's a possible link between the compound once used to make Teflon at the Washington Works in Wood County and six diseases in humans.

"You don't want the fox guarding the hen house," Brooks said.

Dourson's nomination was originally scheduled to be heard Sept. 20 by the U.S. Senate's Committee on Environment and Public Works. It was postponed, possibly to Wednesday.

Sen. Shelley Moore Capito, R-W.Va., is a member of the committee. Capito spokesman Ashley Berrang said the senator would like the opportunity to discuss Dourson's background at a nomination hearing before announcing her position on his nomination.

Jeffrey Dugas of Keep Your Promises DuPont, a watchdog group formed to make sure DuPont remains financial liable for the C8 damages, also used the fox and hen house analogy.

"Michael Dourson spent his career helping chemical companies cover up deadly chemical contamination, and he was directly complicit in the C-8 contamination crisis that has seriously harmed

Web2PDF
converted by Web2PDFConvert.com

thousands in West Virginia and Ohio," Dugas said. *"This nomination is a classic example of the fox guarding the hen house and an insult to everyone in the mid-Ohio Valley."*

More scientists and researchers are concluding that the acceptable level of exposure to C8 is zero and the acceptable concentration in the blood serum should be zero, Brooks said.

It's unlikely, in the event Dourson is confirmed by the Senate, the EPA would raise the acceptable long-term exposure levels from .07 parts per billion, he said. The state of Vermont, for example, supports a level of .01 ppb, Brooks said.

"I don't think there's any chance the EPA will ever raise it up," he said.

"If Mike Dourson is confirmed, the environmental health of every child in the country will be tossed aside, as he will almost certainly continue his work from inside EPA to greenwash chemicals and pesticides to protect the profits of the companies that make them," said Ken Cook, president of the Environmental Working Group. *"Handing the keys to EPA's Office of Chemical Safety and Pollution Prevention to Dourson, who has spent a career opposing both, makes about as much sense as letting the CEO of Philip Morris run the American Lung Association."*

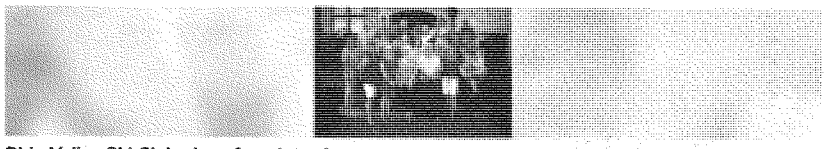
The group points out that in 2000, the state of West Virginia hired Dourson and Toxicology Excellence for Risk Assessment – TERA – which was paid for by DuPont, to determine a *"safe"* level for C8 in drinking water. In 2002, the group reported the safe level was 150 ppb, 150 times greater than what DuPont scientists determined 14 years earlier.

"Some of us are very disturbed by President Trump's nomination of Michael Dourson to lead chemical safety at EPA," said Harry Deitzler, a lead attorney in the original C8 lawsuits in Wood County that led to the creation of the science panel and an attorney in the federal class action suits settled this year with DuPont.

"The New York Times, USA Today and the Associated Press have all pointed out that Dourson has a long track record of downplaying concerns about toxic chemicals," Deitzler said. *"Specifically that includes work that Dourson has done on PFOA. Dourson has worked on dozens of chemicals for dozens of chemical industry clients and has always found reason to suggest looser standards for his clients' products."*

COMMENTS

LOCAL NEWS



Ohio Valley Ski Club plans for winter fun

Glenville State College preps Homecoming

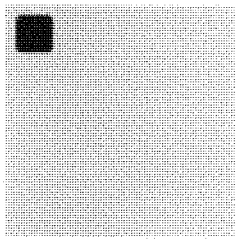
GLENVILLE – The Glenville State College Homecoming Committee has planned activities for students, faculty, staff, ...

Web2PDF
converted by Web2PDFConvert.com

Charleston Gazette-Mail

EPA nominee has ties to WV chemical controversies

By Ken Ward Jr. Staff writer 19 hrs ago (...)



Toxicologist Michael Dourson
Courtesy photo

A longtime industry consultant picked by President Donald Trump to head the U.S. Environmental Protection Agency's chemical safety arm was involved in several major public health controversies in West Virginia.

Toxicologist Michael Dourson was involved in the long saga over DuPont Co.'s contamination of Mid-Ohio Valley drinking water supplies with the chemical C8. Dourson also was a contractor for a team that then-Gov. Earl Ray Tomblin appointed to investigate the potential impacts of the January 2014 Elk River chemical spill.

The Trump administration nominated Dourson to be assistant administrator in charge of EPA's Office of Chemical Safety and Pollution Prevention.

Dourson has most recently been a professor in the Risk Science

Center at the University of Cincinnati.

Dourson worked for EPA for about 15 years, and then formed a nonprofit consulting firm, Toxicology Excellence for Risk Assessment, or TERA, that The New York Times has said "became a line of first defense for companies facing health and safety challenges from the EPA."

The EPA has cited "widespread praise" for the Dourson nomination, but environmental groups are strongly opposing his confirmation by the Senate.

"Dourson has made a career as a hired gun for the chemical industry, helping clients play down concerns over toxic chemicals with known and potentially severe health effects," said the Environmental Defense Fund, one of the groups opposing Dourson. "If confirmed to the top job at the EPA's Office of Chemical Safety and Pollution Prevention, Dourson will be regulating his old industry friends."

Dourson is scheduled to face questioning Wednesday from members of the Senate Environment and Public Works Committee during a confirmation hearing.

In West Virginia in the early 2000s, Dourson and TERA were brought in by the state Department of Environmental Protection to help the government respond to concerns about the contamination of drinking water supplies with the toxic chemical C8 from DuPont's plant near Parkersburg.

The committee Dourson and his firm worked with came up with a standard that set the safe level of C8 in drinking water at 150 parts per billion. Citizen groups warned at the time the number was wrong, and that the committee's work was slanted toward DuPont.

Later, Dourson testified for DuPont in a trial that resulted in a $1.6 million judgment against the company. That case and several others last to a $671 million settlement with thousands of residents.

In 2014, Dourson was brought in by the West Virginia Testing Assessment Project, an effort created by the Tomblin administration to assess the contamination of the Kanawha Valley region's drinking water system following the Jan. 9, 2014, chemical spill at Freedom Industries.

The WVTAP review concluded that a "screening level" for drinking water, set by the U.S. Centers for Disease Control and Prevention, had allowed higher levels of contamination than it should have.

But a health-effects panel chaired by Dourson also pulled some punches in its discussion of the potential impact of the spills, not making its criticism of the CDC especially clear to residents. Also, Dourson was criticized for not making clear from the outset any potential conflicts of interest involved with his previous work for companies that made chemicals that were spilled.

Reach Ken Ward Jr. at kward@wvgazettemail.com, 304-348-1702 or follow @kenwardjr on Twitter.

Senator BARRASSO. Thank you, Senator Gillibrand. Thank you for your patience.

Senator Cardin.

Senator CARDIN. I am not exactly sure how to begin on this, but I think I will start with Mr. Leopold. I have a major concern for the safety of the people in Baltimore. On September the 18th of this year a cloud of chlorosulfonic acid leaked through a valve at Solvay Industry plant in Baltimore. I don't know if you are familiar with that or not.

Thousands of my constituents were told to shelter in place for several hours that morning and early afternoon over fear of their health and safety. It is my understanding that this bill is colorless, and it is very difficult to know its presence other than the effect it has on your skin and respiratory tract. It can be fatal. It is extremely dangerous.

And I would like to get your understanding of what role you will play as counsel in dealing with protecting the people of Baltimore and this nation on this issue. On June 9th Administrator Pruitt signed a final order to further delay the effective date of the RMP Rule amendment, known as the Chemical Accident Safety Rule, for 20 months, until February 19th, 2019.

So I want to get some of your views as to what role you are going to play on implementing the laws of this country through regulations so that we are not bearing in Baltimore this type of safety condition. This is not hypothetical; it happened just a few weeks ago.

So how do you see your role, if confirmed, in using the enforcement of our laws to protect the public health of the people of this country?

Mr. LEOPOLD. Thank you, Senator. I think the general counsel's role on this issue—and my concerns are certainly with the people of Baltimore and those who have experienced releases of chemicals—I think the role of the general counsel of the EPA is to approach this issue as it would any legal issue; to look at the statutes, the regulation the EPA administers.

And in this case EPA has emergency response authority, which in an Office of Emergency Response, which it could activate. I am not privy to any details about what is occurring in the Agency at the moment, but——

Senator CARDIN. Emergency response is one thing. Preventing this is something else. The delay of the rule is delaying protection. Do you believe that you would have a role in making sure that we get timely action taken on these types of rules?

Mr. LEOPOLD. Well, I think the General Counsel's Office, again, the role is to advise the program offices and the Administrator on their authority, and if the Agency has discretion, we would advise, the discretion and the statutory bounds in which the Agency has to operate. Again, that is the role of the counsel, but certainly my commitment, as is the Administrator's, is to the rule of law. And if the law requires a substance to be regulated, I would advise of that, Senator.

Senator CARDIN. And of course, delay is denying the regulation of the law. So they may have discretion of delay, but do you see

an obligation to make sure that the laws that we passed are carried out?

Mr. LEOPOLD. Absolutely, Senator. The obligation of the EPA is to implement the laws that are passed by Congress. In certain instances, the Agency has discretion on when to exercise that discretion, and in other instances statutes are very specific about when the Agency has to take action.

Senator CARDIN. I hear you. I would like to get a greater comfort that public safety is the reason why we pass these laws. There may be discretion on delay, but delay can cost people lives, so there needs to be a sense of urgency on public health.

Mr. Ross, quickly, if I might. We have had several discussions about the Chesapeake Bay Program and the fact that it is a unique program; it is local governments up, we have all the stakeholders working together. Mr. Pruitt, in his confirmation hearing, said very nice things about the Chesapeake Bay, so I assume you are going to say nice things about the Chesapeake Bay Program.

Mr. ROSS. Yes. Thank you for the question. A couple months ago I had the distinct pleasure of driving 16 hours across country with the little ones back here to go from Wisconsin. We dropped our children off at a YMCA camp along the Chesapeake Bay in Maryland, in your State, and my wife and I continued out to the Delaware shore in your State, Senator Carper. So I care very deeply about where my kids play and swim, and the water quality, and I think the Bay is a treasure.

Senator CARDIN. Let me just point out that this Committee just reauthorized the Chesapeake Bay Program, the Federal role in the Chesapeake Bay Program by unanimous vote, and we authorized it at a higher level than the current appropriation levels. It is a clear signal that this program is supported, and for the benefit of your children, we hope that you will be a strong advocate to help us as one of the stakeholders, because without the Federal Government's significant role in this, it is hard for the other stakeholders to work together, because Federal participation is the glue in a program that is really popular among the six States and the District of Columbia and the stakeholders. So we will hold you to helping your children preserve this great heritage.

Thank you.

Senator BARRASSO. Thank you, Senator Cardin.

Mr. Ross, having served both the State of Wyoming and Wisconsin, I think you have an immediate understanding and an intimate understanding of many of the different types of water issues faced by States across the country. Senator Wicker raised some questions about the Waters of the U.S. Could you please just explain to the Committee how you intend to work with western States to solve some of the water and water scarcity issues faced in Wyoming and elsewhere?

Mr. ROSS. Yes. You put your finger on it. I have worked in California, and I studied in Vermont, I have worked in Wisconsin, I spent time in DC; I spent a lot of time in Wyoming, and what I have learned is that each region, each State has unique challenges; and the issues out west are both water quality and water quantity, and that is a really difficult intersection.

And there are some amazing folks, including in Wyoming, the State engineer, the director of the Department of Environmental Quality, they are subject matter experts that understand the issues as well as anyone. My job is to go learn from them and to make sure that the Federal Government works collaboratively with the States to protect the resources.

Senator BARRASSO. And Mr. Baran, I wanted to just follow up. The National Environmental Policy Act, NEPA, that requires agencies to prepare an environmental impact statement. They have to do it for every major Federal action. Well, at the NRC major Federal actions can include the issuance of licenses, license amendments. NEPA requires an agency to provide notice and to take public comments as it prepares an environmental impact statement.

But in contrast to many Federal agencies, the NRC has voluntarily decided to take steps beyond those required by NEPA. Specifically, the NRC allows parties to challenge the NRC's environmental impact statement at its evidentiary hearing on security and safety measures. So, recently what we have seen are anti-nuclear activists. They have argued that if new information is presented at the hearing, then the NRC can't supplement its environmental impact statement.

Instead, these activists are arguing that the NRC has to go back and rewrite the entire environmental impact statement before issuing a license or license amendment. So, if the NRC has already issued a license, these activists argue that the NRC has to then vacate and suspend a license that has already been issued.

A bipartisan majority of the NRC Commissioners has repeatedly rejected this argument by the extremists, but you are the only Commissioner who agrees with these anti-nuclear activists, the only one. So, the issue is now before a Federal appeals court. So, if these activists succeed, it is going to add significant delays, I think, to any NRC licensing processes. This is going to make nuclear energy much more expensive to produce, and in some ways could potentially jeopardize safety.

So, is it still your position—I know how you voted, but is it still your position that if new information is presented at NRC's evidentiary hearings, that the staff must rewrite the environmental impact statement before the NRC issues a license or license amendment? And if the NRC has already issued a license or license amendment, they must then vacate or suspend the license or the license amendment?

Mr. BARAN. Well, my concern is a little bit more specific than that. In the cases I think you are citing, the issue there was that the NRC staff, as you mentioned, made a licensing decision on the basis of an environmental review that our administrative law judges, the agency's administrative law judges later found to be inadequate. So that is the key factor there.

My concern is that at the point we make a decision, when the agency issues a license, at that point we should do so on the basis of an adequate NEPA review. In my view, in the cases you mentioned, that did not happen. And as you mentioned, this question is now pending before the D.C. Circuit Court of Appeals, which will hold arguments on it next week.

Senator BARRASSO. Thank you.

Senator Carper.

Senator CARPER. Thanks, Mr. Chairman.

I think this is a question for Bill Wehrum. Virtually every major clean air regulation that you helped to craft during the Bush administration has been thrown out, I am told, thrown out by Federal courts. Twenty-seven times the courts found that you failed to protect public health as directed by the law. All of the failed regulations you worked on created greater uncertainty for businesses and left the life of those that are most vulnerable at risk.

When you left the EPA in 2007, I am sure you reflected on your time at the Agency in different ways, but one of the ways, the only one we are aware of, is really captured in the following quote from you, and I am going to read what the poster over my head says. It is put in juxtaposition to what Mr. Leopold said earlier in his testimony, and I think it was heartfelt, in his opening statement about a commitment, sort of a moral commitment to clean air, water, and so forth.

I was out of the room when Mr. Ross invoked the verse for the beauty of the earth to talk about his commitment, and the juxtaposition of those two statements and what I am about to quote here from you just could not be stronger. Your quote is saying "I am a much better lawyer now than when I first joined the Agency. To really get to know how the Agency works and how it ticks, I think that is very valuable. I have expanded my capabilities, which will hopefully allow me to be effective in generating business and clients."

Since then you have represented industry 31 times in lawsuits that I am aware of, against EPA, arguing for weaker air toxic mercury and climate protections. Would you just take a minute and tell us why the American people should believe that you will be impartial in making decisions when it comes to protecting public health over the interest of the industries that you spent many years representing?

Mr. WEHRUM. I would love to, Senator. Thank you. First of all, with regard to the cases you cited and also the quote that you provided, both of them are tip of the iceberg situations. With regard to the cases, what gets litigated in the D.C. circuit is a very, very small fraction of what gets done in the Office of Air and Radiation, so I think it is a misrepresentation of my experience at EPA previously to say that that somehow is an indicator that I am not committed to faithfully implementing the law and committed to protecting human health and the environment, so I think that is not representative.

Senator CARPER. Let me just follow up, if I could. I am particularly concerned about your legal efforts against the Obama administration's mercury and air toxic rule for power plants. You argued in court that EPA has not proven that it is appropriate to regulate mercury and air toxic power plant emissions, despite the fact that most utilities are meeting the rule's deadlines and health benefits are being realized faster than predicted.

Administrator Pruitt is reviewing the rule, and you made it clear you in our private meeting that you will not recuse yourself from working on this issue. If the mercury and air toxic rule is revoked, how is that good for public health? And if the rule is revoked, will

power plants stop running pollution control technology they have already bought, paid for, and installed, and how is that good for ratepayers?

Mr. WEHRUM. Well, Senator, I think a point you are trying to make is rule of law is important, and there is no better example than this particular standard. It went all the way up to the U.S. Supreme Court. The U.S. Supreme Court said that EPA made a fundamental flaw in deciding whether to implement this regulation because it did not consider cost in making the threshold judgment as to whether power plants should be regulated as part of the Clean Air Act.

That question is still an open question before U.S. EPA. The Obama administration implemented a rule to address that court finding, but the litigation is still pending, and I believe has now been stayed, and that is an issue that we will have to take up if I am confirmed.

Senator CARPER. My time is almost expired, so I will ask you to hold it there. Thank you for that response.

Mr. Chairman, I ask unanimous consent to submit four cases where Mr. Wehrum represented oil interests against biofuel, biodiesel, and renewable fuel standard regulations. These cases show or suggest that Mr. Wehrum should be very familiar with renewable fuel standard and flexibility given to the Administrator to implement the RFS. I make that unanimous consent request.

Senator BARRASSO. Without objection.

[The referenced information follows:]

Wehrum Cases Related to Biofuels/RFS

National Chicken Council, et al. v. EPA (D.C. Circuit Court of Appeals) (10-1107, consolidated with 10-1108, 11-1030, 11-1089, and 11-1110)

Wehrum represented National Chicken Council, National Meat Association, and National Turkey Federation in challenging EPA's "Regulation of Fuels and Fuel Additives: Changes to Renewable Fuel Standard Program." (75 FR 14670)

Grocery Manufacturers Association v. EPA (D.C. Circuit Court of Appeals) (10-1380, consolidated with 10-1414, 11-1002, 11-1046, 11-1072, and 11-1086)

Wehrum represented Grocery Manufacturers Association, American Petroleum Institute, and other industry groups, in challenging EPA's "Partial Grant and Partial Denial of Clean Air Act Waiver Application Submitted by Growth Energy to Increase the Allowable Ethanol Content of Gasoline to 15 Percent; Decision of the Administrator." (75 FR 68094)

American Petroleum Institute v. EPA (D.C. Circuit Court of Appeals) (11-1344,consolidated with 11-1334)

Wehrum represented API in petition for review of EPA's "Regulation To Mitigate the Misfueling of Vehicles and Engines With Gasoline Containing Greater Than Ten Volume Percent Ethanol and Modifications to the Reformulated and Conventional Gasoline Programs." (76 FR 44406)

Minnesota Auto. Dealers Ass'n v. Stine, No. 15-2045, 2016 WL 5660420 (D. Minn. Sept. 29, 2016).

Wehrum represented a coalition of oil, gas and vehicle manufacturers against Minnesota state officials who were "connected to the implementation and enforcement of the Minnesota Mandate," a state law requiring diesel fuel sold to consumers in Minnesota to contain a specific percentage of biodiesel, alleging that the Mandate conflicted with the RFS, and therefore was preempted by the Supremacy Clause of the U.S. Constitution. Id. at *1, 4. The court sided with Minnesota. Here is the case: http://blogs2.law.columbia.edu/climate-change-litigation/wp-content/uploads/sites/16/case-documents/2016/20160929_docket-15-cv-02045_memorandum-opinion-and-order-1.pdf

Senator BARRASSO. Thank you, Senator Carper.

Senator CARPER. And if I could, just one more unanimous consent. I would like to ask unanimous consent to submit for the record two L.A. Times articles from 2004. These articles report two instances where Mr. Wehrum ignored the EPA career staff and inserted industry language from his former law firm, Latham & Watkins, into two different rules dealing with formaldehyde and mercury emissions. Both professions ended up failing in court. For the mercury rule, the L.A. Times reported that, "Several complete paragraphs were lifted from three memos provided by Latham & Watkins, a national law firm whose clients include large coal-fired utility plants."

I ask unanimous consent.

Senator BARRASSO. Without objection.

[The referenced information follows:]

Los Angeles Times ARTICLE COLLECTIONS

← Back to Original Article

The Nation

EPA Relied on Industry for Plywood Plant Pollution Rule

May 21, 2004 | Alan C. Miller and Tom Hamburger | Times Staff Writers

WASHINGTON — Pushing aside new scientific studies of possible health risks, the Environmental Protection Agency approved an air pollution regulation this year that could save the wood products industry hundreds of millions of dollars.

In doing so, the agency relied on a risk assessment generated by a chemical industry-funded think tank, and a novel legal approach recommended by a timber industry lawyer. The regulation was ushered through the agency by senior officials with previous ties to the timber and chemical industries.

The officials say they advocate a balanced approach to environmental regulation that weighs costs as well as benefits. Their critics say science and public health are losing out.

"This rulemaking veers radically from standard scientific and regulatory practices," said David Michaels, an epidemiologist who was assistant Energy secretary for environment, safety and health in the Clinton administration. Others say it may violate the Clean Air Act.

The regulation addresses emissions of formaldehyde, a chemical used by plywood manufacturers and other industries. Exposure to formaldehyde may cause cancer and lead to nausea and eye, throat and skin irritation. At the time the regulation was being drafted, the National Cancer Institute and the National Institute of Occupational Safety and Health disclosed new studies showing that exposure to formaldehyde might also cause leukemia in humans.

The EPA rule, signed in February, did not mention the possible link to leukemia. Instead, it adopted a standard for exposure based on a cancer risk model developed by the Chemical Industry Institute of Toxicology. That assessment is about 10,000 times less stringent than the level previously used by the EPA in setting general standards for formaldehyde exposure.

Many scientists considered the earlier EPA risk level to be outdated; Canada, for example, used the chemical institute model to help set its formaldehyde standard in 2000. But the accuracy of that model in predicting human risk was a source of debate even before the new leukemia studies.

Citing such concerns, a California scientific advisory panel voted unanimously this week to reject a formaldehyde industry request to reconsider the state's risk assessment of the toxic gas. Panel members said the chemical institute's model needed further development and validation.

The new EPA rule also breaks legal ground in the application of the 1990 Clean Air Act amendments.

At that time, Congress required industry to reduce emissions of toxic pollutants to levels that could be achieved by the best available technology. But it permitted the EPA to spare entire categories of pollution sources from tough controls if all posed less than a one-in-a-million cancer risk. As the wood products regulation was being considered, it was clear the industry could not meet that test. Instead, the EPA created a new category of "low-risk" plants, putting the agency in the role of overseeing, plant by plant, which facilities endangered the public.

The rule initially exempts eight wood products plants from controls on formaldehyde and other emissions. Ultimately, 147 or more of the 223 facilities nationwide could avoid the pollution-control requirements. The exemptions will save the industry as much as $66 million annually for about 10 years in potential emission control costs.

The idea of identifying low-risk plants was suggested to the EPA by a lawyer at the firm of Latham & Watkins, which represents timber interests.

The EPA's top air pollution regulator, Jeffrey R. Holmstead, embraced the concept. He was already familiar with it. A former lawyer at Latham & Watkins himself, he had represented one of the nation's largest plywood producers and other companies seeking to limit pollution regulation.

"The basic approach was something that I had been thinking about for a number of years," said Holmstead, assistant EPA administrator for air and radiation. He also backed the EPA's use of the scientific data from the institute funded by the American chemical industry, another former client.

At the White House, Holmstead found an ally in John D. Graham, regulatory chief of the Office of Management and Budget. He had established the respected Harvard Center for Risk Analysis, which received funding from some of the companies that pushed the new EPA regulation. Graham came to OMB vowing to set new standards for cost-benefit analysis, transparency and reliance on sound science in regulatory decisions.

"Public health should be the regulator's first priority," Graham said in a written response to questions. "However, when the health risks are speculative, it is OMB's job to ask whether the regulation will be good for consumers, workers and businesses. Consumers pay for burdensome regulations in the form of higher prices for homes and products while American jobs are placed at risk."

Some agency veterans say the EPA's approach departs from past practices under both political parties.

"EPA decisions now have a consistent pattern: disregard for inconvenient facts, a tilt toward industry, and a penchant for secrecy," said Eric Schaeffer, a longtime EPA enforcement official who resigned in protest in 2002 and now heads the Environmental Integrity Project, a watchdog group.

*

The Proposal

In early 2002, the EPA was under court order to write regulations governing formaldehyde emissions at wood products facilities. The deadline was Feb. 27, 2004.

Formaldehyde is a naturally occurring chemical released when wood, tobacco and other organic substances burn. It is best known as the key ingredient in embalming fluid; its foul smell is familiar to anyone who dissected frogs in biology class. It is used most frequently as a binding agent in pressed-wood products, furniture, flooring and chemical and household manufacturing.

Although it is classified as a probable human carcinogen, the lack of crystal-clear links between exposure and increased cancer rates has long made regulation controversial.

On Jan. 14, 2002, EPA staffers joined Holmstead in his fifth-floor conference room to meet with a lobbyist for the American Forest & Paper Assn. and the group's Washington lawyer to discuss the upcoming rule-making. Such sessions are routine at the EPA, where regulators and industry experts exchange scientific data and legal theories.

But some staffers found this gathering remarkable.

The forest products lobbyist, Timothy Hunt, was an old acquaintance of Holmstead's. William Wehrum, the air office's general counsel, had represented timber interests as well. The forest association's lawyer, Claudia M. O'Brien, had been a law partner of Holmstead's and Wehrum's at Latham & Watkins.

Hunt and O'Brien were representing a politically well-connected industry. During the 2000 election cycle, timber company employees and their families donated $8.3 million to federal candidates and committees, 83% of it to Republicans, according to the Center for Responsive Politics, a nonpartisan research organization.

O'Brien presented proposals to spare low-risk plywood, particleboard and other plants from strict emission controls. She noted that such facilities were often situated in isolated areas, any harm from their emissions was debatable and, in some cases, the risk to the public appeared low. In addition, the expense of adding new controls to the plants, which the industry said could reach $1 billion, might make them vulnerable to foreign competition.

*

Reopening the Debate

To some EPA staffers, this seemed like reopening a debate Congress had tried to resolve in 1990. In the 20 years after the passage of the 1970 Clean Air Act, the EPA had been able to regulate only a handful of toxic substances because the agency became bogged down in disputes over how to measure health risks. As a result, Congress amended the act in 1990 to require that all large industrial plants reduce emissions of 189 substances using the best available technology as their standard.

But Holmstead was enthusiastic. Before reviewing the proposal with his own legal and technical staff, he declared, "We're going to do this," recalled one staffer who was there.

In a recent interview, Holmstead said he didn't remember the meeting, but added, "I'm sure I would have expressed interest in pursuing that."

He added: "Different people around town had been thinking for a while that it would be good if individual facilities could make a showing that they pose no risk to the community. In that case, why would you require them to spend a lot of money" to reduce emissions?

Throughout his career, Holmstead has sought to scale back environmental regulation of business and represented corporate clients seeking to minimize the effect of air pollution laws.

As an associate White House counsel during the George H.W. Bush administration, he worked with Vice President Dan Quayle's Competitiveness Council, which pushed to reduce environmental and other regulation.

After leaving government, he joined Latham & Watkins, where he represented chemical, semiconductor and other clients on environmental policy issues.

In 1996, he worked with colleagues representing Georgia Pacific in a $35-million settlement with the EPA and Justice Department over alleged Clean Air Act violations. The firm later was among those backing the proposal to exempt low-risk timber-product plants from formaldehyde controls.

Federal conflict-of-interest rules bar appointees from working on particular matters, such as contracts, grants or claims, that will have a financial effect on the appointee or his family. This also applies to matters involving a former employer for one year from the appointee's departure date. But rule-making, which has a broad effect, is exempted from this prohibition

"I meet with hundreds of outside groups representing a wide variety of interests, and it hardly seems right to penalize" past associates "by not allowing them to meet with me," Holmstead said. "It would be very hard to get people who are knowledgeable and qualified to do these jobs if they are unable to talk to people with whom they had affiliations in the private sector."

Graham, too, had past connections to the industries seeking to limit the regulation of formaldehyde. His office at OMB reviews and approves all new federal regulations.

He had testified on behalf of an association of paper companies, including Georgia Pacific, before the Maine Board of Environmental Protection in a 1992 hearing on setting a risk level for carcinogenic pollutants. In addition, the timber company donated to Graham's Harvard Center for Risk Analysis in 1991, 1992, 1995 and 1998. A spokesman said Georgia Pacific's donations were each for no more than $5,000.

The chemical industry's trade association contributed annually to Graham's risk center from 1994 to 1997, and in 1999 and 2001. The center relies on government and foundations as well as a wide range of industry for its funding.

Graham's prior financial ties were reviewed by OMB's ethics counsel when Graham took office and he was not "required to recuse himself from any issues," a spokesman said.

As the proposed rule worked its way through the EPA, career attorneys advised Holmstead that the exemption ran counter to the 1990 Clean Air Act amendments. A confidential March 2003 memo from a lawyer in the general counsel's office highlighted its legal vulnerability.

The proposal "results in a regulatory approach equivalent to the one Congress specifically rejected" in 1990, said the memo, obtained from sources outside the agency. "EPA would have a difficult time articulating any rational basis to defend such a ... scheme."

Holmstead acknowledged the issue was debated by EPA lawyers.

"At the end of the day, the agency determined it was something we did have the authority to do," he said.

That's not the way architects of the 1990 legislation see it.

"I don't have any doubt but that is a way to get around the policy which we worked hard to achieve," said former Sen. David F. Durenberger (R-Minn.). Rep. Henry A. Waxman (D-Los Angeles) declared the timber products exemption "directly contrary to our intent."

The rule has also prompted objections from state regulators.

"It's a serious concern," said Bill Becker, executive director of two national organizations of state and local air pollution control officials. "We learned between 1970 and 1990 that a risk-based approach is totally ineffective in regulating toxics. The analytical tools are not sophisticated enough today to make that determination with confidence."

Meanwhile, as the EPA neared its deadline for approving the wood products regulation, the federal research institutes had updated two of the largest studies of formaldehyde toxicity ever conducted on human subjects. The National Cancer Institute study, published in November 2003, showed that 25,000 workers exposed to formaldehyde had an increased risk of leukemia.

A separate study of 10,000 workers by the National Institute of Occupational Safety and Health also found an elevated leukemia risk, but at different exposure levels. This assessment was posted on the institute's website in early 2004 and published in March.

Conversely, a third study of about 14,000 workers in England published in November 2003 found no such risk.

The authors of the U.S. studies said their work only suggested a link to leukemia, contained seemingly contradictory evidence and didn't explain how formaldehyde might trigger cancer in internal organs. But there was widespread agreement that the findings provided new reason for concern.

*

Studies Back Old Level

An internal EPA calculation showed that taking the new studies into consideration would keep the formaldehyde risk assessment close to the long-standing EPA level. Some staffers contended the agency should wait before finalizing a rule.

As a practical matter, if the EPA went plant-by-plant using its old risk level, about 90 facilities could be exempt from formaldehyde controls. But if the lower chemical institute assessment were employed, an additional 57 plants could qualify for the exemption.

The Chemical Industry Institute of Toxicology, a private, nonprofit research organization, changed its name in 2000 to the CIIT Centers for Health Research. Chemical companies provide most of the institute's funding, although it also receives federal grants and industry contracts.

In an e-mail to colleagues, Peter W. Preuss, who directs the EPA's National Center for Environmental Assessment, said he had "never been comfortable" with the chemical institute formaldehyde risk number or with calling it the "best available science." He is overseeing EPA's own assessment of formaldehyde risk.

And the World Health Organization's cancer research agency had called a meeting for early June to consider the new leukemia findings.

California's Scientific Review Panel on Toxic Air Contaminants cited the upcoming leukemia studies in mid-2003 when it postponed an industry request to adopt a more permissive formaldehyde standard. After further review, the panel, which advises the state's Air Resources Board, voted 6-0 Wednesday to recommend against reopening its risk assessment.

Panel chairman John Froines determined the case for reconsideration, including the chemical institute model, was "not ready for prime time," a spokesman said. And a leading state toxicologist told the panel any reassessment should include the new cancer institute study.

In contrast, EPA leaders decided to complete the federal rule based on the chemical institute science. They said they felt compelled by the court order to sign the new rule by the end of February. Extensions are frequently granted, but EPA did not seek one.

If the EPA's evaluation of formaldehyde risk finds merit in the leukemia studies, administration officials say, the risk assessment could be readily revised. But legal and regulatory experts say the rule has so many untested provisions that such a change would invite lawsuits that could take years to resolve.

"The question is: Are you going to effectively throw away all the work that's been done ... and say we always have to err on the side of any possible uncertainty?" Holmstead said. "At the end of the day, we have to make decisions based on the best available science."

Many scientists, regulatory law experts and environmentalists insist the EPA should have taken the new human research studies into account when it did its risk assessment. The industry and others counter that unresolved questions about the studies made it premature to use them as the basis for regulation.

"The public should not assume a cause-and-effect relationship when only an association is suggested," said Betsy Natz, executive director of the Formaldehyde Council Inc., a trade group.

David Coggon, a British epidemiologist who did the 2003 study that found no increased level of leukemia, nonetheless said of the new American research: "The data are an extremely useful contribution to our knowledge about the potential human carcinogenicity.... Although I believe the risk of leukemia -- if there is one -- is low, I would expect regulators to take account of all the relevant scientific evidence."

At the Office of Management and Budget, Graham said he agreed with the EPA's decision to proceed after his scientists reviewed the new studies and "found that the results are conflicting and difficult to interpret."

In editing the new rule, Graham's office and senior EPA officials made only passing reference to the new scientific studies and rejected any specific discussion of them. The 503-page document contains no mention of a link to leukemia.

*

Researcher Robin Cochran and staff writer Ashleigh Collins contributed to this report.

Los Angeles Times Copyright 2017 Los Angeles Times

Los Angeles Times ARTICLE COLLECTIONS

← Back to Original Article

The Nation

Mercury Emissions Rule Geared to Benefit Industry, Staffers Say

Buffeted by complaints, EPA Administrator Michael Leavitt calls for additional analysis.

March 16, 2004 | Tom Hamburger and Alan C. Miller | Times Staff Writers

WASHINGTON — Political appointees in the Environmental Protection Agency bypassed agency professional staff and a federal advisory panel last year to craft a rule on mercury emissions preferred by the industry and the White House, several longtime EPA officials say.

The EPA staffers say they were told not to undertake the normal scientific and economic studies called for under a standing executive order. At the same time, the proposal to regulate mercury emissions from coal-burning power plants was written using key language provided by utility lobbyists.

The Bush administration has said that the proposed rule would cut mercury emissions by 70% in the next 15 years, and is tied to the president's "Clear Skies" initiative. Critics say it would delay reductions in mercury levels for decades at a risk to public health, while saving the power and coal industries billions of dollars.

Studies designed to address such questions are the ones that were not conducted.

EPA veterans say they cannot recall another instance when the agency's technical experts were cut out of developing a major regulatory proposal.

The administration chose a process "that would support the conclusion they wanted to reach," said John A. Paul, a Republican environmental regulator from Ohio who co-chaired the EPA-appointed advisory panel.

He said its 21 months of work on mercury was ignored.

"There is a politicization of the work of the agency that I have not seen before," said Bruce C. Buckheit, who served in major federal environmental posts for two decades. He retired in December as director of the EPA's Air Enforcement Division, partly because he felt enforcement was stymied. "A political agenda is driving the agency's output, rather than analysis and science," he said.

Russell E. Train, a Republican who headed the EPA during the Nixon and Ford administrations, said: "I think it is outrageous. The agency has strayed from its mission in the past three years."

Buffeted by complaints about the mercury proposal from both within and outside the agency, EPA Administrator Michael O. Leavitt in recent days has called for additional analysis. EPA staffers say they have been asked to suggest possible comparative studies for the agency to run, much like the analysis that, they say, they were ordered not to conduct last year.

"The process is not complete nor is the analysis," Leavitt said in an interview Monday. "I want it done well and I want it done right. And I want it done in a way that will maximize the level of reductions" based on the available technology.

Leavitt noted that while the EPA expressed a clear preference for a more flexible, market-driven plan, its proposed mercury rule also includes an alternative approach using a traditional regulatory system requiring all plants to install pollution controls.

Leavitt portrayed the new period of inquiry as part of the "normal process" of rule-making, noting that the ageney had so far filed only a provisional rule. But veteran regulators say it is unusual to propose a rule first and do extensive comparative studies later -- unless new information emerges.

Leavitt said he could not speak to what happened at the agency before he arrived in November, but that he has had "no pressure to do anything other than the right thing from the White House."

Christie Whitman was the EPA administrator when the career employees say they were told not to conduct the analysis. She left the agency in June, six months before the proposed rule was announced.

"I did not know that we were cutting a process short or shortchanging the analysis," Whitman said in an interview Monday. Had she heard such allegations, she said, she would have intervened.

Five current career employees -- all speaking on condition they not be named for fear of job retribution -- and several former officials provided a behind-the-scenes account of the EPA's decision-making in the mercury case.

*

A cascade of studies in recent years has cast mercury as an escalating health danger, although its threat to the human nervous system has been known since at least the 19th century. That is when hat makers in England literally went mad from exposure to a mercury compound used in processing felt -- hence the expression "mad as a hatter."

Today, the use of mercury in U.S. manufacturing is tightly restricted. But there has been no strict limit on mercury released into the atmosphere from the nation's 1,100 coal-fired power plants, the largest single source of mercury in the U.S.

Mercury occurs naturally in the environment, in fossil fuels like coal, and is released into the atmosphere when those fuels are burned. When mercury particles and gases drop into water, some turn into a more toxic form known as methyl mercury, which then enters the aquatic food chain. People are exposed to mercury chiefly by eating fish.

In 2000, a National Research Council study commissioned by Congress estimated that each year about 60,000 children born in the United States could have neurological problems because they were exposed to mercury before birth. Exposure could lead to developmental problems.

In the past few months, there has been a flurry of other disturbing reports, most focusing on the threat to the fetus from mothers eating fish with elevated levels of mercury. In December, the Food and Drug Administration warned all women of child-bearing age to limit their intake of tuna and other fish because of concern about mercury.

Coal and utility executives don't dispute the dangers of mercury, but they question how much of the threat comes from power plants. And they warn that overly aggressive regulation of the nation's coal-fired plants could damage those industries and the economy and endanger already stretched supplies of electricity.

In its final days, the Clinton administration determined mercury to be a toxic substance and thus subject to strict regulation under the Clean Air Act. The administration's decision required that the EPA propose standards for utility plant emissions by the end of 2003.

As part of this process, the EPA selected a 21-member federal advisory panel in 2001 to make recommendations to the agency.

Mercury was on the agenda at a staff meeting last spring at EPA headquarters presided over by Jeffrey R. Holmstead, a lawyer who represented industry interests on air pollution issues before Bush appointed him to run the EPA's Office of Air and Radiation. Several of the staff members said they had expected to discuss plans to carry out comparative studies of proposals to reduce mercury emissions. The studies had been requested by the federal advisory panel.

The studies were designed to examine the effects of mercury regulation on energy markets, electricity prices and public health. This analysis, generated through EPA computer models, typically becomes the basis upon which agency officials -- and outsiders -- weigh alternatives.

But William Wehrum, a senior advisor to Holmstead who also represented industry clients before joining the Bush administration, told the dozen or so staffers that comparative studies would be postponed indefinitely.

"I was floored," said one participant, who has served several administrations. "We pointed out that the studies were required ... that the data runs were promised to a federal advisory committee."

Holmstead did not respond to expressions of concern, participants said. "There was an awkward silence," one recalled.

After the meeting, two staffers said, Holmstead informed them that the studies would not be conducted partly because of "White House concern."

Holmstead and Wehrum declined repeated requests for comment. On Monday, Leavitt expressed full confidence in them.

Paul, the co-chairman of the advisory committee, which was made up of regulators, environmentalists and industry representatives, says his panel was promised the comparative data last March, but its next meeting was canceled by the EPA and the group never met again.

"We were cut off without any warning or explanation," said Paul, director of the Ohio Regional Air Pollution Control Agency in Dayton, who says he voted for Bush in 2000.

Lisa Heinzerling, a professor at Georgetown University Law Center who specializes in regulatory law and has studied the mercury proposal, said the "EPA's analytical work on mercury was extraordinarily thin."

Even as career staffers and some members of the EPA's advisory panel felt that their contributions to the mercury proposal were being restricted, utility industry lobbyists were given extraordinarily direct input.

When the Bush administration took office in 2001, slowing mercury regulation was a priority for the coal and power industries. Documents obtained under the Freedom of Information Act show that the coal industry dispatched lobbyists to meet with staff of Vice President Dick Cheney's Energy Task Force on mercury and other pollution issues.

Since 1999, coal and electricity companies and executives have donated $40 million to Republican candidates and committees, including $1.3 million directly to Bush campaigns, according to figures compiled by the Center for Responsive Politics.

The administration has responded to key industry priorities: It ended U.S. participation in the Kyoto process to reduce global warming and relaxed regulations that required the power industry to install pollution controls when renovating its plants.

The administration's proposed mercury rule, published in the Federal Register in December, contains numerous paragraphs of verbatim language supplied by two separate industry advocates.

Several complete paragraphs were lifted from three memos provided by Latham & Watkins, a national law firm whose clients include large coal-fired utility plants.

Both Holmstead and Wehrum are former Latham & Watkins attorneys.

More seriously, according to critics, the proposal also includes exact language provided by West Associates, a research and advocacy group representing 20 power and transmission companies in California and other Western states.

The West language suggests a standard for determining likely mercury emissions at power plants.

That standard -- largely incorporated by the EPA -- is enormously beneficial to the industry, according to S. William Becker, executive director of the State and Territorial Air Pollution Program Administrators organization, which represents state and local regulators in Washington.

Leavitt said use of lobbyists' memos in this fashion is not consistent with "normal agency procedure" and that he would prefer that wholesale use of any group's language be disclosed.

Under the proposal, the government would set a national annual cap on emissions but then permit individual companies to choose whether to reduce their own emissions or buy "credits" from other companies that do.

This is designed to provide an incentive to cut emissions nationwide, without limiting them at each individual facility. This approach was widely hailed in the 1990s for reducing power plant emissions that produced acid rain, but critics say it would be ill advised for a toxin such as mercury.

Some scientists believe mercury, which is heavier than acid-rain-producing sulfur dioxide and nitrogen oxide, will remain close to the point of emission, creating "hot spots" of potentially high levels of mercury contamination near power plants. Power plants in communities with high levels of mercury could opt to buy credits rather than spend the money to make reductions.

The EPA's own Children's Health Protection Advisory Committee, which includes academic, industry and environmental professionals, wrote on Jan. 26 that "the cap and trade program, as proposed, may not address existiog hot spots and may create new local hot spots for mercury."

Overall, the committee said the Bush proposal "does not go as far as is feasible to reduce mercury emissions from power plants, and thereby does not sufficiently protect our nation's children."

Today, coal-fired power plants pump out about 48 tons of mercury annually. The Clinton administration order under the Clean Air Act would have mandated reducing the amount produced by coal-fired power plants by as much as 90%, to about 5 tons annually by 2008.

The Bush Clear Skies plan, as modified on Capitol Hill, calls for a national cap of 34 tons in 2010, a level that wouldn't require any extra spending by the industry because it would be automatically reached if utilities added scrubbers and other equipment to comply with the Clear Skies rules regulating nitrogen oxide and sulfur dioxide emissions.

Opponents of the Bush plan contend that setting a lower cap io the near future would encourage innovation by assuring a market for the new equipment. But officials of the coal-fired utility industry argue that forcing rapid adoption of that technology would be so expensive that it would lead electric generators to shift from coal to natural gas.

"The result would be increased electricity prices and higher costs for home heating, food and a host of consumer and industrial products," said Scott Segal, director of a coal utility trade association.

Segal and the coal utility companies that make up the Electric Reliability Coordinating Council back the administratiou's market-based approach as the most effective way to reduce emissions of mercury and other pollutants without harming the economy.

Meantime, longtime EPA employees say the administration exaggerated data on the effectiveness of its proposed rule, which would take effect in December.

In announcing the mercury plan, the EPA said it would reduce mercury emissions from power plants by 70% by 2018.

However, the EPA's own database shows that emissions would, at best, be reduced by only about half by then. And EPA models suggest that the 70% goal may not be reached until 2025, if ever.

In recent days, the administration has backed away from those claims. The 70% reduction will be achieved when the rule is "fully implemented," Leavitt said Monday, without providing a date.

Senator BARRASSO. And I also have a statement for unanimous consent. We have multiple State officials who are supporting Mr. Wehrum's nomination. The Association of Air Pollution Control Agencies is a consensus driven organization, brings together officials from 20 States, a host of local agencies.

Clint Woods, who is the Executive Director of the organization, stated that "Through his comprehensive knowledge of the law and experience in the Federal Government, Bill possesses the background to manage challenging Clean Air Act issues at U.S. EPA and to help continue the tremendous air quality progress that has been achieved in our country over the last several decades."

Without objection, that will be submitted as well.

[The referenced information follows:]

We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

News Releases from Headquarters › Office of the Administrator (AO)

Environmental Leaders Praise Bill Wehrum EPA Nomination

Wehrum Nominated to Head Air and Radiation Office

09/07/2017

CONTACT: press@epa.gov

WASHINGTON (September 7, 2017): Today, President Donald J. Trump announced his intention to nominate Bill Wehrum to serve as EPA Assistant Administrator for the Office of Air and Radiation (OAR). Mr. Wehrum has a long history of public service, and previously served as EPA's acting assistant administrator for Air and Radiation from 2005 to 2007 and as EPA's principal deputy assistant administrator and counsel to the assistant administrator for Air and Radiation. He is currently partner and head of the Administrative Law Group at Hunton & Williams LLP where his practice focuses on air quality issues. Mr. Wehrum's career includes over 31 years working in the environmental field through engineering, legal practice, and administrative duties.

His nomination is receiving high accolades from environmental leaders across the country:

Sean Alteri, director, Kentucky Division for Air Quality and 2017 president of the Association of Air Pollution Control Agencies: "Considering his education and experience as a chemical engineer and an environmental attorney, Mr. Wehrum will be well-positioned to provide clear, concise direction to address the many diverse, complex air quality issues. As a student of the Clean Air Act, Mr. Wehrum's knowledge and experience will greatly benefit EPA, state, and local air pollution control agencies. We look forward to working with Mr. Wehrum and EPA's senior leadership to improve air quality in Kentucky and throughout our nation. The Kentucky Division for Air Quality supports Mr. Wehrum's nomination to serve as the assistant administrator of EPA's Office of Air and Radiation."

John Cruden, president-elect of the American College of Environmental Lawyers and assistant attorney general, Environment and Natural Resources Division, U.S. Department of Justice (12/2014-1/2017): "I have worked with Bill Wehrum while he was a senior official at EPA during the Bush Administration, and have followed his impressive career in private practice. I believe he is committed to achieving clean air for all citizens and carefully following sound and current science."

Jeff Holmstead, assistant administrator, Office of Air and Radiation, EPA (2001 –2005): "Bill is committed to the goals of the Clean Air Act and to the rule of law. He is also a person of the highest integrity. I am confident that, within the framework established by Congress, he will work to protect public health and the environment while at the same time pursuing regulatory reforms that will reduce unnecessary regulatory burdens. Truly, there is no better person to serve as the assistant administrator of EPA's Office of Air and Radiation."

Marcus Peacock, EPA deputy administrator (08/2005 – 01/2009): "Bill Wehrum's understanding of the Clean Air Act may be second to none. His desire to pull up his sleeves and actually make the Clean Air Act work as a practical matter is second to none."

Clint Woods, executive director, Association of Air Pollution Control Agencies: "Through his comprehensive knowledge of the law and experience in the federal government, Bill possesses the background to manage challenging Clean Air Act issues at U.S. EPA and help continue the tremendous air quality progress that has been achieved in our country over the last several decades. Under his leadership, the Office of Air and Radiation will be well-situated to pursue a back-to-basics agenda grounded in cooperative federalism."

LAST UPDATED ON SEPTEMBER 7, 2017

Senator BARRASSO. Senator Inhofe.

Senator INHOFE. Thank you, Mr. Chairman.

During the first round of questions I was critical of the previous administration, Mr. Wehrum, for not following the law. It was ruled that they were not accurately following the law in terms of coming out with the costs and evaluations of various emissions standards, and you said that you would comply with the law if that happens.

But there is another condition that they have where they had not been complying with the law, and that is the Clean Air Act also calls for the Clean Air Scientific Advisory Committee to evaluate implementation issues related to air quality standards. Yet, that wasn't done.

Should it have been done, and will it be done, if you are confirmed?

Mr. WEHRUM. Senator, CASAC has a role specified by statute and advising the Administrator on setting national ambient air quality standards, and there has been a suggestion that CASAC has not been implementing its complete, full set of obligations, focusing only on certain aspects of the job and not others, so I believe it is important for CASAC to fulfill its complete role, sir.

Senator INHOFE. OK.

Mr. Dourson, I have 20 kids and grandkids, and you have a bunch out there, too, and despite what the critics think, we want them to grow up in a healthy environment. I care about the world we are going to leave behind for them, and you, too, are a father and grandfather, and I imagine that your family is a big driver for you in your work over the last 38 years. What led you to pursue this field, and why do you want this job?

Mr. DOURSON. Thank you very much for the question. No, what led me to this field was some time in West Africa with a medical doctor, and I got enamored with the idea of preventive medicine. So after school, graduate school, I went into toxicology. It was funded by the U.S. Government on a stipend. I learned that this particular area was preventive medicine, and so I became enamored with that.

To fulfill my duties of the stipend, I started working with U.S. EPA immediately thereafter, and I have grown to admire the people of the U.S. EPA, and of course, I have had the good time to work with a non-profit organization since then. So, in each of these cases it is the lifelong career objective of protecting the American people and their sensitive individuals and the environment from chemical pollution.

Senator INHOFE. Out of curiosity, where in West Africa was it?

Mr. DOURSON. Liberia, West Africa, before the wars. It was a very peaceful country.

Senator INHOFE. Yes, I know that. When we met in the office last month, you said of your non-profit that only a third of the research was at the request of industry. What was the majority of the organization's work focused on?

Mr. DOURSON. Two-thirds of our work is government organizations, over 70 different government organizations. And also a big part of the work is collaborative opportunities. So we worked with government and industry often in collaborative modes. Many of the

chemicals that came up before where all these numbers were up or down, or something like that, were collaborative ventures, including government and other groups.

Senator INHOFE. Were you involved in pro bono type work? It is my understanding that some 10 percent to 20 percent of TERA's work was also pro bono. Can you provide us with an example of pro bono work?

Mr. DOURSON. Yes. Thank you, Senator. So, when we started TERA, we did this free State help, what we call it SHELP, State Hazard Evaluation Lending Program, and we gave free assistance to any State. We have worked with many States in that capacity.

Another example of scientific societies, the one that is most fulfilling to me is we are a public organization; we have members of the public come in. We had a young mother come in to my office 1 day. She was distraught. No one had been listening to her; she had nowhere to turn. She went to the Web, found our site. As she relayed her story, her family had been poisoned, and it became obvious to me that the poisoning was likely to be hydrogen sulfite, which is a very serious poison. Her four children were affected; her horses were affected; the dogs were dead. I mean, it was a really pretty severe case.

So, after a little bit additional study, we were able to get her the medical attention and then the legal support that she needed to carry on, and that made the local news several times. That was very gratifying, although, honestly, dealing with the public one on one like that is not always the most direct part of our pro bono.

Senator INHOFE. Well, good for you.

Mr. Leopold, you have worked on several large scale environmental issues in your time in private practice and on behalf of the State of Florida. Could you give us a quick overview of these and your work on these issues?

Mr. LEOPOLD. Thank you, Senator. Yes, I have been fortunate to work on some of the biggest environmental cases going. I am very proud that I worked on the BP oil spill enforcement case, spent a couple years helping the Justice Department hold BP accountable for that spill and resulted in the biggest Clean Water Act penalty in U.S. history.

Also, the Everglades litigation. I helped support the State of Florida in advancing restoration on the Everglades.

So those are two of the big ones.

Senator INHOFE. Good.

Thank you, Mr. Chairman.

Senator BARRASSO. Senator Merkley.

Senator MERKLEY. Thank you, Mr. Chairman.

Mr. Wehrum, do you believe with high confidence that human activity is a major driver of climate change?

Mr. WEHRUM. Senator, I am sorry, your question, I didn't hear——

Senator MERKLEY. Do you believe with high confidence that human activity is a major driver of climate change?

Mr. WEHRUM. I think human activity contributes to climate change, Senator, yes.

Senator MERKLEY. When you say yes, do you believe it the major driver of climate change?

Mr. WEHRUM. I believe that is an open question, Senator.

Senator MERKLEY. That is certainly the type of answer that we hear continuously. That is the coached answer that the Koch brothers are asking people to sew this uncertainty, so we have seen that in answer after answer that comes before this Committee, such as statements from Mr. Pruitt, statements from Mr. Tillerson, statements from Mr. Perry, all citing this, oh, we are just not sure if it is significant or not. Maybe it is contributing, but we are just not sure if it is significant.

So let's take a look at the NASA charts. I am going to put up a chart that shows NASA's evaluation of the contribution of solar energy. We see the yellow line on this chart, the flat line that goes across. Virtually no variation over the course of 125 years. And we see the enormous variation in the climate. Do you see any correlation, significant correlation between the yellow line and the black line?

Mr. WEHRUM. Senator, I have no idea what that depicts.

Senator MERKLEY. Well, I just explained it to you, so let's try it again. I think you are supposed to have a background capable of understanding this sort of thing. Solar energy, temperature of the planet. NASA statistics. Does there appear to be any correlation between those two lines?

Mr. WEHRUM. Senator, I will respond to you as I did to questions on the renewable fuel standard. These are very complex issues, and they are very important issues, and I understand that they are important to you, so——

Senator MERKLEY. OK, thank you. We will go on to the next question, because anyone slightly familiar with statistics would say a flat line and a rising line do not show correlation.

Another argument is that volcanic activity, the Earth's orbit, as well as solar activity contribute. That is what NASA has compiled collectively under the bottom chart. We have the natural factors, those three that I just summarized, and then we have the rising temperature in the black line. Does there appear to be any correlation in this case?

Mr. WEHRUM. Again, Senator, I will say I am not familiar with those data; I have no idea what it shows.

Senator MERKLEY. OK. Well, if you can't read a chart, are you qualified to have this role?

Mr. WEHRUM. Senator, what is important is to understand the data underlying the depiction, and I have had no opportunity to see those data or understand how they have been depicted.

Senator MERKLEY. You have been working in air pollution for these decades, and you have no acquaintance with data related to the warming of the planet or the factors that contribute to that?

Mr. WEHRUM. Senator, all I said is I have no idea what data contributed——

Senator MERKLEY. OK. Well, let's turn to the third chart, then. NASA has compiled a third chart. This one, again, shows the rising temperature in the same color, in black, and it shows the rising greenhouse gas emissions. Can you, without great familiarity, acknowledge that these lines generally track each other?

Mr. WEHRUM. Once again, Senator, I am not familiar with those data; I have no idea what it depicts.

Senator MERKLEY. You can see the lines. Do the lines track each other?

Mr. WEHRUM. What is important, Senator, is to know how the data are depicted. Understanding the underlying data and understanding the——

Senator MERKLEY. Yes, it is, but I am just asking you a question. Can you see those two lines and do they generally track each other?

Mr. WEHRUM. Well, again——

Senator MERKLEY. OK, thank you.

What we have seen is this Koch Brother inspired determination not to acknowledge even the most fundamental facts, and continuous excuses that perhaps the temperature of the climate is going up because of solar activity. Oh, no. No, wait, maybe it is volcanic activity. But when NASA presents the information that shows there is no correlation from those factors, and extensive correlation from carbon dioxide and other global warming gases, individuals like you simply refuse to acknowledge it.

Why should the American people put into an office of significant influence someone who refuses to look at the facts directly that are so important to the health of this planet?

Mr. WEHRUM. Senator, as I said a second ago, these are complex issues and very important issues, and I commit myself, if confirmed, to speak——

Senator MERKLEY. Do you think on such a serious—so, in Oregon we have lost a billion oysters due to the increasing acidity of the ocean that is caused by carbon dioxide becoming carbonic acid. Are you familiar with this problem? Yes or no, are you familiar with the increased acidity?

Mr. WEHRUM. I am not familiar with the oyster industry in Oregon, no, sir.

Senator MERKLEY. Are you familiar with the increasing acidity of the ocean?

Mr. WEHRUM. I understand there is an allegation that——

Senator MERKLEY. Oh, my goodness. You have to be kidding me. Really?

Mr. WEHRUM. I understand——

Senator MERKLEY. You are in this field and you have never read anything about the increasing acidity of the ocean? Well, how about the fact that we have a fire season that is 2 months longer than it was 4 years ago? Are you familiar with the growing length of the fire season?

Mr. WEHRUM. I have not——

Senator MERKLEY. Are you familiar with the extending range of pine beetles that are having a devastating impact on our forests and creating an area that you can fly over called the red zone?

Mr. WEHRUM. As I said, Senator——

Senator MERKLEY. Are you familiar with the snow pack in the Cascades? All of these things, no one can look at what is happening on the planet and see that there is nothing happening unless you are deliberately determined to ignore that information, and that makes you really, quite frankly, unacceptable to serve in this capacity.

Thank you, Mr. Chairman.

Senator BARRASSO. Senator Carper.

Senator CARPER. Mr. Chairman, I have a unanimous consent request to enter an op-ed written by Senator Whitehouse that is in my hands, and I would like to ask unanimous consent to be inserted into the record.

Senator BARRASSO. Without objection.

Senator CARPER. Thank you.

[The referenced information follows:]

About membership
Sign in / Sign up



Sheldon Whitehouse
U.S. Senator from Rhode Island, the Ocean State.
Oct 4 · 4 min read

The Corporate Capture of EPA

Anyone who thinks the Environmental Protection Agency should care about public health more than corporate wealth should tune in to today's Senate Environment and Public Works Committee nominations hearing. You'll get to watch the capture of EPA by regulated industries in real time. This ever-deepening reach of corporate interests into our environmental regulator will have consequences for this generation and those to come.

The tone at EPA is set from the top. Administrator Scott Pruitt has a long record of dark money fundraising and cozy relationships with big fossil fuel political donors. Oil and gas giant Devon Energy, for example, has been a generous supporter of Pruitt's campaigns. While Pruitt was in leadership positions with the Republican Attorneys General Association and its predecessor, the Republican State Leadership Committee, Devon give these entities almost one million dollars.

Thanks to Pulitzer Prize-winning reporting by the *New York Times*, we know that backing Pruitt was a good investment. In 2011, then-Attorney General Scott Pruitt took a letter written by Devon Energy, put it onto his Oklahoma Attorney General letterhead,



Never miss a story from **Sheldon Whitehouse**, when you sign up for Medium. Learn more

specifically benefit long-time Pruitt benefactor Devon Energy.

We still don't know the full depths of Pruitt's ties to industry. Senate Republicans jammed his nomination through without demanding answers to questions raised by me and my Democratic colleagues on the Environment and Public Works Committee. And now, 229 days after he was sworn in Administrator, we still wait for Chairman John Barrasso to bring Pruitt before the Committee for an oversight hearing.

After Pruitt's sham of a confirmation, it's no surprise that industry feels free to jam through a slew of industry cronies. Michael Dourson is a prolific industry-funded "scientist" and a key architect of the industrial climate change denial apparatus. In 2012, the Center for Progressive Reform released "Cozying Up: How the Manufacturers of Toxic Chemicals Seek to Co-opt their Regulators." The report detailed the work Toxicology Excellence for Risk Assessment, the "non-profit organization Dourson founded, has done to undermine public health protections." It also found a third of the group's revenue came directly from industry, with another 30 percent coming from "non-profit sources often dependent upon chemical manufacturer support."

If confirmed, Dourson will be in charge of implementing the Frank R. Lautenberg Chemical Safety for the 21st Century Act. He will have the final say over which and how many chemicals are deemed high priority, which uses are considered in risk evaluations, and the stringency of the safety requirements EPA sets for chemicals found to be unsafe. Consumers deserve to be confident that the chemicals in everyday products are safe; they won't have that confidence with Dourson at the helm.

Bill Wehrum has been nominated to serve as EPA's top air official. Wehrum's clients are a who's-who of polluting industry, including the American Petroleum Institute, Koch Industries, American Fuel & Petrochemical Manufacturers, and the Utility Air Regulatory Group. Wehrum's firm, Hunton and Williams, directly contributed to Scott Pruitt's attorney general campaign and gave over $200,000 to RAGA and the

Republican State Leadership Committee.

Through documents produced from Oklahoma Open Records Act requests, we know that Hunton and Williams staff worked with Attorney General Pruitt and industry to get other state attorneys general to oppose EPA's carbon pollution standards for new power plants. Hunton and Williams attorneys also counseled Pruitt's staff on who to approach about signing on, and coached them on how and when to submit the comments.

Wehrum fought EPA's Mercury and Air Toxics Standard, Clean Power Plan, Cross-State Air Pollution Rule, methane standard for new oil and gas development, greenhouse gas reporting rule, and many other environmental protections. If confirmed he'll be in charge of them.

Americans trust the EPA to protect the water we drink and the air we breathe, and to police the chemicals and pesticides to which we're exposed. They should also trust Congress with protecting EPA from being captured by the industries that it regulates.

We've seen too often what happens when wealthy and powerful industries gain excessive influence over the agencies that regulate them. The capture of the Minerals Management Service at the Department of Interior contributed to the oil spill in the Gulf of Mexico in 2010. The Securities and Exchange Commission and other bank regulators looked away as financial services companies created exotic and irresponsible financial products that took our economy to the brink of collapse in 2008.

Regulators who are in the tank won't do their jobs. If we continue to look the other way when nominees like this come before the Senate, we can expect scandals and recurring disasters in the future. That's no way to govern. Regulators owned and controlled by industry are not the American way.



Senator CARPER. I would also like to ask unanimous consent to insert a number of other letters and articles about today's nominees into the record, please.

Senator BARRASSO. Without objection.

Senator CARPER. Thank you.

[The referenced information follows:]

Portfolio Media. Inc. | 111 West 19th Street, 5th floor | New York, NY 10011 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Hunton & Williams Scores EPA Bigwig

By **Anne Urda**

Law360, New York (September 19, 2007, 12:00 AM EDT) -- Continuing to bulk up its environmental law department, Hunton & Williams LLP has snagged a former bigwig at the U.S. Environmental Protection Agency to help further the group's ongoing expansion.

On Wednesday, Hunton & Williams revealed that Bill Wehrum had joined the firm's Washington, D.C. office, where he will serve as a partner in the resources, regulatory and environmental law practice.

"With Bill's experience at EPA, he brings a unique perspective to the problems companies face," said Hunton & Williams partner F. William Brownell, co-head of the firm's resources, regulatory, and environmental law practice. "He will be an invaluable resource for our clients seeking to navigate an increasingly complex regulatory process."

The new hire gives even more heft to an administrative/regulatory practice area that already stands at 115 strong, with half of those devoted exclusively to environmental issues, according to the firm.

Though Wehrum began his career as an environmental engineer for a major U.S. chemical manufacturer and then headed into private practice, the latest Hunton & Williams addition hails most recently from the EPA.

Wehrum started his six-year gig there by serving as chief counsel for the Acting Assistant Administrator for Air and Radiation before assuming the role himself for the past two years.

During his tenure, Wehrum helped to draft and implement the Clean Air Interstate Rule and the Clean Air Mercury Rule, helped revise the EPA's New Source Review permitting program, review and revision of the National Ambient Air Quality Standard for particulate matter, helped put into place federal fuel and emissions standards for heavy duty highway vehicles, and proposed emissions standards for locomotives and marine engines, according to the firm.

Though he views his stint at the EPA as priceless, Wehrum is looking forward to returning to the private sector and tackling the new set of challenges that will accompany this shift.

"I had been at the EPA for six years when I left the agency in June," he said. "I felt like that was a good long run. I had a great experience at the agency but I knew I always wanted to return to the practice of law and this was the right time."

In his new legal home, Wehrum will focus his attention once again on air quality issues, with a particular emphasis on compliance counseling, permit negotiations and regulatory and legislative advice.

Wehrum believes that Hunton & Williams will be the right fit on both a professional and personal level.

"Hunton & Williams has always been a great law firm, and they have a very large and successful environmental practice so from a substance standpoint, it was a really nice match," he said.

In addition to the firm's well-respected reputation in the field, part of Hunton & Williams' appeal for Wehrum arose out of past dealings with his future colleagues.

"They are great lawyers and great people," he said. "That was a big attraction."

With the U.S. Supreme Court's recent ruling in the Massachusetts v. EPA case and other important regulatory cases pending, Wehrum and the other members of the environmental group will likely have their hands full in the coming years.

"The Clean Air Act is the statute that just keeps on giving," he said. "It's been almost 20 years since the Clear Air Act was last amended but there continue to be a series of issues that spin off the Act. I think it's going to be a source of work for a lot of people for a long time to come."

To that end, Wehrum believes that his tenure at the EPA will prove to be important as he settles into his new role at Hunton & Williams.

"I'm a much better lawyer now than when I first joined the agency," he said. "To really get to know how the agency works and how it ticks, I think that is very valuable. I have expanded my capabilities which will hopefully allow me to be effective in generating business and clients."

All Content © 2003-2017, Portfolio Media, Inc.

THE LEADER IN ENERGY AND ENVIRONMENT NEWS

REGULATIONS

'People are designed to deal with dust' — EPA air nominee

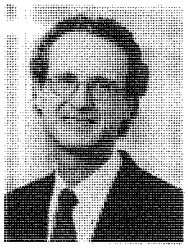
Amanda Reilly, E&E News reporter

Published: Tuesday, September 26, 2017

President Trump's pick to head U.S. EPA's air office attempted today to poke holes in the scientific justification for Obama administration standards meant to protect workers from inhaling tiny and sometimes deadly silica particles.

Representing industry challengers, attorney William Wehrum in part argued that people had "physiological mechanisms" to deal with dust at the levels that the Occupational Safety and Health Administration says are harmful and cause respiratory diseases.

"People are designed to deal with dust," Wehrum said. "People are in dusty apartments all the time and it doesn't kill them."



William Wehrum. Hunton and Williams LLP.

Wehrum was one of eight attorneys to argue today over the future of the Obama administration's silica standards. A three-judge panel of the U.S. Court of Appeals for the District of Columbia Circuit heard more than two hours of arguments in a packed courtroom.

Earlier this month, Trump nominated Wehrum, who leads the administrative law group at Hunton & Williams LLP, to serve as assistant administrator for EPA's Office of Air and Radiation.

Wehrum is a former EPA official in the George W. Bush administration, joining EPA as counsel in 2001 and becoming acting air chief in 2005. Bush nominated Wehrum to serve permanently, but his record came under biting attack by Democrats and he was never confirmed.

Environmentalists have opposed Wehrum's nomination to the top air office position, where he would be in charge of unraveling some of the Obama administration's signature air rules. He has yet to go through his Senate confirmation hearing (*E&E Daily*, Sept. 20).

The focus of today's arguments was not an EPA regulation but rather a rule issued by the Department of Labor's OSHA in 2016.

In its rule, OSHA decreased the 1971 exposure limit to silica particles from 100 micrograms of respirable crystalline silica per cubic meter of air for general industry to 50 micrograms, which it said would substantially reduce the risk of public health impacts. The Obama administration also increased protections in all affected industries, with exceptions for some agriculture practices (*Greenwire*, March 24, 2016).

Crystalline silica is ubiquitous in construction and manufacturing industries around the world. It's a major component of most building products, including brick, concrete, shingles and ceramic tile, and is present in crushed stone and gravel used to construct roads.

But inhaling tiny silica particles can cause health problems, including silicosis, respiratory diseases such as COPD, lung cancer and kidney disease.

According to OSHA, the new standard would prevent 642 deaths and 918 silica-related illnesses a year, with a monetized annual benefit of $8.6 billion. In all, the rule was expected to affect nearly 700,000 facilities in the United States and more than 2.3 million workers.

Dozens of industry entities and trade unions sued over the rule, which became effective in June 2016 with phased-in compliance deadlines. A special judicial panel on multidistrict litigation sent the consolidated challenges to the D.C. Circuit.

'Significant risk'

Industry calls the rule "one of the most far-reaching health standards promulgated by OSHA in the last two decades."

One of industry's main arguments is that OSHA failed to show that there's a significant risk at exposure levels of 100 micrograms and that lowering the limit to 50 micrograms for general industry will substantially reduce health risks.

"We believe that when you take a hard look, in fact, their level of proof doesn't rise to the level of substantial evidence," said Wehrum, who's representing the Brick Industry Association and National Stone, Sand & Gravel Association in the litigation.

The groups have accused OSHA of cherry-picking data from studies to support a policy choice to lower the standard.

"We assert that OSHA had a thumb on the scale," Wehrum said.

They also say OSHA's analysis was flawed because it made the "unsupportable assumption" that there's no threshold exposure level of silica-related respiratory disease. In other words, OSHA assumed there's no exposure level at which a person will not become ill and that people will become ill and die at levels below 50 micrograms.

OSHA "predicts bodies in the streets," Wehrum said, adding that "objective evidence" doesn't support the conclusion.

He also pointed to trend lines showing that deaths related to silicosis have fallen more then 90 percent between the early 1970s, when the country's first silica standard was put in place, and 2010.

"Common sense" says that the current standard "seems to be working," he argued.

But D.C. Circuit Chief Judge Merrick Garland appeared skeptical. "There are scientists that believe the opposite of you," he said.

Garland, who presided over today's arguments, noted that on issues where there's a legitimate scientific dispute, it's "perfectly appropriate" for OSHA to weigh in favor of more protections for workers.

Judge David Tatel, a Clinton appointee, also took issue with arguments presented by the U.S. Chamber of Commerce on death certificate data kept by the Centers for Disease Control and Prevention. Michael Connolly, an attorney representing the U.S. Chamber, argued that the data "fundamentally undermines" the new standard because it shows an "enormous decline" in silicosis deaths.

But Tatel called OSHA's argument "logical" that the data represent a decline in workforce participation during that time.

Kristen Lindberg, a senior attorney at OSHA, urged the court to uphold the standards.

"Industry petitioners want you to reject conclusions that have overwhelming support among scientists," she said.

Feasibility

Industry's other key argument is that the rule is neither technologically nor economically feasible for the foundry, hydraulic fracturing and construction industries. OSHA says control technologies are widely available, but industry says the agency never identified how the lower standard could be met and whether employers can even achieve it at all.

The new standard "will serve only to impose enormous new costs on industry with no cognizable health benefits for workers at all," the groups said in a court brief.

In the construction industry, the standard cannot be met most of the time by engineering controls, meaning workers will frequently have to wear respirators, said Bradford Hammock, an attorney at Jackson Lewis, arguing on behalf of industry trade groups.

Hydraulic fracturing is another industry that's significantly affected by the rule. Drillers inject silica sand to drive out oil.

OSHA estimated that it would cost hydraulic fracturing operations 0.56 percent of their annual revenues, or 7.94 percent of annual profits, to meet the new standards. The agency identified certain controls, including exhaust ventilation and passive dust collection systems, to lower silica dust.

Other technologies are under development and can be widely implemented within the five-year compliance deadline for the sector, OSHA says. But industry contends that OSHA underestimated compliance costs and that control technologies are not on the "horizon."

At the arguments today, judges dug into the competing studies, models and mathematic calculations presented by industry and OSHA on the rule's costs, technologies and variability among operations.

Judge Karen LeCraft Henderson, a George H.W. Bush appointee who was otherwise relatively quiet during the arguments, saved one of her few questions for the rule's impact on hydraulic fracturing. At the time of the rule, OSHA found that many operations hadn't yet met the previous standard of 100 micrograms.

"How are they doing so far?" Henderson asked.

Lauren Goodman, an OSHA attorney, said control technologies were being rolled out but conceded that there was limited data. She said standards can be "technology forcing."

Later, she pushed back on industry's arguments over the economic feasibility of the rule.

"An OSHA rule is not infeasible just because it is costly or even very costly," Goodman said. Judges could only find an OSHA rule is economically infeasible "if it threatens the downfall of an entire industry," she said.

Union challenges

Labor unions intervened in the litigation on behalf of OSHA but also filed their own challenges to the rule. Unlike industry, they argue that the rule is too weak.

At issue: OSHA's decision not to protect workers from losing pay if a doctor recommends they be removed from a job due to silica exposure. Unions are also protesting the rule's medical surveillance requirements for construction workers.

"OSHA was required to do more to protect the hundreds of thousands of workers who continue to face significant health risks from exposure to silica under the new standard," the unions said in a court brief.

Twitter: @apeterka | Email: areilly@eenews.net

Advertisement

The essential news for energy & environment professionals

© 1996-2017 Environment & Energy Publishing, LLC Privacy Policy Site Map

Opinion EDITORIAL

Dubious Choices

APRIL 24, 2006

President Bush has asked the Senate to approve nominees for two important federal posts with great influence over environmental policy. Neither candidate is particularly good news. One should certainly be rejected.

Mr. Bush has nominated William Wehrum to succeed Jeffrey Holmstead to head air pollution programs at the Environmental Protection Agency. The Holmstead era produced several positive initiatives. But it will be remembered chiefly for its efforts to weaken the Clean Air Act (particularly with respect to rules governing mercury emissions and older power plants), to manipulate science and to elevate corporate interests above those of the public.

Mr. Wehrum, who served as Mr. Holmstead's deputy and doctrinal hit man, could make things worse. Opposition to his nomination has been huilding rapidly in the Senate Environment and Public Works Committee, where the vote could break largely along party lines. If it does, the nomination may hinge on two senators whose views on Mr. Wehrum are not known: James Jeffords, an independent from Vermont and a consistent critic of the administration's clean air policies, and Lincoln Chafee, an environmentally inclined Republican moderate from Rhode Island.

The second controversial nominee is Dirk Kempthorne, the Idaho governor who is Mr. Bush's choice to succeed Gale Norton as secretary of the interior. Mr. Kempthorne, a former senator, is sure to be approved despite a poor environmental record.

Perhaps his experience in the Senate, with its tradition of give-and-take, will make him more amenable to compromise than the ideologically driven Ms. Norton, who tended to favor commercial interests at the expense of publicly

owned resources and who acquiesced in a series of disastrous cuts in conservation programs.

OFFICE OF INSPECTOR GENERAL

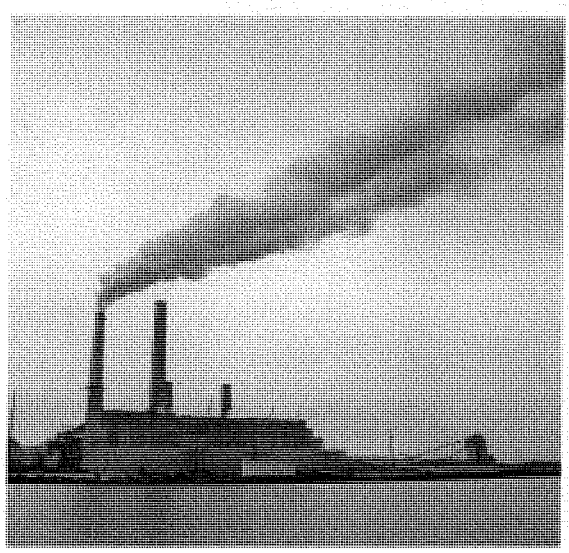
Catalyst for Improving the Environment

Evaluation Report

Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities

Report No. 2005-P-00003

February 3, 2005



Report Contributors:

Rick Beusse
Carolyn Blair
Hilda Canes
Sarah Fabirkiewicz
James Hatfield
Erica Hauck
James Huber

Abbreviations

CAA	Clean Air Act
CAIR	Clean Air Interstate Rule
CHPAC	Children's Health Protection Advisory Committee
EPA	Environmental Protection Agency
FACA	Federal Advisory Committee Act
OIG	Office of Inspector General
ICR	Information Collection Request
IGCC	Integrated Gasification Combined Cycle
IPM	Integrated Planning Model
OMB	Office of Management and Budget
MACT	Maximum Achievable Control Technology
NTEC	National Tribal Environmental Council
NO_X	Nitrogen Oxide
OCHP	Office of Children's Health Protection
SO_2	Sulfur Dioxide

Cover photo: Virginia Electric Power Company's coal-fired plant at Mt. Storm, West Virginia.
Source: http://www.oag.state.ny.us/press/2000/nov/nov16a_00_pictures.html

U.S. Environmental Protection Agency
Office of Inspector General

2005-P-00003
February 3, 2005

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

Members of the Senate Environment and Public Works Committee requested that we review EPA's development of its proposed rule for controlling mercury emissions from coal-fired electric utilities.

Background

Coal-fired electric utilities represent the largest source of airborne mercury emissions in the United States. Once airborne, mercury can be deposited into water, where it bio-accumulates in fish and animals at the top of the food chain. Human consumption of fish is the primary method of exposure to mercury, which has been shown to cause neurological and fetal developmental problems.

On January 30, 2004, EPA proposed rules for regulating mercury emissions from coal-fired steam generating electric utility units. EPA proposed two options for controlling mercury emissions, one a control technology standard with emission limits and the other a performance based cap-and-trade approach.

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link: www.epa.gov/oig/reports/2005/20050203-2005-P-00003.pdf

Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities

What We Found

Evidence indicates that EPA senior management instructed EPA staff to develop a Maximum Achievable Control Technology (MACT) standard for mercury that would result in national emissions of 34 tons annually, instead of basing the standard on an unbiased determination of what the top performing units were achieving in practice. The 34-tons-per-year target was based on the amount of mercury reductions expected to be achieved from implementation of nitrogen oxide (NOx) and sulfur dioxide (SO_2) controls under a separately proposed, but related, air rule. According to EPA officials, 34 tons represents the most realistic and achievable standard for utilities. However, because the results of the MACT standard were prescribed and prior estimates were lower than what was proposed, the standard likely understates the average amount of mercury emissions reductions achieved by the top performing 12 percent of utilities, the minimum level for a MACT standard required by the Clean Air Act. Further, this MACT standard, as proposed, does not provide a reasonable basis for determining whether the MACT or cap-and-trade approach provides the better cost benefit.

The Agency's cap-and-trade proposal can be strengthened to better ensure that anticipated emission reductions would be achieved. For example, utilities would not need to install mercury-specific controls to achieve the interim cap, but could meet the cap by implementing NOx and SO_2 controls associated with another proposed trading program. Also, the proposal does not adequately address the potential for hot spots. Further, provisions for units emitting small amounts of mercury could be improved.

We also found that EPA's rule development process did not comply with certain Agency and Executive Order requirements, including not fully analyzing the cost-benefit of regulatory alternatives and not fully assessing the rule's impact on children's health.

What We Recommend

We recommend that EPA re-analyze mercury emissions data collected for the top performing 12 percent of units to develop a MACT floor. The Agency should also conduct a revised cost-benefit analysis for the updated MACT that takes into account the impact of mercury co-benefits achieved through the proposed Clean Air Interstate Rule. The results of the cost-benefit review should be compared to the cost-benefit of the proposed cap-and-trade option to determine the most cost beneficial option for controlling mercury emissions. We also recommend that EPA strengthen its cap-and-trade proposal by more fully addressing the potential for hot spots; revising the safety valve proposal so that it is used only as intended during periods of unanticipated market volatility; and revising the proposed exemption for small emitters. Further, we recommend that the Agency conduct more in-depth analyses of the regulatory alternatives and children's health impacts as required by Executive Orders. The Agency's response to the draft report did not specifically address our recommendations, but raised concerns about certain aspects of the report.

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

THE INSPECTOR GENERAL

February 3, 2005

MEMORANDUM

SUBJECT: Evaluation Report: Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities
Report No. 2005-P-00003

TO: Jeffrey R. Holmstead
Assistant Administrator for Air and Radiation

This memorandum transmits the results of an Office of Inspector General (OIG) evaluation regarding the Environmental Protection Agency's (EPA) development of the proposed rule for regulating mercury emissions from coal-fired steam generating electric utility units. This report contains findings that should help EPA in its efforts to develop the final rule. Also, the report contains corrective actions the Office of Inspector General (OIG) recommends. This report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final EPA position. Final determinations on matters in this report will be made by EPA managers in accordance with established procedures.

Action Required

In accordance with EPA Directive 2750, as the action official, you are required to provide this Office with a written response within 90 days of the final report date. The response should address all recommendations. For the corrective actions planned but not completed by the response date, please describe the actions that are ongoing and provide a timetable for completion. Where you disagree with a recommendation, please provide alternative actions for addressing the findings reported.

We appreciate the efforts of EPA officials and staff in working with us to develop this report. If you or your staff have any questions regarding this report, please contact me at (202) 566-0847 or Kwai Chan, Assistant Inspector General for Program Evaluation, at (202) 566-0827.

Nikki L. Tinsley

Attachment

cc: Steve Johnson, Acting Administrator
William Farland, Acting Deputy Assistant Administrator for Science, ORD
Ann Klee, General Counsel
Pete Cosier, Audit Followup Coordinator, OAR
Kwai Chan, Assistant Inspector General for Program Evaluation, OIG
Mark Bialek, Counsel, OIG

Table of Contents

At a Glance

Chapters

1 **Introduction** 1

Purpose 1
Background 1
Scope and Methodology 8
Results in Brief 10

2 **Mercury MACT Development Compromised** 11

Requirements for MACT Standards 11
EPA's Process for Addressing Variability in Computation of Mercury MACT Floor 12
EPA Staff Instructed to Develop MACT Floor That Would Result in National Emissions of 34 Tons 13
Conclusions 16
Recommendations 16
Agency Comments and OIG Evaluation 16

3 **Cap-and-Trade Option Can Be Strengthened** 18

EPA's Proposed Cap-and-Trade Approach 18
Proposed Cap-and-Trade Program Needs to Further Address Certain Issues 19
Proposed Emissions Trading Rule Should Also Address Tribal Concerns 24
Conclusions 25
Recommendations 25
Agency Comments and OIG Evaluation 26

4 **Rule Development Process Not Consistent with Expected and Past Practices** 27

Description of Rulemaking Process 27
Some FACA Members Considered Job Unfinished 28
Intra-Agency Review Limited 30
Requirements for Cost-Benefit Analyses Not Fully Implemented 32
Required Children's Health Analysis Not Completed 33
Scope Limitations: Inter-Agency Review 34
Conclusions 35
Recommendations 35
Agency Comments and OIG Evaluation 35

Appendices

A Timeline of Events Related to Development of Mercury Rule 37

B OIG's Request for Documents Related to Development of Utility MACT 39

C Different MACT Floor Proposals 43

D EPA's Rule Development Process 44

E Agency Comments to the Draft Report and OIG Evaluation 46

F Distribution 54

Chapter 1
Introduction

Purpose

The Office of Inspector General (OIG) initiated this review based on a request from members of the Senate Environment and Public Works Committee. In their written request, the Senators expressed concerns with the process used to develop the Environmental Protection Agency's (EPA's) January 2004 proposed rule for regulating mercury emissions from coal-fired steam generating electric utility units. The proposed rule included two different options for regulating mercury emissions. One approach was a Maximum Achievable Control Technology (MACT) standard that would establish emission limits applicable to all coal-fired utility units. The other approach was a mercury cap-and-trade approach that would establish a national cap on mercury emissions and allow individual utilities to trade emissions allowances in a market-based system. The objectives of our evaluation were to determine:

- Do the data and analyses in the docket demonstrate that the proposed MACT option reflects the maximum achievable reductions from coal-fired steam generating electric utility units?
- Is the mercury cap-and-trade option, as proposed, sufficient to ensure public health protection?
- What process did EPA follow in developing the proposed rule, and was this process consistent with applicable statutes, regulations, policy, guidance, and past Agency practice?

Background

Mercury is released globally into the environment through natural processes, such as volcanoes, and also from human activity. Man-made releases of mercury are primarily due to the burning of mercury-containing fuels and wastes, and through industrial manufacturing processes. Man-made mercury emissions from the United States are estimated to account for roughly 3 percent of total global mercury emissions. Mercury from lead smelters, municipal waste combustors, hospital waste incinerators, manufacturing operations, and other sources are largely already regulated by EPA. In the United States, the largest source of airborne mercury emissions is the coal-burning electric utilities industry, representing an estimated 40 percent of total U.S. man-made airborne mercury

emissions. EPA has estimated that one-third of all U.S. emissions of mercury are deposited within the contiguous United States, while the remaining two-thirds enter the global cycle. The January 2004 proposal is the first attempt to regulate mercury emissions from these utilities at the Federal level.

Airborne concentrations of mercury are generally considered to be small and not a serious health concern while still in the air. However, once mercury enters fresh-water and salt-water bodies, either directly or through air deposition, it can bioaccumulate in fish and other animal tissues in its more toxic form, methylmercury. As mercury bioaccumulates in the food chain, its concentration becomes increasingly higher in animals at the top of the food chain (such as larger predatory fish) that consume smaller contaminated organisms. Because of the bioaccumulation of methylmercury, the primary route of human exposure to mercury is through the consumption of fish, both salt water and fresh water. Excessive human exposure to mercury has been associated with severe detrimental neurological and developmental health effects. Depending on the dose, human health effects from exposure to mercury can include subtle losses of sensory and cognitive ability, tremors, inability to walk, and death. The developing fetus may be particularly sensitive to the detrimental effects of methylmercury; thus, exposure to mercury by women of child-bearing age is of particular concern.

From a global perspective, mercury accumulation in salt-water fish is a public health concern. EPA and the Food and Drug Administration have cautioned that young children, as well as women who might become pregnant, are pregnant, or are nursing should limit their consumption of certain salt-water predatory fish. Mercury bioaccumulation in U.S. water bodies is also a public health concern, and 45 States issued fish advisories for mercury in 2003. Many of these fish advisories caution that women and young children should limit their consumption of certain types of fish.

EPA Reference Dose for Methylmercury

Based on studies showing adverse health effects from exposure to methylmercury, EPA set a reference dose for methylmercury that was designed to protect the most sensitive subgroup (i.e., developing fetuses). An EPA reference dose reflects the estimate of daily exposure to the human population, including sensitive subgroups, that is not likely to cause harmful effects during a lifetime. The current EPA reference dose for methylmercury – which was included in EPA's 1997 Mercury Study Report to Congress – is 0.1 micrograms per kilogram of body weight per day.

Subsequent to EPA's 1997 Mercury Study Report to Congress, Congress directed[1] EPA to request the National Academy of Sciences to perform an independent study on the toxicological effects of methylmercury and to prepare recommendations on the establishment of a scientifically appropriate exposure reference dose. The National Academy of Sciences completed its review in 2000, and concluded that the EPA reference dose of 0.1 micrograms per kilogram was a scientifically justifiable level for the protection of health.

The most recent results from Centers for Disease Control and Prevention's ongoing National Health and Nutrition Examination Survey show that mercury blood levels of most children and women of childbearing age were below levels of concern corresponding to the EPA reference dose. However, 5.66 percent of childbearing-aged woman had blood mercury levels at or above the reference dose. The survey also questions participants about their fish consumption. For the 1999-2000 survey period, tuna and shrimp were the two most frequently cited types of fish/shellfish consumed. These results, and other studies, suggest that seafood (as opposed to fresh-water fish) is the predominant source of mercury exposure in the United States. However, some subpopulations in the United States consume more fish, including fresh-water fish, than the general population. These groups may be at increased risk from mercury exposure. For example, studies have shown elevated blood levels of mercury in some Native American tribes that consumed fresh-water fish.

Statutory Requirements for Controlling Mercury Emissions from Utility Plants

The Clean Air Act (CAA) requires EPA to regulate emissions of 188 air toxics (also known as hazardous air pollutants), including mercury. EPA was to identify and establish emission standards for major source categories emitting these pollutants. Specifically, section 112(d) of the CAA requires EPA to establish emission limits for major source categories emitting air toxics, commonly referred to as MACT standards. The MACT standard is to require the maximum degree of reductions achievable for the source category, taking into consideration cost and any non-air quality health and environmental impacts.

A key requirement of section 112(d) is that emission standards for existing sources in a category or subcategory shall not be less stringent than the average emission limitation achieved by the best performing 12 percent of the existing sources for which the Administrator has data. The emission limitation achieved by the best performing 12 percent of sources is referred to as the "MACT floor."

---

[1] H.R. Rep. No. 769, 105th Cong., 2d Sess. at 281-282 (1998). This is the Conference Report to accompany H.R. 4194, October 5, 1998.

The CAA also established specific requirements with respect to air toxics emissions from utilities. Section 112(n)(1)(A) requires EPA to perform a study of the hazards to public health that are reasonably anticipated to occur as a result of air toxics emissions from electric utility steam generating units. This study was to develop and describe alternative control strategies for emissions that may warrant regulation under section 112. Further, with respect to regulating emissions from utility plants, section 112(n)(1)(A) states:

> *The Administrator shall regulate electric utility steam generating units under this section, if the Administrator finds such regulation is appropriate and necessary after considering the results of the study required by this subparagraph.*

EPA published its Final Report[2] with respect to utilities in February 1998, but deferred making a determination as to whether regulation of these units was appropriate and necessary. However, the Final Report concluded that:

- Mercury from coal-fired utilities was the air pollutant of greatest potential concem to public health from utilities;
- Coal-fired utilities are estimated to emit about one-third (51 tons based on 1994 emissions) of U.S. anthropogenic (man-made) mercury emissions per year;
- Ingestion of contaminated fish is the most important route of exposure to mercury; and
- Modeling in conjunction with the available scientific data provides evidence for a plausible link between emissions of mercury from utilities and the methylmercury found in soil, water, air, and fish.

In its Final Report, EPA listed a number of research needs related to mercury emissions. These included obtaining additional data on mercury emissions, such as the amount emitted from various types of units; the proportion of divalent versus elemental mercury;[3] and how factors such as the control device, fuel type, and plant configuration affect emissions and speciation.

---

[2] Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units - - Final Report to Congress, EPA-453/R-98-004a, February 1998.

[3] Airborne divalent mercury is adsorbed onto particles or bound to other compounds and is deposited sooner and mainly in the vicinity of the emissions sources (local to regional distances), while elemental mercury (vapor) remains airborne longer and is transported on a hemispherical/global scale.

Information Collection Request

Based on the research needs outlined in the Final Report, the then-EPA Administrator concluded that obtaining additional information from owner/operators of coal-fired electric utility steam generating units was needed to determine whether regulation of electric utility steam generating units was appropriate and necessary. Accordingly, EPA used its authority under CAA section 114 to collect data from all domestic coal-fired electric utility steam generating units. The resulting information collection request (ICR) consisted of three phases of data collection:

- **Phase I** collected general information on every coal-fired electric generating utility unit and was completed in January 1999.

- **Phase II** consisted of obtaining information on the amount of coal received on a per shipment basis for the 1999 calendar year for every facility. In addition, the mercury and chlorine content of the coal was reported for every sixth shipment.

- **Phase III** consisted of emissions testing at 80 units,[4] which were selected to represent a cross-section of boiler and control device types. For each of the 80 units selected, testing for mercury was conducted at the inlet and outlet of the last pollution control device on the unit. Each unit was to conduct three separate test runs and to also sample and analyze the coal used during each of the three separate runs.

December 2000 Findings and Determination

In a December 20, 2000, Federal Register Notice, EPA published its finding that regulation of mercury emissions from coal-fired utility plants was appropriate and necessary. The notice described four primary sources of information for the finding:

- EPA's February 1998 "Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units -- Final Report to Congress."
- An ICR to all coal-fired electric utility steam generating units requesting coal data for 1999 and a request to certain units for stack test results to evaluate air toxics emissions.
- An evaluation of the mercury control performance of various emission control technologies currently in use to control other pollutants or that could be applied to such units to control mercury emissions.

---

[4] Emission tests were actually conducted at 79 different units with 2 tests conducted at 1 unit for a total of 80 tests.

- An evaluation of available health data related to mercury conducted by the National Academy of Sciences.

The Notice concluded that, ". . . during the regulatory development process, effective controls for mercury and other HAPs (hazardous air pollutants) can be shown to be feasible." The Notice recognized the considerable interest in using economic incentive programs, such as emission trading, to achieve emission reductions. However, in its December 2000 notice, EPA cited concerns about the potential local impact of emissions trading and noted that any trading program must be constructed in a way that assured communities nearest a source were adequately protected. The Notice stated:

> *Thus, in developing a standard for utilities, the EPA should consider the legal potential for, and the economic effects of, incorporating a trading regime under section 112 in a manner that protects the local populations.*

After issuance of these findings and its determination that regulation of utilities was appropriate and necessary, EPA began to develop a MACT standard for mercury emissions from coal-fired electric utility units. Additionally, a workgroup was established in August 2001 under the Clean Air Act Advisory Committee to provide EPA with input regarding Federal MACT regulations for coal-fired electric utility steam generating units. Appendix A provides a timeline of events associated with the development of the MACT rule.

Clear Skies Proposal

Concurrent with EPA's initial efforts to develop a MACT for utility units, legislation was proposed in Congress[5] to establish a multi-pollutant approach for addressing mercury, sulfur dioxide (SO_2), and nitrogen oxide (NOx) emissions from utilities. This legislation, referred to as Clear Skies, proposed a cap-and-trade approach to controlling emissions of these three pollutants. With respect to mercury, the initial Clear Skies legislation called for an interim cap on total U.S. mercury emissions of 26 tons per year by 2010. Based on modeling done in support of the Clear Skies Proposal, EPA estimated that some facilities would install mercury-specific technology by 2010 in order to meet the 26-ton cap. Clear Skies proposed a final cap of 15 tons on mercury emissions by 2018, and EPA analysis projected that additional sources would choose to install mercury-specific controls to meet the cap.

When Clear Skies legislation stalled in Congress, EPA decided to propose a cap-and-trade approach for controlling mercury emissions as an alternative to a

[5] Clear Skies was proposed in both the U.S. House of Representatives and Senate in July 2002, and reintroduced as the Clear Skies Act of 2003 on February 27, 2003.

MACT standard. EPA proposed these regulatory alternatives in the January 30, 2004, Federal Register Notice. In addition to the proposed mercury rule alternatives, EPA on January 30, 2004, also proposed new air rules for reducing SO_2 and NOx emissions. This proposed rule, now known as the Clean Air Interstate Rule (CAIR), would establish a cap-and-trade program for 29 States in the Eastern United States and the District of Columbia whose SO_2 and NOx emissions significantly contribute to fine particle and ozone pollution problems in other downwind States. Together, the CAIR and mercury proposals would create a multi-pollutant approach to controlling emissions from utilities similar to what was originally proposed in the Clear Skies legislation.

Proposed Mercury Rule

As a result of a prior court settlement[6], EPA had agreed to issue proposed power plant mercury emission standards by December 15, 2003. In the January 30, 2004, Federal Register Notice, EPA proposed its rule for regulating mercury emissions from coal-fired steam generating electric utility units. This proposal includes two different approaches for controlling mercury emissions from utilities: a MACT standard or a mercury cap-and-trade program.

EPA's Proposed MACT Standard Approach: EPA proposed separate emission limits to be achieved by 2008 for five subcategories: three subcategories for different coal types (bituminous, sub-bituminous, and lignite); one for coal refuse or waste; and one for a specific type of combustion process known as Integrated Gasification Combined Cycle (IGCC).[7] Table 1-1 shows the specific per unit emissions limits for existing units in the proposed rule.

Table 1-1: Proposed MACT Emission Limits

Subcategory	Emission limit (lbs/TBtu)*
Bituminous	2.0
Sub-bituminous	5.8
Lignite	9.2
Coal-Refuse	0.38
IGCC	19.0

* = pounds per Trillion British thermal units.

These emission limits were based on what EPA determined to be the MACT floor. EPA proposed that the MACT standard be based on the MACT floor as

[6] Under a settlement agreement reached in 1998 with the Natural Resources Defense Council, EPA agreed to issue a proposed rule for regulating mercury from power plants by December 15, 2003, and a final rule by December 2004. (*Natural Resources Defense Council v. EPA*,D.C. Cir., No. 92-1415, 4/15/98). Natural Resources Defense Council later agreed to extend the deadline for the final rule to March 15, 2005.

[7] The IGCC process converts coal into gas and uses the coal gas as fuel for generating electricity.

opposed to a beyond-the-floor[8] level because it concluded that technologies for reducing mercury emissions were not commercially available and, thus, beyond-the-floor emission standards were not achievable. EPA estimated that total national mercury emissions would be reduced from 48 to 34 tons per year if the proposed MACT rule was implemented.

EPA's Proposed Cap-and-Trade Approach. In lieu of adopting a MACT standard to regulate mercury emissions from utilities, EPA presented an alternative proposal that would regulate mercury emissions from utility units under a national cap-and-trade program implemented under section 111 of the CAA.[9] The cap-and-trade proposal included an unspecified interim cap on mercury emissions in 2010 and a final cap of 15 tons by 2018. Though EPA did not specify an interim cap level, the Agency proposed that it be based on the maximum amount of mercury reductions that could be achieved through implementing the controls necessary to reduce SO_2 and NOx emissions, i.e., the mercury co-benefit of these controls through implementation of CAIR. The preamble to the rule states that EPA modeling indicated an expected co-benefit level, which is the result of implementing the CAIR rule, resulting in mercury emissions of 34 tons per year. EPA also took comment on administering the cap-and-trade approach under CAA section 112 instead of section 111.[10] The primary difference between these two approaches is that a section 112 cap-and-trade program would be administered centrally by EPA while the section 111 program would be administered individually by States.

Scope and Methodology

We conducted our field work from May 2004 through December 2004, and did so in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. We performed field work in EPA's Office of Air and Radiation locations in Washington, DC, and Research Triangle Park, North Carolina. We interviewed staff from EPA offices and outside organizations to gain an understanding of the rule as developed, other options considered, and the rule development process. We interviewed officials from EPA's Office of Air and Radiation; Office of Research and Development; Office of Enforcement and Compliance Assurance; and Office of Policy, Economics, and Innovation. We also contacted environmental and utility industry representatives, and State, local, and tribal organizations interested in the development of this proposed rule, to

[8] A MACT standard more stringent than the floor is referred to as "beyond-the-floor."

[9] Concurrent with this approach, EPA proposed to revise its December 2000 finding that regulating utilities under section 112 was necessary and appropriate.

[10] This approach would not require EPA to revise its December 2000 finding, but would require EPA to "de-list" utilities as a source category requiring a MACT standard.

obtain their views. We reviewed data and analyses developed in support of the rule, and public comments included in the rulemaking docket. We also reviewed related information provided by both EPA and non-EPA officials contacted.

The Government Accountability Office is conducting a review of technology-related issues for the proposed mercury rule, which is an important consideration in determining whether the MACT standard can be set at a level that is more stringent than the floor. The Government Accountability Office report was not available in December 2004 for consideration in the OIG report.

Limitations

Our evaluation was conducted and completed before the Agency had completed the rulemaking process. Accordingly, our observations and characterizations about the process reflect the status of the rulemaking process at the time we completed our review. Issuance of the final rule is planned for March 15, 2005, and the final rule may consider additional information or analyses not available at the time we completed our review. For example, EPA released a notice of data availability for the proposed Clean Air Mercury Rule on December 1, 2004. The notice requests additional public comment on issues addressed in this report, and solicits further comment on new data and information to help EPA evaluate which regulatory approach will best reduce mercury emissions from power plants. We did not specifically consider the notice because it was released after we had completed our review and analyses. However, the notice includes information available previously in the public comment docket for this rule, and it is possible we had considered some of that information during our review.

The OIG was not provided with several important documents it requested from the Agency; therefore, that information was not available for consideration in this report. Our memorandum detailing the requested information, as well as specifics on what information was provided by the Agency, are provided in Appendix B. Consideration of the inter-agency review process was limited to information from EPA staff and information available in the docket only. We were not able to discuss the inter-agency review process with Office of Management and Budget (OMB) staff who were responsible for coordinating the inter-agency review process. The OIG did not independently analyze the databases or computer modeling programs that EPA used in developing the proposed rule. With respect to the development of the MACT standard, the OIG did not attempt to independently calculate the MACT floor.

Results in Brief

Evidence indicates that EPA senior management instructed EPA staff to develop a MACT standard for mercury that would result in national emissions of 34 tons annually, instead of basing the standard on what the top performing units were achieving in practice. Also, we determined that EPA's mercury cap-and-trade proposal – a nationwide emissions trading program for an air toxic – can be strengthened to better ensure that human health is protected and anticipated emission reductions achieved, should this approach to reducing mercury emissions be adopted. Further, although EPA rulemaking procedures are not consistently applied, Agency staff told us that they would have expected greater adherence to the guidance for mercury rule development due to the significance of this particular regulatory action, but this did not happen.

We recommend that EPA re-analyze mercury emissions data collected, and conduct a revised cost-benefit analysis for the updated MACT that takes into account the impact of mercury co-benefits achieved through the proposed CAIR. We also recommend that the Agency strengthen its cap-and-trade proposal. Further, we recommend that the Agency conduct an integrated analysis with respect to whether emissions reductions under either of these proposals are the most child-protective, timely, and cost-effective.

The Agency disagreed with certain aspects of our draft report, and offered suggested changes or revisions. The Agency's response did not specifically address our recommendations. We made changes to the final report based on the Agency's comments, as appropriate. See Appendix E for the full text of the Agency's official comments to our draft report and our response to these comments.

Chapter 2
Mercury MACT Development Compromised

Evidence indicates that EPA senior management instructed EPA staff to develop a MACT standard for mercury that would result in national emissions of 34 tons annually, instead of basing the standard on an unbiased calculation of what the top performing units were achieving in practice. The CAA requires that a MACT standard should, at a minimum, be based on the emissions levels achieved by the top performing 12 percent of units, not a targeted national emissions result. The 34-tons-per-year target was based on the co-benefits expected to be achieved from implementation of NOx and SO_2 controls under the proposed CAIR. EPA noted that this target was based on extensive analysis and, in EPA's judgment, represented the lowest level of mercury emissions that it could reasonably expect the utility industry to achieve.

Because the results of the MACT standard were prescribed and prior estimates were lower than what was proposed, we believe it likely that the standard understates the average amount of mercury emissions reductions achieved by the top performing 12 percent of power units. Some Agency officials told us that, in their opinion, the true MACT floor would result in lower mercury emissions than the 34 tons estimated from current MACT floor limits. Therefore, if this proposed MACT standard was adopted, it would not achieve the maximum emission reductions achievable and the associated health benefits. Further, this MACT standard, as proposed, does not provide a reasonable basis for comparison in determining which of EPA's two proposed regulatory alternatives (i.e., the MACT standard or the mercury cap-and-trade program) provides the better cost-benefit.

Requirements for MACT Standards

In accordance with the CAA, EPA is to establish MACT standards that require the maximum emissions reductions the Agency believes are achievable for a major source category. At a minimum, the MACT standard cannot be less stringent than the average emission reductions achieved by the top performing 12 percent of units in a category (e.g., all coal-burning utilities) or subcategory (e.g., utilities burning bituminous coal) for which the Administrator has data. EPA has wide latitude in the types of emissions data used to determine the MACT floor, including the discretion to select a reasonable method to estimate emissions achieved, and to address variability to account for the most adverse operating conditions reasonably foreseeable. If EPA decides to set a limit beyond the floor, it must consider the cost of achieving those reductions, any resulting non-air quality and environmental impacts, and energy requirements.

In accordance with a court settlement, EPA had agreed to publish its final mercury rule by December 15, 2004. This date was re-negotiated with the court petitioner and the final rule deadline was extended to March 15, 2005.

EPA's Process for Addressing Variability in Computation of Mercury MACT Floor

As provided under CAA section 112(d), EPA first determined whether a MACT standard should be developed for all coal-fired units or sub-categories. EPA analyzed the ICR data and identified the top performing units from all units for which emissions data were collected. Evaluation of the ICR data for the top performing units focused on coal type, plant processes, and control technology. EPA could not identify a common attribute that contributed to mercury emission reductions for all of the top performing units that would allow development of a single MACT emissions limit for all units. Additionally, it was determined that no units had installed mercury-specific control technology, although controls installed to reduce emissions of other pollutants also helped reduce mercury emissions. When no single common factor was identified, EPA evaluated the data further and determined that sub-categorization by coal type, which is also a driving factor in plant design, was warranted to establish the MACT. One additional sub-category was established for a particular plant type – Integrated Gasification Combined Cycle – because the plant burns gas from coal rather than any particular type of coal.

For each sub-category, EPA identified the top performing units based on emission tests collected during the ICR. However, EPA determined that these emission tests alone did not sufficiently estimate the effect of fuel variability over time on the emissions of the best performing units. To account for this variability, EPA used coal composition data (i.e., mercury and chlorine content) for coal shipments collected during the ICR to estimate emissions throughout the year for the top performing units in each subcategory. This increased the number of emission points available from which to calculate the MACT limits. [11]

The emission points for each of the top performing units were ranked and then EPA selected one of the highest emissions points (i.e., the 97.5 percentile) for each unit. According to EPA, this emission point reflects the best performance under the worst foreseeable operating conditions for the unit. EPA took the average of these selected emission points for each sub-category and adjusted this

[11] Prior court cases have upheld EPA's right to consider variability in developing MACT floors. For a discussion of the appropriateness of EPA's efforts to account for variability, see *Cement Kiln Recycling Coalition v. Envt'l Protection Agency*, 255 F.3d 855 (D.C.Cir. 2001), *examining, Sierra Club v. Envt'l Protection Agency*, 167 F.3d 658 (D.C.Cir.1999) and *National Lime Ass'n v. Envt'l Protection Agency*, 233 F.3d 625, 629 (D.C.Cir.2000) ("National Lime II").

average to further account for variability (i.e., the 97.5 percent upper confidence level of the average). This adjusted average was established as the MACT floor and the proposed standard for each subcategory.

Unlike many previous MACT standards, the proposed utility MACT standard would not require the installation of a specific control technology since no mercury-specific control technology had been installed in utilities. EPA determined that emerging mercury-specific technologies were not yet commercially available for the utility industry. The Government Accountability Office is conducting a study to assess the current state of mercury control technology.

EPA Staff Instructed to Develop MACT Floor That Would Result in National Emissions of 34 Tons

Evidence indicates that EPA staff were instructed to develop a MACT standard that would result in national emissions of 34 tons per year. Some staff told us that they heard these specific directions and others told us that they heard in different meetings during rule development that the application of the MACT floor to utilities should equal 34 tons per year (a 29-percent reduction from the present 48-tons emitted nationwide). These statements were further corroborated by internal EPA e-mails, which specifically identified 34 tons per year as the number desired despite the fact that prior modeling results did not result in 34 tons. E-mails between EPA staff discussed various MACT emission limits by subcategory and modeling scenarios that could be used to get closer to the 34 tons target. For example, a November 2003 e-mail stated that:

> *If the 14+K of subbit ACI is using the 90% option and we restrict this to 60%, perhaps we can get in the 34 tpy range. I don't think that restriction would be considered inappropriate for a 2007 MACT analysis.*

EPA documents and an analysis of the process used to compute the MACT floor support EPA staff's statements that the MACT floor computations were developed to produce the desired national emissions of 34 tons per year. Documentation that we reviewed indicated that EPA conducted at least three Integrated Planning Model (IPM)[12] runs in order to reach the pre-determined target for national mercury emissions of 34 tons. The initial IPM run to try to reach the 34-tons target yielded a national emission of 29 tons (i.e., the IPM model indicated that mercury could be reduced from 48 tons to 29 tons). After changing the proposed MACT emission limits, a second IPM model yielded a

[12] EPA uses ICF Resources Incorporated's Integrated Planning Model for air emission modeling. The model projects what decisions utilities would make for meeting air emission regulations based on economic considerations.

national emission of 27 tons. While we were provided summary information about these two IPM model runs, they were not included in the EPA rulemaking docket.

An Agency source indicated that these results were not acceptable to senior management because they were not close enough to the 34-tons target. A third run performed, based on the proposed emission limits, showed 31 tons. EPA cited the 31-tons model results in the proposed rule, but explained in the preamble that 34 tons is the more probable emissions level because the model used to estimate emissions was underestimating the amount of mercury emissions that would occur. EPA noted that the IPM model may have understated mercury emissions by 2.3 tons for units burning bituminous coal.[13] Table 2-1 depicts the emission limits used in the three IPM runs and the resulting total national emissions:

Table 2-1: Results of Proposed MACT Scenarios to Reach 34 Tons

Coal type	Run #1	Run #2	Run #3 (Proposal)
Bituminous	0.57 *	1.4 *	1.9679 *
Sub-bituminous	6.46 *	5.06 *	5.8 *
Lignite	18.45 *	19.48 *	9.2 *
Total National Mercury Emissions (tons-per-year)	29-30 **	27.2-27.9**	30-31**

* Proposed per unit mercury emission standard expressed in pounds per trillion British thermal units (lb/TBtu).

** Estimated tons of national mercury emission resulting from modeling the application of the unit emission standard to all utility units.

The emission limits shown in Run #3 above, ultimately proposed as the MACT standard, were based on a multi-variability analysis submitted by WEST Associates (a western utility consortium).[14] However, EPA adjusted this approach, increasing the MACT floor emission limits for two of the three subcategories beyond those derived by WEST Associates. For example, WEST Associates used an upper confidence level of 95 percent of the mean of the best performing units to account for variability. EPA adjusted the confidence level to

[13] The IPM model only allows Activated Carbon Injection technology, a mercury specific control technology, to reduce mercury emissions at 60% and 90% levels. The inability of the model to address the full range of reductions between these two levels means that the model may have understated mercury emissions by as much as 2.3 tons for bituminous-fired units.

[14] The analysis was submitted during the last Federal Advisory Committee Act meeting, convened in March 2003.

97.5 percent, which resulted in an increase in the emission limit for two of the three sub-categories. According to EPA's variability analysis, this adjustment was made to account for EPA's interpretation of the number of units that should be included in the MACT floor analysis.[15] These adjustments increased the MACT floor closer to a national emission level of 34 tons per year.

Relationship of the 34-Ton Estimate to Cap-and-Trade Proposals

The 34-tons-per-year target is important because it is based on mercury emission modeling results used in two separately proposed cap-and-trade programs for utilities – CAIR and the mercury cap-and-trade program – proposed as alternatives to the mercury MACT. EPA has stated its intent to implement its multi-pollutant (mercury, SO_2, and NOx) cap-and-trade programs, originally included in stalled Clear Skies legislation, through the proposed CAIR and mercury regulations.

EPA has also proposed that the mercury reductions gained from implementing CAIR should serve as the interim cap on mercury emissions in the mercury cap-and-trade program. According to the preamble to the mercury rule, the reason for basing the interim cap on the co-benefits from CAIR is that the Agency does not believe mercury control technology that has been demonstrated for all coal types is commercially available. In addition, Agency officials stated that the 34-tons-per-year target was based on the co-benefits expected to be achieved from implementation of NOx and SO_2 controls under the proposed CAIR. They noted that this target was based on extensive analysis and, in EPA's judgment, represents the lowest level of mercury emissions that they could reasonably expect this industry to achieve by 2010.

Additional Estimates of Mercury Emissions

Interviews with sources both inside and outside the Agency suggest that if unbiased analyses of data were conducted, a range of possible MACT floor levels would most likely result. One EPA official stated that the true range of possible MACT floors was probably as low as 8 to 10 tons per year up to the mid-20s, but that either end of that range would be a stretch. Further, the source stated that the real range is about 15 tons per year to the low 20s for this MACT, and that anything above or below those numbers was a stretch. This includes the 34 tons proposed by the Agency. These statements about the possible range of MACT floors are supported by results of different MACT floor limits and/or varying model assumptions used by some organizations providing comments to the

[15] For example, West Associates used 5 units for each sub-category, while EPA used 4 units for the bituminous and sub-bituminous sub-categories and 5 units for lignite sub-category.

proposed rule. For example, the Clean Air Task Force evaluated the ICR data to develop MACT floor limits that were different than those developed by EPA. Applying these limits to the same IPM model used by EPA resulted in national mercury emissions of 12 tons[16] (i.e., a 75-percent reduction from 48 tons). Modeling by the Electric Power Research Institute and Edison Electric Institute used the MACT floor limits proposed in the rule and showed an estimated 32 tons of mercury emissions nationwide (i.e., a 33-percent reduction from 48 tons). Examples of varying modeling efforts and results can be found in Appendix C.

Conclusions

EPA's current estimate of the amount of mercury emissions occurring after implementing SO_2 and NOx controls, called for in EPA's CAIR, is 34 tons. Given (1) that EPA is attempting to implement the Clear Skies multi-pollutant approach through regulation; (2) the numerous modeling runs conducted to determine national emission resulting from different MACT emission limits; (3) the adjustments made in the accounting for variability; (4) the statements of EPA officials involved in the rulemaking process; and (5) EPA e-mails reviewed, we believe EPA's approach for developing the MACT floor was compromised. Further, it is unlikely that an unbiased calculation of the MACT floor would produce emission limits that would result in estimated national mercury emissions of 34 tons per year (i.e., EPA's current estimate of the co-benefit of SO_2 and NOx proposed regulations).

Recommendations

We recommend that the Assistant Administrator for Air and Radiation:

2-1 Conduct an unbiased analysis of the mercury emissions data to establish a MACT floor in accordance with the requirements of CAA section 112(d).

2-2 Re-negotiate with the court petitioner for an extension of the final rulemaking deadline sufficient to solicit and accept public comments on the unbiased analysis of mercury emissions data in an open, public, and transparent manner.

Agency Comments and OIG Evaluation

The Agency commented that the draft report incorrectly characterized the calculation of the MACT standard, and that the Agency had calculated the MACT

[16] The Clean Air Task Force considered the effect of implementing the proposed CAIR rule on the mercury MACT. EPA did not consider the impact of implementing CAIR in its MACT modeling efforts. More information on this issue is found in Chapter 4 of this report.

floor in accordance with the requirements of CAA section 112(d). The Agency also maintained that its extensive work, including development of the proposed Clear Skies legislation, showed that, in the absence of immediately available mercury control technology, the mercury reductions as co-benefits of SO_2 and NOx controls represent the lowest level of mercury emissions that the Agency reasonably expects could be achieved. We believe our report accurately characterized the MACT development process. Our observations were based on review of supporting documentation related to MACT development, and interviews with Agency staff and stakeholders involved in the process, including State and local, environmental, and industry groups. Although the MACT floor was ostensibly based on data from the top performing 12 percent of units, this data was analyzed with a final target already in mind, i.e., 34 tons. While the Agency has conducted analysis to determine the co-benefit of SO_2 and NOx controls, we do not believe this meets the requirements of CAA section 112(d) in developing the MACT standard. The Agency's complete response to the draft report and our evaluation of its response are in Appendix E.

Chapter 3
Cap-and-Trade Option Can Be Strengthened

EPA's mercury cap-and-trade proposal – a nationwide emissions trading program for an air toxic – can be strengthened to better ensure that human health is protected and that anticipated emission reductions are achieved, should this approach to reducing mercury emissions be adopted. The cap-and-trade proposal could be strengthened by:

- Adequately addressing the potential for hot spots.
- Establishing an interim cap that would provide greater incentive for utilities to install mercury-specific control technology by 2010.
- Setting a reasonable safety valve provision.
- Clarifying conditions pertaining to exemptions for small emitting facilities.

These changes could help ensure that the proposed mercury cap-and-trade program obtains the desired emissions reductions in a timely manner.

EPA's Proposed Cap-and-Trade Approach

A cap-and-trade program could provide several benefits in terms of controlling emissions. Trading programs generally provide regulated units with more flexibility to meet overall emissions reductions than do conventional command-and-control approaches because a unit may apply whichever control method it finds to be most appropriate and cost-effective to meet emission limits. This flexibility serves to minimize overall control costs in the market. Furthermore, cap-and-trade programs can provide greater environmental certainty by establishing fixed national emissions caps that cannot be exceeded. However, a cap-and-trade program's environmental benefits will depend on the adequacy of the cap.

Under EPA's proposed mercury emissions trading program, units that cannot cost-effectively reduce emissions through controls may buy allowances from units that were able to reduce emissions beyond their established allowance limits and are willing to sell their extra allowances. Each unit is required to possess one emissions allowance per each ounce of mercury it emits. Units would be allowed to buy and sell credits among one another in a national emissions market. EPA's proposed cap-and-trade alternative proposes that the interim mercury emissions cap for 2010 be based on the amount of mercury reductions achieved solely as a co-benefit through implementation of SO_2 and NOx controls under the proposed CAIR. As noted in Chapter 2, EPA's latest estimate of the mercury benefit from implementing CAIR is 34 tons per year. The cap-and-trade proposal sets a final cap of 15 tons per year in 2018.

Proposed Cap-and Trade Program Needs to Further Address Certain Issues

The proposed cap-and-trade rule for mercury meets the three basic guiding principles of trading programs as defined by EPA: a cap on emissions, accountability, and simplicity of design and implementation. However, we identified four issues with EPA's mercury cap-and-trade proposal that need to be further addressed. Details follow on each issue.

Interim Cap Could Be Tightened to Force Earlier Development of Mercury-Specific Control Technology

Although EPA has not yet set a specific interim cap for 2010, the preamble to the proposed rule states that the interim cap will be based solely on the mercury emissions reductions achieved as co-benefits of regulating SO_2 and NOx under CAIR, estimated by EPA to be 34 tons. Thus, it would not be necessary for units to install mercury-specific controls in order to meet the 2010 interim cap, and this would limit the effectiveness of the regulation to force new technological advances in mercury control. If the interim cap under this proposal is set at 34 tons, utilities could delay consideration of installing new mercury-specific technology until meeting the more stringent cap in 2018 is imminent. However, according to EPA officials, if the banking provision of the cap-and-trade program operates as intended, some facilities would have the incentive to implement mercury-specific controls before 2018, which would reduce emissions beyond the interim cap level before the final cap becomes effective. EPA officials also pointed out that experience under other cap-and-trade programs has shown that the largest emitters are typically the first to reduce emissions and will generally achieve the greatest level of reductions. According to the preamble, the reason for basing the interim cap solely on the co-benefits from CAIR is that EPA does not believe mercury control technology that has been demonstrated for all coal types is commercially available.

Further, the proposed rule does not address what would happen under the cap-and-trade approach if CAIR is not implemented. Given that the 2010 cap is based solely on the co-benefits from CAIR, it is unclear what would occur under the proposed rule if CAIR is not implemented.

An EPA official stated that although some EPA staff indicated they would like to see analyses on different cap levels for comparison purposes, no such formal analyses were conducted. EPA conducted one IPM run based on an interim cap of 34 tons and a final cap of 15 tons (in conjunction with CAIR), but no runs were conducted using alternative caps for comparison. Clear Skies analyses were made available in the proposed mercury rule docket, and according to an EPA official the mercury cap-and-trade IPM run is comparable to the Clear Skies IPM runs. According to this EPA official, one such run of Clear Skies had a different interim

cap (26 tons) and this run, while not exactly matching the modeling conducted for the proposed mercury cap-and-trade program, provides an idea about the costs of an alternative mercury cap.

Potential for Hot Spots Not Fully Analyzed

EPA did not fully analyze the potential for hot spots (i.e., areas of elevated pollutant concentrations) to occur under its proposed cap-and-trade option. The potential for hot spot formation under the proposed cap-and-trade rule has generated a great deal of concern and debate among various stakeholders. Modeling and projecting the likelihood of hot spots under the proposed rule is made difficult by the relatively high degree of uncertainty involved with mercury transport and deposition patterns (i.e., when the airborne mercury is deposited onto the ground or into water bodies), particularly local or near-field deposition.

Further complicating efforts to use computer models to determine where mercury deposition will occur is the fact that three different chemical forms of mercury are emitted by utility units and each has varying deposition patterns. For example, oxidized and particulate mercury are more likely to deposit locally or regionally, while elemental mercury travels and is more global in nature. Although air emission-related hot spots are generally thought of in terms of high ambient air concentrations near a source, this is not the only consideration with mercury. The main health risk associated with mercury is not its ambient concentrations, but rather its deposition into water bodies and resulting bioaccumulation in fish. However, the connection between air emissions and levels of mercury ultimately found in fish tissue is not yet fully understood.

EPA's Clean Air Markets Division conducted a Proximity Analysis to determine "where, in relation to water bodies, emissions would occur" under the mercury emissions trading provision of the Clean Air Interstate Rule. However, as noted in the analysis, the issue of hot spots was not fully analyzed:

> *This examination of projected mercury emissions has significant limitations and does not constitute an analysis of "hotspots." Such an analysis of hotspots would, in part, necessitate detailed assessments of the atmospheric fate, transport, and deposition of mercury from power generating sources, and assessments of the potential population exposure to mercury contaminated fish in water bodies due to generating and other sources.*

Although EPA did not conduct the detailed assessment of hot spots described above, EPA stated in the preamble to the proposed rule that it does not expect hot spots to occur for several reasons, as follows:

- Modeling suggests that the largest emitters, which are more likely to produce local deposition, will be the first to implement control technology under a cap-and-trade approach and will reduce emissions by the largest amount.

- CAIR would result in implementation of control technologies for SO_2 and NOx that also provide the co-benefit of reducing emissions of the types of mercury (oxidized and particulate) that are likely to deposit locally.

- The Acid Rain program has not resulted in the formation of hot spots.

- States have "the ability to address local health-based concerns separate from the mercury cap-and-trade program requirements," and under the proposed State-administered program would "retain the power . . . to adopt stricter regulations to address local hot spots or other problems."

- The proposed final cap would be a 70-percent reduction in mercury emissions from current uncontrolled levels (from 48 to 15 tons).

However, potential problems arise with EPA's reasoning. For example, the Acid Rain program controls for SO_2 emissions, which are primarily deposited regionally and globally, not locally, while mercury can deposit locally as well as regionally and globally. Trading programs are generally thought to be most effective for pollutants that do not deposit locally. Further, the Acid Rain program co-exists with the National Ambient Air Quality Standards program, which has established a minimum level of air quality for SO_2, while no such minimum standards exist as a back-stop in the mercury cap-and-trade proposal. In addition, the Acid Rain program contains a provision stipulating that, in the case of delayed implementation due to litigation, a more conventional command-and-control approach would take effect, but the proposed cap-and-trade rule for mercury lacks a similar provision.

While the preamble to the proposed rule notes that individual States have the authority under section 111 to adopt stricter regulations than those set by EPA, it does not address whether States would have this same authority under a section 112 cap-and-trade program. Further, approximately one-third of States have laws limiting "the ability of their regulatory agencies to adopt regulations that are more stringent than any federal environmental regulation." Thus, these States may not be able to adequately address hot spots, should they arise.

EPA has recognized that additional information is needed to better understand and address potential hot spots. For example, in the preamble to the proposed rule, EPA states its intent to reassess the hot spot issue by taking a ". . . hard look at the Hg emissions inventory after full implementation of the first phase cap. . . ," and also requested comments on how it might address hot spots in a cap-and-trade program. In addition, EPA suggested the use of trading ratios between regions as

a way to address potential regional deposition differences. The Agency also requested site-specific data on areas where commenters believe hot spots would continue to exist if a cap-and-trade program were implemented.

Due to time constraints, the OIG did not fully evaluate potential environmental justice implications resulting from a cap-and-trade program, nor did we fully assess the extent of the Agency's analysis of these issues.

Safety Valve Provision May Not Encourage Reductions

The proposed safety valve price may be set too low to achieve the intended effect of reducing mercury emissions through the installation of control technology and the open-market trading of emission allowances. The safety valve provision in the proposed cap-and-trade mercury rule provides a price cap on the cost of emissions reductions, and was included in the proposed rule due to uncertainties associated with future costs and the availability of mercury control technologies. Under the safety valve provisions of the proposed rule, if the price of allowances reaches a certain level, units will be permitted to borrow allowances from the future for a fixed price. To help ensure that the overall cap on emissions is met over the long-term, units can borrow only from their own bank of future allowances. The provision is intended to "minimize unanticipated market volatility" and ensure that "the cost of control does not exceed a certain level." Thus, in effect, units may emit more in the current period, but would be forced to emit less in the future because they are using future allowances. However, we identified two concerns with the proposed safety valve provisions.

Safety Valve Price. For a safety valve provision to be used appropriately (that is, only when market volatility makes it necessary), the price should be set so that it is higher than the market price of allowances or the actual cost of abatement (emission reduction). If this price is too low, it may be cheaper for the unit operator to purchase future emissions allowance at the safety valve price rather than installing emission controls. Under the proposed rule, the safety valve price is set at $35,000 per pound, or $2,187.50 per ounce, adjusted annually for inflation. This figure was decided upon during development of the Clear Skies Initiative, but new analyses have estimated that the actual cost of abatement will be substantially higher than $35,000 per pound.

Although EPA stated in one of the rule's supporting documents that, "based on current technological capabilities, the cost of mercury removal is expected to reach the safety valve price ($35,000/lb) by 2010," it further stated that "technological improvements could decrease the cost of mercury control over time and cause prices to remain below safety valve levels." Staff within EPA indicated that the current safety valve price of $35,000 was too low based on new analyses. For example, 2003 and 2004 Department of Energy estimates show the "baseline costs" of mercury removal to be $50,000 - $75,000 per pound, with cost

reductions expected over time. However, senior EPA officials told us that they did not believe the safety valve price would be reached because they expect the cost of activated carbon injection, a mercury-specific control technology, to decrease over time. According to these officials, the IPM does not account for this variable and may be misleading since it shows the cost of activated carbon injection remaining constant over time.

Safety Valve Borrowing. The proposed rule stated that units may purchase safety valve allowances from "following years," and the supplemental notice stated they may be purchased from allowances available for allocation in the next control period. The supplemental notice also provided an example of how a State could incorporate the safety valve provision into its cap-and-trade program. However, the proposed safety valve provision does not place a limit on the number of allowances a unit can borrow under this provision. As the Clean Air Task Force writes in its comments, a unit could, theoretically, continue borrowing indefinitely from future years by buying safety valve allowances in lieu of installing controls or buying allowances on the open market. Such an approach would make economic sense as long as the proposed safety valve price was set lower than the baseline cost of controls. In the proposed rule, EPA acknowledges that its "proposed approach may create implementation problems associated with the need to 'reconcile' at some point in time the allowances borrowed from future compliance periods," and requests comment on the issue.

Small Emitters Exemption Needs To Be Clarified

EPA has proposed that utility units emitting less than 25 pounds of mercury per year be exempt from the cap-and-trade program, but has not completely addressed how their exemption and the national emission cap will be impacted if their emissions increase. EPA included this exemption because of concerns that new mercury-specific control technologies expected to be developed may not practicably apply to these units. Based on EPA data developed for units operational in 1999, 396 of the 1,120 units operational in 1999 were estimated to have emitted less than 25 pounds of mercury per year each. These 396 units made up 35.4 percent of the total operating units, but contributed only 3,742 of the 95,975 pounds of estimated mercury emissions, or 3.9 percent in 1999. According to the proposed rule's preamble, EPA states there is reason to believe that the 15-tons Phase II cap can be achieved in a cost effective manner, even if the lowest emitting 396 units are excluded from coverage under this cap. EPA is soliciting comment on this proposal.

One commenter noted that both capacity utilization and emission rate increases could occur in small emitting sources after they have been exempted from cap-and-trade requirements. EPA does not address this issue in the proposed rule. Another commenter stated that EPA had done no analysis of the small emitter exemption with respect to either costs or impacts. According to this commenter, a

vast majority of the units emitting less than 25 pounds of mercury are part of a multi-boiler facility, and it is entirely likely that at some facilities all of the boilers are tied into common duct work for pollution control. Consequently, these units should be considered as one unit emitting over 25 pounds and not eligible for the exemption.

While we did not fully assess the impact of this, we believe the commenters have raised valid concerns. Further, we noted that the relative significance of these small emitters increases as the cap-and-trade program progresses. For example, in 2018, these emitters, based on their 1999 emissions, would represent 12.5 percent of the total 15 tons in emissions allowed under the final cap. If EPA moves forward with its cap-and-trade proposal, the Agency can better ensure that anticipated emission reductions are achieved if it clearly addresses the circumstances under which small emitters would have to participate in the cap-and-trade program.

Proposed Emissions Trading Rule Should Also Address Tribal Concerns

Although Executive Order 13175 requires EPA to develop an "accountable process to ensure meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications,"[17] tribal concerns were not addressed during development of the proposed cap-and-trade rule. In the preamble, EPA states that the proposed rule may have tribal implications because two coal-fired utility units are located in Indian Country. Representatives from the National Tribal Environmental Council (NTEC) informed us that neither they nor their approximately 180 member tribes had any involvement in the development of the proposed mercury rule. This was confirmed by an EPA official at a March 2004 public meeting on the proposed mercury rule.

Among NTEC's greatest concerns over the proposed mercury rule are:

- the absence of tribal involvement and/or consultation in the development of the proposal;
- a failure to adequately monitor mercury deposition on tribal lands, which means that the impact of mercury is unknown; and
- lack of consideration for American Indians and Alaska Natives' dependence upon fish and the terrestrial animals that feed on those local fish.

The average tribal member and child eats much more fish than the typical consumer and the representatives explained that tribes (especially children and the expanding youth population) are faced with increased adverse health effects

[17] Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 6, 2000).

caused by such exposure.

NTEC does not support the cap-and-trade program and noted that, if the program is implemented, there is no mechanism currently in place for the tribes to enter into cap-and-trade allowance sales. In fact, allowances are only available to the States. NTEC cited the U.S. Government's trust responsibility, which includes looking after the health and survival of tribes. This responsibility is met in part by conducting tribal consultation on a government-to-government basis.

EPA officials noted that other organizations, including States, were not consulted during the development of the cap-and-trade proposal. Although States were not consulted, we noted that States were allotted mercury allowances while the Tribes were not.

Conclusions

The cap-and-trade proposal can be strengthened to better ensure that the anticipated emission reductions are achieved, should this approach be adopted by EPA. First, the interim cap suggested under the current proposal is set at a level that could be met without installing mercury-specific control technology, thus potentially delaying installation of mercury-specific controls until 2018. Also, the cap-and-trade option has not adequately addressed the potential for hot spots. In addition, EPA needs to ensure that it establishes a safety valve provision that will have the intended effect of encouraging unit operators to install controls or buy emission credits. Further, EPA needs to ensure adequate tribal involvement for the proposed mercury rule to ensure that tribes are not negatively impacted by a cap-and-trade rule.

Recommendations

We recommend that the Assistant Administrator for Air and Radiation:

3-1 Re-assess the basis for the interim and final caps. This analysis should consider the results of the re-assessed MACT floor (see Recommendation 2-1).

3-2 Further assess the risk of hot spots and, if CAA section 112 residual risk requirements are not implemented, then section 111 cap-and-trade regulations should specifically identify how EPA will meet its intention to reassess the hot spots issue.

3-3 Strengthen the safety valve provision so that the safety valve price is set at a level whereby it is only used for its intended purpose of minimizing unanticipated market volatility. Altematively, EPA may stipulate other

controls over borrowing from future allowances, such as imposing a greater than 1:1 allowance trading ratio; and allowances borrowed from the future will be reconciled to ensure that facilities cannot borrow indefinitely into the future.

3-4 Reassess the necessity of a small emitter exemption, and if a decision is made to exempt, explain in sufficient detail the reasoning for such a provision and establish how small emitters will be handled within the cap-and-trade program should they exceed emissions of 25 pounds a year.

3-5 Address tribal issues by: developing a mercury emissions consultation strategy with tribes, with the assistance of tribal representatives, that will ensure the Agency fulfills its trust responsibility and conducts proper government-to-government consultation with tribes; and establishing a mechanism for coal-fired utilities located on tribal lands to participate in the cap-and-trade approach.

Agency Comments and OIG Evaluation

The Agency's comments expressed a concern that the report does not "comprehensively and accurately describe" how the proposed cap-and-trade approach would work. The Agency also expressed concern that we did not highlight the knowledge EPA has gained from modeling and past experience with cap-and-trade programs. We believe our draft report portrayed an accurate representation of how the proposed mercury cap-and-trade program would work. One of the objectives of our review was to evaluate whether the proposed cap and trade rule was sufficiently protective of public health. As a result, we highlighted certain concerns with the rule as proposed. We made revisions, where appropriate, based on technical comments made by Agency staff and officials. However, there are several important differences between the Acid Rain program, to which the Agency often refers when discussing past cap-and-trade experience, and the proposed mercury cap-and-trade program. The Agency's complete response to the draft report and our evaluation of its response are in Appendix E.

Chapter 4
Rule Development Process Not Consistent with Expected and Past Practices

Although EPA rulemaking procedures are not always applied consistently, many Agency staff told us that they would have expected greater adherence to the guidance for mercury rule development due to the significance of this particular regulatory action, but this did not happen. When the Clear Skies legislation stalled, EPA decided to address the Clear Skies program in a regulatory manner instead. This led to EPA including a mercury cap-and-trade option, similar to Clear Skies, in its proposed mercury rule. As focus on the cap-and-trade approach increased, EPA began to de-emphasize the mercury MACT development process. This included:

- Cancelling the next scheduled Federal Advisory Committee Act (FACA) meeting and ending communication with FACA members.
- Abridging the normal intra-agency review process, particularly at the staff level.
- Failing to fully address the cost-benefit of MACT alternatives and not analyzing the potential impact of implementing CAIR on the proposed MACT option.
- Not fully analyzing the impact of the proposed mercury cap-and-trade program on children's health.

Description of Rulemaking Process

EPA's Action Development Process: Guidance for EPA staff on Developing Quality Actions outlines steps EPA staff and management are to follow when developing Agency actions, such as rules, policy statements, and statutorily mandated reports to Congress. The guidance suggests that EPA staff follow a prescribed set of steps beginning with tiering the action based on several of its characteristics. Once tiered, a standard process exists for developing the proposed action. As a Tier One action, the proposed mercury utility rule was considered a top action that would ". . . demand the ongoing involvement of the Administrator's office and extensive cross-Agency involvement on the part of the AAs/RAs (Assistant Administrators and Regional Administrators)."

The Action Development Process guidance contains five key elements, which are summarized below. These include steps for:

- planning sound scientific and economic analysis;

- developing and selecting regulatory options based on relevant scientific, economic, and policy analyses;
- involving affected Headquarters and Regional managers early and continuing involvement until the final action is completed;
- ensuring active and appropriate cross-Agency participation; and
- encouraging appropriate and meaningful consultation with stakeholders through substantive consultative procedures.

Appendix D describes the rule development process in detail.

Some FACA Members Considered Job Unfinished

Within EPA, the creation of an advisory committee is not required for MACT rule developments, but such groups have been formed to advise the Agency in past MACT rulemakings and can provide a means of substantive consultation with stakeholders. An EPA official noted that for contentious rulemakings where a great deal of stakeholder involvement and public comment is anticipated, such as the mercury rule, it is not uncommon for an advisory committee to be formed. FACA allows for the creation of committees, boards, commissions, councils, and similar groups to furnish expert advice, ideas, and diverse opinions to officers and agencies in the executive branch of the Federal Government. The Act notes that the function of committees is advisory only, and decisions on how the advice will be used is determined by the official, agency, or officer involved.

The FACA working group for this rulemaking, known as the Utility MACT working group, was formed within the Permits/New Source Review Air Toxics Subcommittee of the larger Clean Air Act Advisory Committee. Working group members consisted of representatives from State and local agencies; environmental organizations; industry; control equipment vendors; and coal interests, producers, and unions. Both co-chairs of the group indicated that they believed the working group had balanced stakeholder representation.[18] The working group was formed for an initial period of 1 year and met approximately once per month starting August 2001.

The working group was charged with providing input for the development of a MACT standard for utilities. In a presentation given to the group by the EPA co-chair, the group was instructed that they were not to reconsider the Agency's prior finding that regulation of coal-fired electric steam generating units under section 112 of the CAA was necessary and appropriate, nor were they to consider a cap-and-trade option. Although a cap-and-trade option was introduced in Congress in July 2002 in the Clear Skies legislation, this option was not considered by the working group.

[18] Although the working group did not include tribal representation, EPA solicited their participation.

In October 2002, the working group issued its final report, *Recommendations for the Utility Air Toxics MACT: Final Working Group Report,* in which it identified issues that "EPA must consider and resolve in its drafting of the utility MACT." Some of the issues identified included:

- sub-categories;
- floor levels;
- beyond-the-floor levels of mercury;
- compliance method (monitoring); and
- compliance time.

The working group decided early that consensus among its various stakeholder groups was unlikely, and did not attempt to reach agreement on specific recommendations it could make to the Agency. Instead, the report presented the opinions of all the stakeholders on the issues.

Though the working group issued the final report in October 2002, it held another meeting on March 4, 2003, just after Clear Skies legislation was re-proposed in February. Certain members of the working group had requested that EPA conduct additional analyses using the IPM to further explore the cost-benefit of different MACT proposals as presented by the working group members. Members of the working group did not have direct access to the IPM, as EPA contracts for its use through a third party, and thus requested that EPA have the additional analyses run and then provide the group with the results. According to several members of the working group we contacted, it was expected that the working group would receive the results of the additionally requested IPM runs at the March 4 meeting, but were instead told the runs were not yet complete. Another meeting was scheduled for April 15, 2003, to provide the results of the IPM runs, but members were notified by EPA of its cancellation via e-mail on April 1.

In July 2003, Administrator Whitman responded to Congressman Waxman's request for the status of IPM runs for the working group. The Administrator stated that it was the Agency's intention to convene an additional FACA meeting when the IPM analyses were complete. However, in March 2004, the Assistant Administrator for Air and Radiation said the Agency would not provide the additional MACT IPM analyses and would instead focus resources on developing a cap-and-trade alternative, the administration's preferred regulatory approach.

The working group has not met since its last meeting in March 2003 and has not been officially contacted by the Agency since its planned April 15, 2003, meeting was cancelled. A formal notice of termination has not been issued to the working group and, according to some members, they were not given an explanation as to why the working group ended. EPA has stated on its web site that it began proceeding with a cap-and-trade regulatory approach in the absence of Congressional action on Clear Skies legislation. The FACA working group's

deliberations were stopped after Clear Skies was re-proposed and before EPA began developing its proposed cap-and-trade regulation. While some working group members indicated satisfaction with the work completed by the group, others considered the job unfinished due to the lack of opportunity to consider the additionally requested runs.

According to senior EPA officials, the working group's original charter was for only one year. One of the officials acknowledged that EPA had initially intended to conduct the runs requested by the working group but later decided that it would not be beneficial. These officials further indicated that since the working group had not reached consensus, the Agency did not believe the working group should have been extended.

Intra-Agency Review Limited

According to staff involved, the intra-agency work group review process followed in this rulemaking varied significantly from past Agency practice and applicable guidance for Tier One rules in that the group only met two times and was not given an opportunity to provide meaningful feedback on the proposed rule. According to the Agency's regulatory development guidance, a work group is to meet frequently enough to ensure that all significant issues and options are discussed and agreed upon. Then, the significant issues and several options to resolve each issue are to be provided to senior management. Senior management then selects those options they believe will best achieve the goals of the action for a Final Agency Review.

The work group's first meeting was held on February 27, 2003, and the second and final meeting took place on August 7, 2004. In preparation for the first meeting, the work group chair e-mailed to the work group members a copy of the Utility MACT FACA working group's final report, along with a draft analytical blueprint for the rulemaking. According to EPA's Action Development Plan, an analytical blueprint is "a document that spells out a work group's plans for data collection and analyses that will support development of a specific action," and is intended to be developed as "a collaborative effort." The draft blueprint stated, "the intent of the rule is to require that oil-and-coal-fired units achieve a MACT-level of control," and it listed the "minimum analytical needs" for the rulemaking:

- A regulatory impact analysis, assessing the economic impact on industry of levels beyond the MACT floor.
- Assessment of multi-pathway concerns.
- A regulatory flexibility analysis addressing small business concerns.
- Assessment of environmental justice concerns.
- Children's health concerns.
- Unfunded mandate assessment, evaluating the impact of the rulemaking on State/local/tribal governments, some of which own or operate coal-fired units.

- ICR issues.

Although the above issues were identified for study in the draft analytical blueprint, some were never fully addressed, such as the children's health study and an assessment of environmental justice concerns. The draft blueprint also stated that:

> *". . . the EPA believes that emissions trading is prohibited under Section 112 of the CAA. However, industry, and to a more limited extent, some other stakeholders would like to explore emissions trading as an option (perhaps in beyond-the-floor analyses) for this rulemaking."*

Members of the work group, including the Office of Research and Development and the Office of Policy, Economics, and Innovation, submitted comments to the draft analytical blueprint via e-mail to the work group chair. But work group participants we interviewed stated that they received no feedback or modified drafts of any work products based on their comments and input.

In preparation for the second intra-agency workgroup meeting, members were asked to review and comment on four sections (approximately 42 pages) of an early version of the draft (July 3, 2003) preamble. However, intra-agency workgroup members received no modified work products that incorporated their feedback. Additionally, no Final Agency Review meeting was held for the proposed mercury rule whereby core intra-agency review participants had the opportunity to concur or nonconcur with the proposed rule before it was sent to OMB for review and final action.

Several EPA staff who were involved in the abbreviated intra-agency work group review process told the OIG that it was made clear to them by their managers, and in the case of one work group representative, by the work group chair, that decisions about this rule were being made at a "higher level." For example, in an e-mail discussing intra-agency comments, a member of the work group was told:

> *The decision was made at a much higher level than mine to "bypass" the normal EPA Work Group procedure prior to the proposal and we have been told that all the Office directors were contacted about both the process change and rulemaking.*

Similarly, these officials told us that it became clear to members that their feedback would not likely be considered. One Agency source said that, in general, there was not a meaningful opportunity for EPA offices to comment on this rule. Some Agency officials said they considered the intra-agency review process to have been conducted, but at a higher staff level and with less input than usual from lower staff levels. However, at least one office usually involved in the intra-agency review process – the Office of Enforcement and Compliance

Assurance – was neither given the opportunity to review nor submit comments regarding the proposed rule before it was sent to OMB, according to former and current Office of Enforcement and Compliance Assurance officials contacted.

According to senior EPA officials it is not unusual during the development of high-profile rules, particularly those under a tight deadline, for EPA to not strictly follow the Agency's prescribed rulemaking process.

Requirements for Cost-Benefit Analyses Not Fully Implemented

Although EPA conducted certain required analyses, other analyses were not completed. For rulemakings with an annual economic impact of $100 million or more, Executive Order 12866[19] requires that Federal agencies, in deciding whether or how to regulate, assess all costs and benefits of available regulatory alternatives and provide the reasoning for selecting the proposed regulatory action over such alternatives. This Executive Order also directs that Federal agencies base their decisions on the best reasonably obtainable scientific, technical, and economic information concerning the need for, and consequences of, the intended regulation.

EPA staff told OIG that senior management instructed them not to undertake certain scientific and technical analyses that they thought necessary. For example, staff were instructed during meetings not to conduct IPM runs (which could have been helpful in considering alternatives) until they were told the national mercury emissions per year desired for the MACT. As discussed in Chapter 2, EPA conducted analyses of various MACT floor levels, but presented only a 34-tons-per-year option to the public. In addition, the Agency did not fully analyze a beyond-the-floor MACT alternative.

EPA's cost-benefit analysis of the MACT proposal did not take into account mercury emissions reductions that would be gained as co-benefits resulting from NOx and SO_2 controls installed under the proposed CAIR. However, the Agency's cost-benefit analysis of the cap-and-trade option did consider CAIR co-benefits. This prevents a balanced comparison of the two options. EPA staff told us that a MACT-plus-CAIR alternative was not analyzed because, when the MACT floor was completed, CAIR had not yet been proposed. However, EPA issued a December 2004 Notice of Data Availability for the proposed rule, which included an analysis submitted by the Clean Air Task Force that estimates the impact (in terms of emission reductions) of CAIR in conjunction with the proposed MACT standard. The notice did not include a similar analysis by EPA.

The Agency did not monetize the health benefits of mercury reductions, though

[19] Regulatory Planning and Review, 58 FR 51735, October 4, 1993.

Office of Air and Radiation staff have said the final rule will include quantitative, non-monetized endpoints as well as a qualitative discussion. EPA staff told us that they have ongoing efforts to develop a benefits analysis, but that it is slow moving and has not been completed. Since March 2004, when the Administrator stated the Agency would take a closer look at the issue, there has been a process to try and do a full benefits analysis, but the process is moving slowly. While a benefits analysis should be based on scientific literature, staff told us that there had been pressure to base the analysis on public comment through the Notice of Data Availability. The notice presents a methodology for determining the benefit of mercury reductions and requests comment on this methodology.

Required Children's Health Analysis Not Comprehensive

EPA did not adequately evaluate the environmental health effects of the proposed rule on children. Executive Order 13045[20] requires such an evaluation because "[a] growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks." In prior MACT rulemakings EPA had determined that Executive Order 13045 and, therefore, a children's health evaluation, is not applicable because MACTs are technology standards and apply consistently to covered sources. However, since the proposed rule includes a cap-and-trade option, which is a performance standard that could result in an uneven distribution of emissions, it is covered under Executive Order 13045 and, therefore, an analysis of the rule's impact on children's health is required.

Although the proposed rule states that EPA evaluated health and safety effects pertaining to children, our review of the proposal and docket did not show that EPA performed such analyses in accordance with Executive Order 13045. We requested such analyses from EPA, but were not provided with any specific studies of the rule's impact on children's health. Interviews with officials from EPA's Office of Children's Health Protection indicated they were not involved during the rule development. However, Office of Children's Health Protection staff said their lack of involvement in such functions is not unusual due to limited staffing.[21] Members of the Children's Health Protection Advisory Committee (CHPAC) told us that the proposed rule does not adequately take into account children's vulnerabilities. The CHPAC outlined their concerns in a January 26, 2004 letter to the Administrator, in which they made several recommendations, including that the Agency "[e]valuate the possibility that hot spots could result"

[20] Protection of Children From Environmental Health Risks and Safety Risks, 62 FR 19885, April 23, 1997.

[21] A May 2004 OIG report found that there was no overall, coordinated strategy integrating children's environmental health efforts into the Agency as a whole (*The Effectiveness of the Office of Children's Health Protection Cannot Yet Be Determined Quantitatively*; OIG Report No. 2004-P-00016; May 17, 2004).

from the cap-and-trade program as proposed.[22] In a subsequent June 8, 2004 letter to the Administrator, CHPAC additionally recommended that EPA "[e]valuate the relative health benefits of reducing mercury exposure for children and women of child-bearing age under the MACT and cap-and-trade regulatory options."

EPA senior officials noted that prior studies on the health impact of mercury addressed the impact of methylmercury exposure on children and, therefore, the rule itself addresses children's health. We recognize that current reference dose levels for mercury exposure are based on the impact to children's health. However, we were not provided any analyses assessing the extent to which the proposed rule may result in uneven distribution of mercury deposition that could increase some children's exposure to mercury. Office of Research and Development officials noted that regardless of the extent of any additional analysis, they do not know what the impact of reducing sources emissions by a certain percentage would have on deposition or in what timeframe. However, they noted that reductions in emissions will reduce atmospheric mercury, which in turn will result in less deposition, lower mercury levels in fish, and ultimately reductions in human exposure to mercury. EPA officials stated that this type of extensive analysis had not been done for the proposed rule, but they hoped to have a more detailed assessment for the final rule. They further explained that the Notice of Data Availability issued in December 2004 proposed a process for quantifying the proposed rule's impact on mercury deposition and the resulting bioaccumulation in the environment.

Scope Limitation: Inter-Agency Review

Due to time constraints[23] and the fact that OMB controls this process and not EPA, the OIG did not evaluate the inter-agency review process and EPA's response to the edits resulting from that process. The inter-agency review process occurs under the direction of OMB after a proposed rule is submitted to the Office of Information and Regulatory Affairs in OMB for review, as stipulated in Executive Order 12866. The process is typically informal and, according to one EPA official, details on the meetings between OMB and other agencies, as well as comments submitted to OMB during the review, often are not included in the formal docket.

It is difficult to determine every agency involved in the editing process, which agency made specific edits to the proposal, or the timing of these edits based on inter-agency review documents contained in the docket. We identified comments from at least four agencies or offices other than EPA and OMB: the Department

[22] Chapter 3 of this report recommends that EPA further assess the risk of hot spots.

[23] Our field work in some areas was limited in order to provide the results of our review to EPA management in time for them to consider our recommendations in developing the final rule.

of Energy; the Department of the Interior; the Small Business Administration; and the Council on Environmental Quality.

Conclusions

The rulemaking process did not meet the expectations of some EPA staff and FACA work group members, and did not fully address certain Executive Order requirements to conduct cost-benefit and children's health analyses. These deviations from prior practice and Executive Order requirements appeared to have occurred, in part, because of the Agency's decision to include a proposed cap-and-trade option in the proposed rule, as well as a need to meet the deadlines for the proposed MACT rule reached in prior court settlements.

Recommendations

We recommend that the Assistant Administrator for Air and Radiation:

4-1 Ensure that the Office adheres to the Action Development Process during EPA's future rulemaking actions to include obtaining input from all relevant Agency Offices.

4-2 Conduct more in-depth cost-benefit analyses of the proposed mercury options to determine the preferred approach.

4-3 Conduct a more in-depth analysis of the impact of the proposed options on children's health.

Agency Comments and OIG Evaluation

The Agency stated that the draft report failed to recognize the nature of the regulatory development process and incorrectly stated that EPA did not adequately evaluate the proposed rule's impact on children's health. Further, the Agency stated that the draft report improperly characterized the process by suggesting that it had not been sufficiently inclusive. We believe the draft report accurately described the rulemaking process, and continue to believe that the Agency should have more comprehensively evaluated the proposed cap-and-trade rule's impact on children's health. A cap-and-trade program, while reducing overall emissions, can result in geographically uneven distributions of emissions. The proposed rule did not include an analysis of where or how likely such varying mercury emissions and resulting depositions could occur, and what impact this may have on children's health. The OIG does not agree that the Agency review process was inclusive. As we noted in our draft report, according to staff involved, the intra-agency work group review process followed in this rulemaking varied significantly from past Agency practice and applicable guidance for Tier

One rules. Given this rule's far-reaching national implications for human health, the environment, and the economy, the OIG believes it was important for the Agency to have been more inclusive of available Agency expertise and external stakeholder input to develop this rule. The Agency's complete response to the draft report and our evaluation of its response are in Appendix E.

Appendix A

Timeline of Events Related to Development of Mercury Rule

Date	Event
November 15, 1990	President signs CAA Amendments of 1990. Section 112 requires EPA studies of mercury and Hazardous Air Pollutant emissions from utilities.
December 1997	EPA issues "Mercury Study Report to Congress." Emissions trading discussed as a control option.
February 1998	EPA issues "Study of Hazardous Air Pollutant Emissions from Electric Utility Steam Generating Units." Defers decision on whether regulation of utilities is necessary and appropriate under CAA section 112.
July 11, 2000	National Academy of Sciences releases report, "Toxicological Effects of Methylmercury," which concludes that EPA's reference dose for methylmercury is a scientifically defensible level. Estimates that 60,000 newborns a year could experience neurological damage due to mercury.
December 2000	EPA Issues Federal Register Notice making final determination that regulation of mercury from utilities under CAA section 112 is "appropriate and necessary." Discusses cap-and-trade as an option but states that such an approach must protect local populations close to a source.
August 1, 2001	First meeting of Utility MACT working group. Charge to the Group is to develop a MACT standard. Explicitly directed not to consider trading.
July 2002	Clear Skies Act of 2002 introduced in the Senate and House of Representatives. Proposed a multi-pollutant approach to controlling SO_2, NOx, and mercury emissions from power plants.
August 28, 2002	EPA contractor memo outlines options for developing proposed MACT floor.
October 2002	Utility MACT working group issues final report. Consensus not reached. Additional IPM runs recommended based on MACT emission limit proposals from stakeholder groups.
February 27, 2003	Initial meeting of intra-agency work group (one of two total meetings). Analytical blueprint prepared for group addresses traditional MACT, not cap-and-trade, and identifies minimum analyses needed.
February 27, 2003	Clear Skies re-introduced in House and Senate as Clear Skies Act of 2003.
March 4, 2003	WEST Associates issues white paper proposing multi-variability method for determining MACT floor; presented at last meeting of Utility MACT working group. Paper presented to FACA at its last meeting. Method eventually adopted by EPA but with some changes.
March 4, 2003	Last meeting of Utility MACT working group. April meeting canceled by EPA; group had planned to discuss results of recommended IPM runs.
March 14, 2003	Briefing provided to Administrator Whitman. Presentation states EPA will continue to develop a section 112 MACT standard unless Congress removes the requirement.

Date	Event
April 1, 2003	EPA cancelled last FACA working group meeting. E-mail indicates runs not yet available, and meeting would be rescheduled at a later date.
August 7, 2003	Second (and final) intra-agency work group meeting held, reviewing draft preambles. Several MACT emission limits proposed, none of which match those in published proposed rule.
November 4-5, 2003	E-mails between EPA officials discuss efforts to establish MACT floor resulting in mercury emissions of 34 tons per year, based on IPM runs using various proposed MACT emission limits.
November 26, 2003	EPA memo to file explaining MACT floor (based on WEST Associates method).
December 15, 2003	"Regulatory Flexibility Act Analysis" entered in Docket.
December 2003	EPA contractor issued memorandum discussing beyond-the-floor analysis.
December 15, 2003	Proposed mercury rule signed.
January 2004	EPA Report on Benefit Analysis entered in Docket.
January 28, 2004	"Energy and Economic Impact Analysis" entered in Docket.
January 30, 2004	Proposed mercury rule published in the Federal Register.
March 16, 2004	Supplemental Notice issued to the original proposed rule providing procedures for implementing cap-and-trade proposal.

Appendix B

OIG's Request for Documents Related to Development of Utility MACT

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF INSPECTOR GENERAL
OFFICE OF PROGRAM EVALUATION
1301 CONSTITUTION AVENUE, N.W.(2460T)
EPA WEST BUILDING
WASHINGTON, DC 20004

November 15, 2004

MEMORANDUM

Subject: Document Request for Assignment Number 2004-1021 - Development of the Proposed MACT for Utility Units

To: Jeffrey Holmstead,
Assistant Administrator for Air and Radiation

From: Kwai Chan, /s/
Assistant Inspector General for Program Evaluation

This memorandum is a formal request to you and your staff cc'ed below for several documents that we need in order to complete our work on the subject evaluation. The majority of these documents have already been requested and are listed again herein. In addition, we are requesting specific information (see item 7 below) not previously requested that is needed for us to fully and comprehensively address our evaluation objectives. We request that you provide us with the following information by November 26, 2004, in order that this information can be fully considered in our review:

1. Any and all statistical analysis and related internal correspondence for the two MACT IPM runs conducted in November 2003, including electronic records, that are not included in the docket.
2. Any and all written OGC analysis concerning use of Section 111 vs. Section 112, both for the December 2000 findings and determination and the January 2004 proposed rule, including electronic records.
3. Any and all documentation showing final intra-agency concurrence (or equivalent)

for issuing the proposed rule, including electronic records.

4. Any and all written comments resulting from the intra-agency review process, including electronic records.
5. The analysis related to children's health that was specifically referred to in the proposed rule's preamble on page 4715 of the Federal Register Notice.
6. The Agency analysis determining the origination of Latham and Watkins language that was included in the proposed rule's preamble, and
7. Any and all internal and external Agency correspondence or other written communications related to the development of the MACT floor that were developed, transmitted, and/or received during the period October 15, 2003 through December 15, 2003, including e-mails meeting the definition of Federal Records.

We appreciate your prompt response to this request. Please contact Jim Hatfield, Assignment Manager, at 919-541-1030, or Carolyn Blair, Project Manager, at 919-541-7702, to coordinate the submittal of information related to this request. If any of the above information does not exist please indicate that fact in your response.

cc: Robert Brenner, Deputy Assistant Administrator for Air and Radiation
Bill Wehrum, Office of the AA for OAR
Jason Burnett, Office of the AA for OAR
Stephen Page, Director, OAQPS
Sally Shaver, Director, Emissions Standards Division, OAQPS
Bob Wayland, Combustion Group Leader, ESD, OAQPS
William Maxwell, Principal Rulemaking Contact, Proposed MACT for Utility Units, ESD,
Nikki Tinsley, Inspector General
Eileen McMahon, Assistant Inspector General for Congressional and Public Liaison
Mark Bialek, Counsel, OIG

Status of Agency's Response to OIG's Request for Documents Related to Development of Utility MACT

Item Requested	*Status*
1. Any and all statistical analysis and related internal correspondence for the two MACT IPM runs conducted in November 2003, including electronic records, that are not included in the docket.	1. We received limited information after the draft report was provided to the Agency for comment. Specifically, we were provided copies of Agency e-mails that discussed how the information used in these MACT IPM runs was developed.
2. Any and all written OGC analysis concerning use of Section 111 vs. Section 112, both for the December 2000 findings and determination and the January 2004 proposed rule, including electronic records.	2. Since this was a legal issue before the courts, we determined that we would not address this, so the information was not needed.
3. Any and all documentation showing final intra-agency concurrence (or equivalent) for issuing the proposed rule, including electronic records.	3. No documentation provided.
4. Any and all written comments resulting from the intra-agency review process, including electronic records.	4. No documentation provided.
5. The analysis related to children's health that was specifically referred to in the proposed rule's preamble on page 4715 of the Federal Register Notice.	5. Additional information in general was provided after the draft report was issued, but no analysis on children's health specific to this rule was included.
6. The Agency analysis determining the origination of Latham and Watkins language that was included in the proposed rule's preamble, and	6. The Agency pointed out the information in the docket related to this issue, but did not provide specific Agency analysis. Since this issue was related to inter-agency review process, which is controlled by OMB, we did not fully address this issue (See Scope Limitation in Chapter 4 of this report.)

7. Any and all internal and external Agency correspondence or other written communications related to the development of the MACT floor that were developed, transmitted, and/or received during the period October 15, 2003 through December 15, 2003, including e-mails meeting the definition of Federal Records.	7. No documentation or response received other than the limited information in the e-mails provided for Request 1 above.

Different MACT Floor Proposals

Source	Emission Limits (Input base - lbs/Tbtu)													
	Process Sub-Categories								Coal Type Sub-Categories					
	FBC	FBC (sub-Bit. + Bit)	FBC - Lignite	Other	Bit. - Hot	Bit. - Wet	Bit. - Saturated	IGCC	Sub-Bit. + Bit.	Bit.	Sub-Bit.	Lignite	Coal Refuse	Total Estimated Emissions
EPA Proposed Rule	NA	NA	NA	NA	NA	NA	NA	19.0	NA	2.000	5.800	9.200	0.4	34 [1]
FACA-Environmental	0.190	NA	NA	0.210 [2]	NA	NA	NA	NA	NA	NA	NA	NA	NA	1.9 [3]
FACA - Industry	2.000	NA	NA	NA	3.700	3.200	2.200	NA	NA	NA	4.200	6.500	NA	25-30 [3] 36 [6]
FACA - State & Local - Option 1	NA	NA	NA	NA	NA	NA	NA	NA	0.600	NA	NA	NA	NA	6.7 [3]
FACA - State & Local - Option 2	NA	NA	NA	NA	NA	NA	NA	NA	0.400	NA	NA	NA	NA	6.3 [3]
FACA - Clean Energy Group	NA	0.320	12.0	NA	NA	NA	NA	NA	1.223	NA	NA	9.091	NA	13.1 [3]
Clean Air Task Force [4]	NA	NA	NA	NA	NA	NA	NA	4.9	NA	0.420	1.500	4.500	0.1	12 [5]

Abbreviations

Bit.: Bituminous
FACA: Federal Advisory Committee Act
FBC: Fluidized Bed Combustion
lb/Tbtu: pounds per Trillion British thermal units
IGCC: Integrated Gasification Combined Cycle
MACT: Maximum Achievable Control Technology
NA: Not Applicable

Notes:

1 Estimate based on Integrated Planning Model results.
2 Applied to all units except FBC
3 Based on estimates developed by Northeast States for Coordinated Air Use Management.
4 Clean Air Task Force preferred a MACT with no sub-categorization but re-computed a MACT floor based on EPA's proposed subcategories.
5 Based on Integrated Planning Model run and includes co-benefit reductions from Clean Air Interstate Rule.
6 Based on calculations performed by the industry group.

Appendix D

EPA's Rule Development Process

EPA actions are assigned to one of three tiers based on the nature of the anticipated issues and the level of cross-Agency interactions needed to ensure a quality action. The proposed rule is a Tier one rule and meets the following criteria.

Tier 1 Criteria: Administrator's Priority Actions
This tier will include top actions that demand the ongoing involvement of the Administrator's office and extensive cross-Agency involvement on the part of the Assistant/Regional Administrators.

Factors to consider in making a judgment about placing an action in Tier 1 are:

- major cross Agency or cross-media policy implications or precedents
- potential for major or precedent-setting implementation issues
- potential for major cross-Agency, cross-media, or inter-agency controversy
- potential for major economic impact on other levels of government or the regulated community
- highly controversial in terms of external interest
- ongoing, formal involvement of the Agency's highest level of management (Administrator, Deputy Administrator) is necessary or desired
- presents a significant opportunity for the Agency to advance the Administrator's priorities

Action should be placed in Tier 1 if...

- science issue(s) are precedent setting and controversial
- economically significant per Executive Order 12866 (i.e., > $100 million), unless the program office can justify placement in Tier 2
- economics issue(s) are precedent setting and controversial

The program office develops the proposed rule, which may take months to years depending on the complexity of the rule, priorities, and court/statutory deadlines. Rule development follows five major stages, as outlined in the Agency's Action Development Plan. The first stage is determining the proper tier for the action based on the criteria outlined above. The following table describes the five stages of an Action Development Plan.

Five Major Stages of an Action Development Plan
Stage 1. Tiering the Action
• Understand tiering
• Place action in the appropriate tier
• Obtain tiering approval
Stage 2. Developing the Proposed Rule or Draft Action
• Charter the workgroup
• Get the workgroup underway
• Prepare the preliminary analytic blueprint and get early guidance from senior management
• Prepare the detailed analytic blueprint
• Senior management approval of analytic blueprint
• Complete data gathering, consultation, peer review, analyses, and options development
• Select Options
• Develop the proposed action by preparing preamble, rule, and supporting documents
• Conduct Final Agency Review to ensure senior management approval
• Office of Policy, Economics, and Innovation review for rules deemed as "significant" under Executive Order 12866
Stage 3. Requesting OMB Review for Proposed and Final Actions (if necessary)
• Determine if OMB review is necessary. Only those regulatory actions designated "significant" under Executive Order 12866, "Regulatory Planning and Review" are subject to review by OMB (e.g., actions having an annual effect on the economy of $100 million)
• Prepare regulatory action for submission to OMB
• Address OMB's comments
• Docket the OMB review process
Stage 4. Requesting the Administrator's Signature and Publishing an Action
• Request the Administrator's signature
• Publish the action in the Federal Register and open docket(s)
Stage 5. Developing the Final Action and Ensuring Congressional Review
• Receive public comments
• Consider and address public comments
• Determine next steps
• Submit actions to Congress under the Congressional Review Act or the Courtesy Copy Policy

Appendix E

Agency Comments to the Draft Report and OIG Evaluation

MEMORANDUM

SUBJECT: Comments on the December 17, 2004 Draft Evaluation Report Entitled, Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities

FROM: Jeffrey R. Holmstead
Assistant Administrator for Air and Radiation
U.S. Environmental Protection Agency

William H. Farland, PhD
Acting Deputy Assistant Administrator for Science
Office of Research and Development
U.S. Environmental Protection Agency

TO: Nikki Tinsley
Inspector General
U.S. Environmental Protection Agency

DATE: January 24, 2005

Thank you for giving us the opportunity to review the draft report referenced above and to open dialogue with OIG staff. We have substantial concerns with the referenced draft including several inaccuracies and flaws that we feel must be addressed before the report is finalized. This memorandum briefly summarizes our major concerns.

Agency scientists and experts know a great deal about mercury: what are the sources, both domestically and internationally; where does mercury in this country come from; what is the chemistry that converts mercury deposited on the land and in the water into mercury that becomes available to the food chain; what are the routes of exposure in this country to mercury; what are the potential impacts of controls on that exposure; and what is the status of the various technologies now being studied.

While some questions remain in our understanding of many of these linkages, this will not prevent the Agency from regulating mercury from power plants, and it will do so as effectively as possible, informed by the full body of knowledge it now possesses. The Agency also recognizes that mercury emissions from facilities as complex as coal-fired power plants should not be considered in isolation of the other efforts to reduce air pollution; hence the Administration's strategy to further control SO_2 and NOx while instituting new, specific regulations for mercury. The Agency believes that such a

a strategy can deliver significant overall health benefits to a broad segment of the American public.

EPA strongly urges the IG to take the broad base of information we know about mercury, as well as the outstanding unanswered questions, into consideration when developing the final report.

1. **The draft report criticizes the rulemaking process as being incomplete even before a final rule is issued.** This critique rings hollow given the iterative nature of rulemaking. The rulemaking process consists of a proposed rule, a public comment period and often additional information before final decisions are made. The IG characterized the process as incomplete before the process had finished. For example, a number of the issues regarding benefit-cost analysis raised in the draft report are issues that the Agency is working on as evidenced by its Notice of Data Availability on November 30, 2004.

> ***OIG Response:*** *Our review was initiated at the request of seven U.S. Senators, who asked that we complete this review in sufficient time to allow the Agency to address any issues raised in our report. We have added information to the Scope and Methodology section in Chapter 1 of the Final Report explaining that our review was completed while the Agency was still in the process of finalizing the rule. Accordingly, our report reflects findings and observations about the status of the process at the time we completed our review. We look forward to seeing the results of the Agency's additional cost-benefit analyses, as recommended in our report.*

2. **The draft report inaccurately suggests that US power plant mercury emissions represent a large part of the human exposure problem.** Most exposure to mercury comes from eating fish from the world's oceans and the mercury in these fish comes from a variety of sources released over many years, including natural emissions like volcanoes, and anthropogenic emissions from many countries, representing emissions from a variety of sectors, in addition to emissions from US power plants. It is because US power plants are part of the larger problem that EPA has proposed, for the first time ever, to require reductions from this sector.

Given the global nature of mercury exposure and the uncertainty in the time to realize benefits from current emission reductions, the action to reduce mercury emissions from power plants must be seen in the larger context of all the activities EPA and others in the international community are implementing to reduce exposure to mercury.

OIG Response: *Our draft report did not suggest that mercury emissions from U.S. power plants represent a large part of the human exposure problem. Power plants are one of many sources of mercury emissions. The primary objective of our review was to assess EPA's development of the proposed rule for regulating mercury emissions from coal-fired electric utility units, and we included information in our draft report on mercury emissions and mercury health effects for background purposes. Nonetheless, we have included additional information in Chapter 1 of the Final Report to put total U.S. mercury and U.S. power plant emissions in the context of global mercury emissions. We understand that primary route of human exposure to mercury is through the consumption of fish and that the Centers for Disease Control and Prevention surveys indicate that seafood is the predominant type of fish consumed by women of child-bearing age and children. However, certain subgroups, such as Native Americans, eat more fresh-water fish and may be more susceptible to mercury exposure than others. We added this information to the background section of our final report.*

3. **The draft report does not comprehensively and accurately describe how the proposed cap-and-trade system would work, leading the reader with misimpression about what our experience and modeling has taught us.** The draft report fails to recognize that a cap-and-trade system requires emissions reductions on a concrete timeline of declining caps, thus leading to continual reduction of emissions and promotion of new technologies. It also fails to acknowledge that, under this system, the largest emitters typically will be the first to reduce their mercury emissions and will generally achieve the greatest level of reductions.

The draft report criticizes the cap-and-trade proposal for not requiring the installation of mercury-specific controls until 2018, but this is inaccurate and reflects a misunderstanding about how cap-and-trade works. The report should recognize the fact that it is reductions in mercury emissions that will lead to improvements in public health and these reductions will occur much earlier than 2018. Moreover, neither the Maximum Achievable Control Technology (MACT) approach nor the cap-and-trade approach would require any particular technology for controlling mercury. Either approach would require power plants to meet certain standards for mercury control, and then let individual plants find the best way to meet those standards.

OIG Response: *One of the objectives of our review was to evaluate whether the proposed mercury cap-and-trade rule was sufficiently protective of public health. As a result, we highlighted certain concerns with the rule as proposed. As such, we limited our focus of the mercury cap-and-trade proposal to concerns about the interim cap level, the potential for hot spots formation, the safety valve provision, the exemption of small emitters, and tribal impacts.*

Our draft report portrayed an accurate representation of how the mercury cap-and-trade program works. While the proposed mercury cap-and-trade rule should ultimately result in emissions reductions, we do not agree that the proposal provides a "concrete timeline of declining caps." For example, the proposed rule provides an interim cap that is based on co-benefits from existing technologies and can be achieved without the implementation of mercury-specific controls. Since the interim cap for mercury emissions can be achieved without mercury-specific controls, the proposed rule may not adequately promote the use of new technologies. Also, the only other mercury cap is the 2018 final cap, and EPA modeling indicates it may not be met in 2018 due to the banking provisions of the proposed mercury trading program. Finally, our draft report noted that neither the proposed cap-and-trade nor the MACT option require the use of any specific technology.

While EPA has experience with cap-and-trade programs such as the Acid Rain program, there are differences in the transport and fate of SO2 and mercury emissions which need to be addressed in a cap-and-trade approach to controlling mercury emissions. For example, SO_2 emissions are primarily deposited regionally and globally, while mercury can deposit locally. Additional differences between these two cap-and-trade programs were highlighted in Chapter 3 of the draft report.

4. The draft report incorrectly characterizes the calculation of the MACT standard. The draft report did not independently calculate the MACT floor, but instead simply relied on assertions made by critics of the proposal as the basis for their critique. The proposed MACT floor was calculated in accordance with the requirements of CAA Section 112(d) by basing the standard on what the top performing 12 percent of units were achieving in practice, taking into account subcategorization and variability.

Contrary to the claims in the draft report, the Agency did investigate beyond-the-floor MACT alternatives and did propose a beyond-the-floor standard where technology was found to be available (i.e., Integrated Gasification Combined Cycle (IGCC) subcategory).

OIG Response: *The OIG did not inaccurately characterize the calculation of the MACT floor. Our analysis was based on discussion with a number of EPA stakeholders and EPA officials, and review of supporting documentation. We found evidence that although the MACT floor was ostensibly based on data from the top performing 12 percent of units, this data was analyzed with a final target already in mind, i.e., 34 tons. As stated in the Agency's Comment 5 to our draft report, this "floor" of 34 tons was obtained during the Clear Skies legislative process. Accordingly, we do not consider this floor to be based on an unbiased analysis of what the top performing 12 percent of units were achieving.*

With respect to IGCC units, our review focused primarily on the development of the standards for existing units. Of the over 400 coal-fired power plants in operation in the U.S., two are IGCC plants. Although EPA did not propose a beyond-the-floor standard for existing IGCC units, EPA proposed an emission limit for new IGCC units that was below the calculated floor for IGCC units and was based on EPA's determination that mercury reduction of 90 percent could be obtained for this subcategory through the use of carbon bed technology.

5. The draft report suggests that the proposed rule was flawed because other regulatory alternatives that would achieve emissions levels lower than about 34 tons per year were not developed or proposed. In particular, the draft report makes much of the fact that the MACT proposal was developed with the goal of achieving a nationwide emissions level from affected power plants of about 34 tons per year. The report fails to consider the fact that EPA had developed extensive information about mercury emissions and control techniques in the power sector during the MACT regulatory development process and during the development of the Clear Skies initiative. That work caused us to conclude that mercury reductions could, in fact, be achieved in the power sector over the 3-4 year MACT compliance period specified by the statute. However, these reductions would not come for the most part from mercury-specific controls (such as activated carbon injection). Extensive work conducted by the Office of Air and Radiation and the Office of Research and Development indicated that mercury-specific controls will not become readily available for commercial application to this industry until 2010 or later - well beyond the MACT compliance period. Consequently, the proposed rule is predicated on the assumption that virtually all mercury reductions during the MACT compliance period would have to be accomplished as a co-benefit of installing air pollution controls designed to remove SO_2 or NOx. As part of the Clear Skies effort, EPA had extensively studied the capacity of the power sector to install SO_2 and NOx controls during the period up to 2010. That work showed that 34 tons per year was the lowest level of mercury emissions that we could reasonably expect the power sector to achieve through the aggressive application of SO_2 and NOx controls up to 2010. Further, as a part of the FACA process established for this rulemaking, industry submitted what they thought would be possible under a true co-benefit approach (i.e., no mercury-specific controls). Their estimate was that 36 tons per year of mercury would be emitted under a MACT approach. The EPA proposal is grounded in careful analysis as to what levels of mercury control reasonably can be expected over the MACT compliance period.

OIG Response: *Our draft report concluded that the MACT development process was compromised for several reasons. This included the fact that several MACT floor proposals were lower than the EPA's proposed MACT rule, including several proposals developed by EPA in trying to achieve a floor that would result in annual emissions of 34 tons. This included two EPA IPM runs that showed national emissions of 29 tons and 27 tons, that were not included in the rulemaking docket or available for public comment. While the Agency has conducted analysis to determine the co-benefit of SO_2 and NOx controls, we do not believe this meets the requirements of CAA section 112(d) in developing the MACT standard. For example, the co-benefit is based on an average performance of all units, not just the best performers. We continue to believe the Agency should conduct additional analyses before finalizing the rule. As noted in the draft report, the Government Accountability Office is conducting a review of technology-related issues for the proposed mercury rule.*

6. The draft report fails to recognize the nature of the regulatory development process and incorrectly states that EPA "did not adequately evaluate the environmental health effects of the proposed rule on children." We have made it clear from the start of the rulemaking process that the health effects of greatest concern are possible developmental effects in fetuses and young children exposed to unsafe levels of methylmercury. Unlike most other rules that EPA develops, this rulemaking is singularly directed at developing an appropriate regulatory approach for addressing the potential impacts on children. Evidence of this can be seen in EPA's first guiding principle in the development of a final mercury rule which states that the rule will concentrate on the need to protect children and pregnant women from the health impacts of mercury.

Consistent with this principle, EPA Office of Air and Radiation participated in an ongoing dialogue with the Children's Health Protection Advisory Committee (CHPAC) and responded to CHPAC's recommendations on mercury exposure in children. Further, EPA and others have conducted extensive work on the health effects of mercury for the developing fetus and young children, including a National Academy of Sciences review completed in 2000. The Inspector General's draft report misses this key point.

OIG Response: *We do not believe we failed to recognize the nature of the rulemaking process. Further, the Agency should have more comprehensively evaluated the proposed cap-and-trade rule's impact on children's health. A cap-and-trade program, while reducing overall emissions, can result in geographically uneven distributions of emissions. The proposed rule did not include an analysis of where or how likely such varying mercury emissions and resulting depositions could occur, and what impact this may have on children's health.*

Children's Health Protection Advisory Committee members did not characterize their interaction with the Agency as an ongoing dialogue. Committee members told us that the Agency's response to their concerns with the proposed rule did not satisfactorily address their recommendations.

7. The draft report improperly characterizes the process by suggesting that it has not been sufficiently inclusive. EPA has held dozens of high-level inter-office and external meetings on this rule. This inclusive process was needed both because the rule has far-reaching national implications for human health, the environment, and the economy and also because a well-informed decision on an issue this complicated requires hearing diverse perspectives. While there is always room to improve communications within and with those outside of EPA, there is little basis to fault the Agency in this case.

OIG Response: *The OIG does not agree that the Agency review process was inclusive. As we noted in our draft report, according to staff involved, the intra-agency work group review process followed in this rulemaking varied significantly from past Agency practice and applicable guidance for Tier One rules. Specifically, the work group process followed in this rulemaking was unusual in its short duration, infrequent meetings, late start with respect to the final rule deadline, and overall lack of communication and feedback between the work group and Agency decision makers. Further, work group members were not given the opportunity to review and comment on an entire draft proposal before it was published in the Federal Register. For example, staff from the Office of Enforcement and Compliance Assurance were never given a draft of the proposed rule to review or comment on, thus this office could not assess the adequacy of the proposed rule's monitoring, record keeping, or reporting provisions as it typically does for Tier One MACTs. With respect to meeting with external stakeholders, tribal representatives told us that they were not consulted during the development of the proposed cap-and-trade option. Given this rule's far-reaching national implications for human health, the environment, and the economy, the OIG believes it was important for the Agency to have been more inclusive of available Agency expertise and external stakeholder input in developing this proposed rule.*

Again, thank you for the opportunity to review the draft report. We would be happy to work with you and your staff to ensure that you promptly receive all the information and analysis you need to finalize the report. The final report should include an improved discussion of (1) the global nature of mercury exposure and the uncertainty in the time to realize benefits from current emission reductions; (2) how a proposed cap-and-trade system would require emissions reductions on a concrete timeline; (3) the approaches to calculation of the MACT floor; (4) the substantial effort EPA devoted to evaluating the risk of mercury exposure on children; and (5) the inclusiveness of EPA's process towards reaching a final rule.

OIG Response: *The Agency's comments have been included in the final report as appropriate. We appreciate the efforts of both the Office of Air and Radiation and the Office of Research and Development in working with us to clarify certain technical issues and in providing prompt input so that we could issue our report in a timely manner.*

Appendix F

Distribution

Acting Administrator (1101A)

Assistant Administrator for Air and Radiation (6101A)

Deputy Assistant Administrator for Air and Radiation (6101A)

Acting Deputy Assistant Administrator for Science, Office of Research and Development (A101R)

Acting Deputy Assistant Administrator for Management, Office of Research and Development (A101R)

General Counsel, Office of General Counsel (4010A)

Agency Followup Official (the CFO) (2710A)

Agency Followup Coordinator (2724A)

Audit Followup Coordinator, Office of Air and Radiation (6102A)

Audit Followup Coordinator, Office of Research and Development (A102R)

Associate Administrator for Congressional and Intergovernmental Relations (1301A)

Associate Administrator for Public Affairs (1101A)

Director, Office of Air Quality Planning and Standards (C404-04)

Deputy Director, Office of Air Quality Planning and Standards (C404-04)

Audit Liaison, Office of Air Quality Planning and Standards (C404-2)

Inspector General (2410)

OFFICE OF INSPECTOR GENERAL

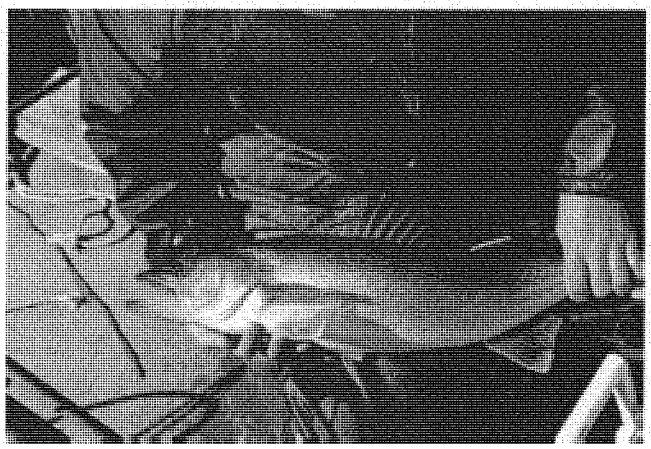
Catalyst for Improving the Environment

Evaluation Report

Monitoring Needed to Assess Impact of EPA's Clean Air Mercury Rule on Potential Hotspots

Report No. 2006-P-00025

May 15, 2006



Report Contributors: Rick Beusse
Carolyn Blair
Hilda Canes
Susan Charen
Sarah Fabirkiewicz
James Hatfield
Erica Hauck
James Van Orden

Abbreviations

CAMR	Clean Air Mercury Rule
CMAQ	Community Multiscale Air Quality
EPA	Environmental Protection Agency
Hg	Mercury
IPM	Integrated Planning Model
km	kilometer
MACT	Maximum Achievable Control Technology
MDN	Mercury Deposition Network
mg/kg	milligram per kilogram
OIG	Office of Inspector General

Cover photo: A fisherman holding a walleye, a predator fish for which mercury contamination is a concern (photo courtesy EPA).

U.S. Environmental Protection Agency
Office of Inspector General

2006-P-00025
May 15, 2006

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

In support of its Clean Air Mercury Rule (CAMR), the Environmental Protection Agency (EPA) conducted a detailed analysis of mercury emissions and deposition. EPA concluded that "utility-attributable" hotspots would not occur after implementation of CAMR's mercury trading program. This evaluation assesses the basis for EPA's conclusion.

Background

About 40 percent of U.S. man-made airborne mercury is emitted from coal-fired utilities. EPA revised a previous finding that mercury emissions from coal-fired utilities be regulated with a Maximum Achievable Control Technology standard. Instead, EPA adopted a cap-and-trade program to reduce mercury emissions. Several State agencies and environmental groups objected to these actions. One concern was that a cap-and-trade program could result in localized areas with unacceptably high levels of mercury, or "hotspots."

For further information, contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2006/20060515-2006-P-00025.pdf

Monitoring Needed to Assess Impact of EPA's Clean Air Mercury Rule on Potential Hotspots

What We Found

EPA brought significant scientific, technical, and modeling expertise to bear in developing a specific methodology to consider the potential for mercury hotspots. Several uncertainties associated with key variables in the analysis could affect the accuracy of the Agency's conclusion that the Clean Air Mercury Rule (CAMR) will not result in "utility-attributable" hotspots. We noted:

- gaps in available data and science for mercury emissions estimates,
- limitations with the model used for predicting mercury deposition,
- uncertainty over how mercury reacts in the atmosphere, and
- uncertainty over how mercury changes to a more toxic form in waterbodies.

Two recent studies support the need for additional monitoring to ensure that EPA's analysis has properly estimated the contribution of local, regional, and global sources on U.S. deposition. These studies are "*Mechanisms of Mercury Removal by O_3 and OH in the Atmosphere,*" published in *Atmospheric Environment* in June 2005; and "*Sources of Mercury Wet Deposition in Eastern Ohio, USA,*" submitted for publication in a scientific journal in February 2006. Results of both studies were not available until after EPA issued CAMR in March 2005, and thus could not have been considered in EPA's deliberations on CAMR. Although EPA indicated in CAMR that it would monitor the impact of the cap-and-trade rule on mercury deposition, the Agency has not yet developed a monitoring plan for this purpose. Without field data from an improved monitoring network, EPA's ability to advance mercury science will be limited and "utility-attributable" hotspots that pose health risks may occur and go undetected.

Based on our interpretation of CAMR, EPA could not take action to mitigate a mercury hotspot unless the Agency first determined that the hotspot was solely "utility-attributable." Therefore, EPA could not require additional utility emission reductions if utilities contributed significantly, but not solely, to a mercury hotspot. This could limit EPA's ability to mitigate human health hazards by reducing potentially harmful levels of mercury in waterbodies and fish tissue. This could also limit EPA's ability to reduce the number of waterbodies with fish consumption advisories.

What We Recommend

We recommend that EPA develop and implement a mercury monitoring plan to (1) assess the impact of CAMR, if adopted, on mercury deposition and fish tissue; and (2) evaluate and refine mercury estimation tools and models. Further, if CAMR is adopted after the rule reconsideration process is complete, we recommend that EPA clarify in the final rule that the "utility-attributable" hotspot definition does not establish a prerequisite for making future revisions to CAMR. In response to the draft report, the Agency agreed that additional mercury monitoring is needed and explained that CAMR does not establish the "utility-attributable" hotspot definition as a prerequisite for future changes to CAMR.

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

OFFICE OF
INSPECTOR GENERAL

May 15, 2006

MEMORANDUM

SUBJECT: Monitoring Needed to Assess Impact of EPA's Clean Air Mercury Rule on Potential Hotspots
Report No. 2006-P-00025

TO: William L. Wehrum
Acting Assistant Administrator for Air and Radiation

This is our report on the subject evaluation conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). This report contains findings that should help EPA to better monitor the impact of the Clean Air Mercury Rule and refine performance standards under the rule, if necessary. This report represents the opinion of the OIG and the findings in this report do not necessarily represent the final EPA position. Final determinations on matters in the report will be made by EPA managers in accordance with established procedures.

Action Required

In accordance with EPA Manual 2750, as the action official, you are required to provide a written response within 90 days of the final report date. The response should address all recommendations. For the corrective actions planned but not completed by the response date, please describe the actions that are ongoing and provide a timetable for completion. Where you disagree with a recommendation, please provide alternative actions for addressing the findings reported.

We appreciate the efforts of EPA managers and staff in working with us to develop this report. If you or your staff have any questions regarding this report, please contact me at 202-566-0847, or Rick Linthurst at 919-541-4909.

Sincerely,

Bill A. Roderick
Acting Inspector General

Table of Contents

At a Glance

Chapters

1 **Introduction** 1

Purpose 1
Background 1
Scope and Methodology 5

2 **Monitoring Plan Needed to Address Uncertainties In EPA's Hotspots Analysis** 6

EPA Analyzed Potential for "Utility-Attributable" Hotspots 6
Data and Science Gaps Exist for Mercury Emissions Estimates 8
CMAQ Model Uncertainties and Limitations 9
Study Finds Different Rates of Atmospheric Chemical Reactions 10
Uncertainties Noted with Methylation and Bioaccumulation 10
Study Shows Significant Deposition from Local Sources 12
Uncertainties Underscore Need for Mercury Monitoring Plan 13
Conclusion 15
Recommendation 15
Agency Comments and OIG Evaluation 15

3 **EPA Needs to Clarify Conditions Under Which CAMR Performance Standards Can be Tightened** 17

EPA Provides "Utility-Attributable" Hotspot Definition 17
"Utility-Attributable" Definition Could be Interpreted to Limit EPA's Ability to Mitigate Hotspots 18
CAMR and Revision Must be Read Together 18
Conclusion 20
Recommendation 20
Agency Comments and OIG Evaluation 20

Appendices

A **Details on Scope and Methodology** 21

B **Models Used in CAMR Analysis** 24

C **Agency Response to Draft Report** 25

D **Distribution** 28

Chapter 1
Introduction

Purpose

A prior Environmental Protection Agency (EPA) Office of Inspector General (OIG) report cited concerns about EPA's limited assessment of the potential for mercury hotspots resulting from a cap-and-trade program under the Clean Air Mercury Rule (CAMR). We issued this prior report, *Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities* (Report No. 2005-P-00003), on February 3, 2005. In support of CAMR, EPA conducted a detailed analysis of mercury emissions and deposition and concluded that "utility-attributable" hotspots would not occur after implementation of the mercury emissions trading program.

EPA's Water Quality Trading Assessment Handbook defines hotspots as "localized areas with unacceptably high levels of pollutants." In this evaluation report, however, a hotspot is a waterbody containing consumable fish with elevated levels of methylmercury in their tissues.

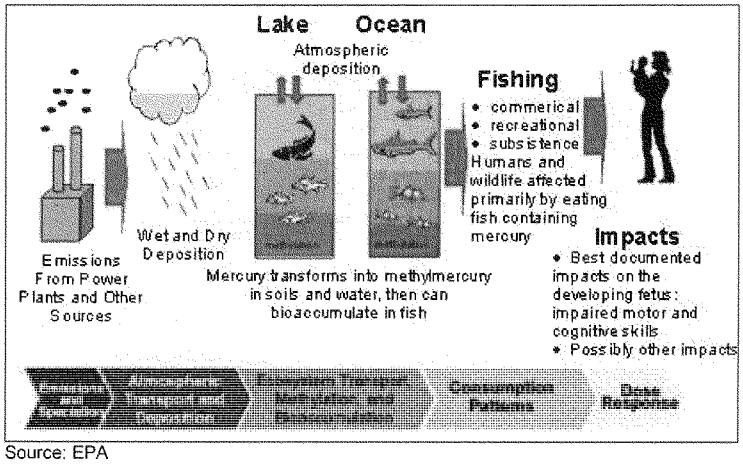
We conducted this evaluation to assess the basis for the Agency's determination that CAMR would not result in "utility-attributable" hotspots.

Background

Mercury (Hg) is released into the atmosphere through natural processes and through human activities, such as combustion processes. Once emitted, atmospheric mercury undergoes several chemical and physical processes and can then be deposited to the ground or waterbodies via wet or dry processes. In wet deposition, mercury is deposited by precipitation, such as rain or snow. In dry deposition, mercury settles to the earth's surface and sticks to or is absorbed by trees, soil, water, or other surfaces. The largest source of airborne mercury emissions in the United States is the coal-fired electric utilities industry, representing an estimated 40 percent of total U.S. man-made airborne mercury.

Although airborne mercury is generally not considered to be a serious health concern, once mercury enters freshwater and salt-water bodies, it can bioaccumulate in fish and other animal tissues in its more toxic form, methylmercury. As methylmercury bioaccumulates in the food chain, its concentration becomes increasingly higher in animals at the top of the food chain (such as larger predatory fish) that consume smaller, contaminated organisms. Figure 1-1 illustrates the exposure pathway of mercury.

Figure 1-1: How Mercury Enters the Environment



Source: EPA

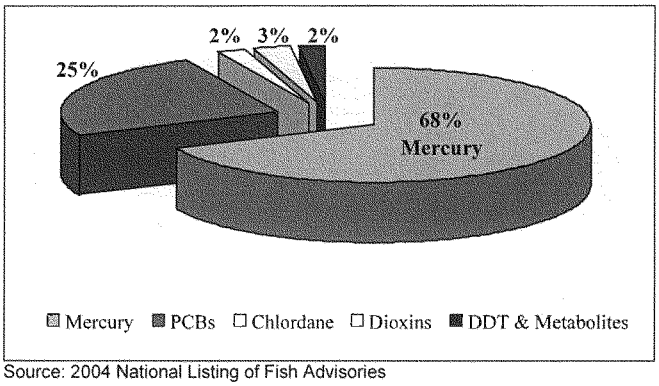
Fish consumption is the main route by which methylmercury harms human health. Excessive human exposure to methylmercury has been associated with severe detrimental neurological and developmental health effects. Research has shown that the developing fetus is at risk for impaired motor and cognitive skills. Thus, exposure to mercury by women of child-bearing age is of particular concern.

Most U.S. Fish Advisories Due to Mercury Contamination

When levels of chemical contamination in fish are considered unsafe, States, tribes, and territories can issue consumption advisories that may recommend that people limit or avoid eating certain species of fish caught in certain places. Each State sets its own criteria and decides which bodies of water to monitor. Monitored waterbodies may vary from year to year. Fish advisories are voluntary State recommendations not governed by Federal regulations. In 2004, 44 States issued fish advisories for mercury. The number of mercury-related fish advisories continues to rise as States increase fish tissue testing.

EPA recently reported in its 2005 *Performance and Accountability Report* that the Agency did not meet its goal of reducing the number of overall fish advisories by at least 1 percent from 2002 levels. From 2003 to 2004, the number of mercury advisories rose from 2,362 to 2,436, or 3.1 percent. According to the 2004 National Listing of Fish Advisories, the vast majority (68 percent) of fish advisories in the United States are due to mercury contamination, as illustrated in Figure 1-2.

Figure 1-2: Percent of Fish Advisories for Each of the Top Five Bioaccumulative Contaminants in 2004



Source: 2004 National Listing of Fish Advisories

CAMR First Rule for Mercury Emissions from Coal-Fired Utilities

On March 15, 2005, EPA issued CAMR, which established the country's first regulation of mercury emissions from coal-fired power plants. CAMR uses a declining cap-and-trade approach to regulating coal-fired utilities under Section 111 of the Clean Air Act by setting a fixed national cap. Utilities can buy and sell credits among one another in a national emissions market. Utilities that cannot cost-effectively reduce emissions may buy allowances from units that reduced emissions below established allowance limits. Under CAMR, an interim national cap of 38 tons per year becomes effective in 2010 and a final annual cap of 15 tons becomes effective in 2018. EPA's first cap is based on mercury reductions expected to be achieved as a co-benefit of implementing the Clean Air Interstate Rule, issued in March 2005. That rule requires utilities to take actions to reduce emissions of sulfur dioxide and nitrogen oxides, and those actions are also projected to reduce mercury emissions.

EPA Revised its Prior Regulatory Finding Regarding Utilities

To use a cap-and-trade program to regulate coal-fired utilities, EPA first had to revise a December 2000 regulatory finding[1] that indicated it was appropriate and necessary to regulate coal-fired utilities under Section 112 of the Clean Air Act. This finding required EPA to regulate utilities using a Maximum Achievable Control Technology (MACT) standard. MACT standards are

[1] *Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units,* December 20, 2000; Vol. 65, No. 245.

industry-specific, technology-based standards designed to reduce hazardous air pollutant emissions. These standards can require facility owners/operators to meet emission limits, install emission control technologies, monitor emissions and/or operating parameters, and use specified work practices. In March 2005, EPA issued a *Revision of December 2000 Regulatory Finding,*[2] stating that the Agency no longer found it appropriate or necessary to regulate utilities under Section 112. This released the Agency from the requirement to regulate utilities using a MACT standard. EPA issued the finding the same day it issued CAMR, which established a mercury cap-and-trade program under Section 111.

For its *Revision of December 2000 Regulatory Finding*, EPA interpreted Section 112(n) to mean that utilities alone had to be the sole cause of a health hazard in order to be regulated under Section 112 and subject to MACT standards. Specifically, EPA developed the following "utility-attributable" hotspot definition for its revision: ". . . a waterbody that is a source of consumable fish with Methylmercury tissue concentrations, attributable solely to utilities, greater than EPA's Methylmercury water quality criterion of 0.3 milligrams per kilogram (mg/kg)."

EPA Response to Petitions for Reconsideration

Several State agencies and other organizations oppose EPA's adoption of a cap-and-trade program for mercury. These groups separately petitioned for reconsideration of the *Revision of December 2000 Regulatory Finding*. Among other things, they asserted that, in its analysis, EPA underestimated the impact of deposition resulting from local and regional sources and overestimated the impact of emissions from global sources. Thus, they argue, some mercury hotspots already exist, and requiring sources to comply with MACT standards would immediately reduce deposition in those areas. Further, these opponents to the cap-and-trade program believe the program could result in new mercury hotspots if some utilities bought excess emission credits instead of reducing emissions.

On October 21, 2005, EPA reopened for public comment certain aspects of its CAMR and, in a separate action, reopened for public comment certain aspects of its *Revision of December 2000 Regulatory Finding*. The action to reopen comment on CAMR was taken in response to petitions filed by 14 States, 5 environmental groups, a public utility, and a waste services association. The Agency stated that it agreed to reconsider several aspects regarding CAMR. The action to reopen comment on EPA's *Revision of December 2000 Regulatory Finding* was based on two petitions, one from 14 States and a second from 5 environmental groups and 4 Indian tribes. The Agency agreed to reconsider the legal issues underlying the decision as well as the methodology used to assess the

[2] *Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants from Electric Utility Steam Generating Units and the Removal of Coal- and Oil-fired Electric Utility Steam Generating Units from the Section 112(c) List; Final Rule*, March 15, 2005.

amount of "utility-attributable" mercury levels in fish tissue and the public health implications of those levels. The Agency also agreed to reconsider how it defined a utility hotspot for the purposes of its finding concerning regulation of Utility Units under Clean Air Act Section 112. Comments regarding this reconsideration were accepted until December 19, 2005. The Agency was still evaluating comments at the time our field work ended.

Scope and Methodology

We conducted our review from September through December 2005, in accordance with *Government Auditing Standards* issued by the Comptroller General of the United States. We performed field work at EPA's Office of Air and Radiation in Washington, DC; the Office of Air and Radiation's Office of Air Quality Planning and Standards in Research Triangle Park, North Carolina; the Office of Research and Development in Research Triangle Park; and the Office of Water in Washington.

To answer our evaluation's objective, we examined: (1) the basis for the Agency's "utility-attributable" hotspot definition and the consistency of this definition with any prior Agency decisions regarding hotspots; (2) the key attributes, assumptions, and limitations of the models used to assess the impact of mercury emissions from coal-fired electric utility units under CAMR; and (3) the key variables used as inputs to the models as well as the basis for selecting these variables.

To gain an understanding of the definition of "utility-attributable" hotspots, the modeling and analyses EPA used to determine the potential for "utility-attributable" mercury hotspots after CAMR, and the inputs and assumptions associated with the Agency's analyses, we interviewed EPA staff involved in the development of CAMR or knowledgeable about the processes and models used in EPA's analyses. We also interviewed officials from State agencies and external organizations familiar with CAMR's development and EPA's hotspots analysis. We reviewed data and analyses developed in support of the rule, and selected public comments included in the rulemaking docket. We also reviewed related information provided by both EPA and non-EPA officials.

Our analysis focused on the key assumptions and limitations of the Community Multiscale Air Quality model, which was used to estimate mercury transport and deposition. We did not review in detail the assumptions, limitations, and uncertainties associated with the other models used in the Agency's analyses.

Appendix A provides additional details on scope and methodology.

Chapter 2
Monitoring Plan Needed to Address Uncertainties in EPA's Hotspots Analysis

As with any modeling assessment, uncertainties may exist. Uncertainties regarding EPA's analysis and conclusion that CAMR will not result in "utility-attributable" hotspots include:

- gaps in available data and science for mercury emissions estimates,
- limitations with the model used for predicting mercury deposition,
- uncertainty over how mercury reacts in the atmosphere, and
- uncertainty over how mercury changes to a more toxic form in waterbodies (i.e., methylation) and accumulates in fish tissue.

Two recent studies support the need for additional monitoring to ensure that EPA's hotspots analysis has properly estimated the contribution of local, regional, and global sources to U.S. deposition. These studies are:

(1) "*Mechanisms of Mercury Removal by O_3 and OH in the Atmosphere,*" Calvert, J.G., Lindberg, S.E., (published in *Atmospheric Environment*, Volume: 39, Number: 18, Page: 3355-3367), June 5, 2005, referred to in this report as the "Mechanisms of Mercury Removal Study;" and

(2) "*Sources of Mercury Wet Deposition in Eastern Ohio, USA,*" Keeler, G.J., et al., referred to in this report as the "Steubenville Study" (a peer review of the Steubenville Study was completed in December 2005 and the study was submitted for publication in a scientific journal in February 2006).

Results of both studies were not available until after EPA issued CAMR in March 2005, and thus could not have been considered in EPA's deliberations on CAMR. We believe the uncertainties associated with its CAMR analysis underscore the need for EPA to develop and implement a plan for monitoring the impact of CAMR on mercury deposition and mercury concentrations in fish tissue. Without implementation of a monitoring plan and/or improvements to current models, "utility-attributable" hotspots that can pose health risks may occur and go undetected.

EPA Analyzed Potential for "Utility-Attributable" Hotspots

In its *Revision of December 2000 Regulatory Finding,* EPA states it "does not believe that there will be any [utility-attributable] hot spots after implementation of CAIR [Clean Air Interstate Rule] and CAMR." EPA's analyses of mercury hotspots considered many factors that influence the way mercury is deposited to land and waterbodies. For its CAMR analysis, EPA used the Community

Multiscale Air Quality (CMAQ) model as the principal tool to predict patterns of mercury deposition and as an important part of assessing the potential for "utility-attributable" mercury hotspots under CAMR.

EPA considers the CMAQ to be the most capable model available for assessing the impacts of CAMR on mercury deposition within the United States. The model is designed to estimate pollutant concentrations and depositions over large areas, such as the continental United States. The model accounts for variations in mercury emissions, differences in the atmospheric reactions of mercury, and the impact of those factors on deposition.

However, there are important limitations associated with some of the inputs EPA used in CMAQ for its CAMR analysis. The July 2005 *Final Report: Second Peer Review of the CMAQ Model*, conducted by an independent panel that included State, academic, and private organizations, notes the following limitations:

> *CMAQ is a modeling system that simulates a wide range of physical, chemical and biological processes . . . Some of these processes are well understood, some reasonably well understood, and some only poorly understood. This wide range in the level of knowledge about the processes being modeled, and the fact that uncertainties in characterizing some of the processes correspond to areas of active research worldwide, means that some parts of the model code are sufficiently well established as to be considered fixed, while other parts of the code are under continuing development.*

Other models also played a role in EPA's analysis of the potential for hotspots under CAMR by contributing input data to CMAQ (see Appendix B for details on some of these other models). For example, a separate model was used to estimate the amount of mercury emissions from utilities based on certain economic assumptions, and another was used to predict weather patterns. Both the emissions and weather data were fed into CMAQ, and CMAQ predictions on deposition were fed into another model to estimate the effects of deposition on future mercury fish tissue concentrations.

In its hotspots analysis, the Agency discussed instances where conservative assumptions were used to avoid underestimating the impact of utilities. For example, in its hotspots analysis EPA did not screen out watersheds in which sources of mercury other than air deposition were significant. According to EPA, this may result in higher concentrations of methylmercury in fish being attributed to power plants than would be the case had EPA been able to account for non-air sources. In addition, EPA's hotspots analysis discusses the conservative estimates used in determining the oral reference dose for mercury (i.e., an estimate of the daily exposure to the human population, including sensitive subgroups, that is without an appreciable risk of deleterious effects during a lifetime). The reference dose and human exposure information were used to establish the water

quality criterion for methylmercury in fish tissue, the criterion used by EPA to represent a mercury hotspot.

Data and Science Gaps Exist for Mercury Emissions Estimates

While EPA has conducted activities to greatly increase its knowledge of mercury emissions from coal-fired utility plants, the Agency acknowledges that some uncertainty still exists when estimating total and speciated[3] mercury emissions and in projecting these emissions after implementation of various control technologies.

CMAQ requires the input of emissions inventory data to predict how emissions will transport and deposit. CMAQ was first run with a full emissions inventory to establish a base case scenario assuming the presence of all emissions. Next, CMAQ was run with emissions from coal-fired utilities removed, in what is called a "zero-out" run, to determine the impact of the variable that was zeroed out. EPA used this zero-out method to determine that no "utility-attributable" hotspots would occur after accounting for emissions reductions expected to be achieved from the Clean Air Interstate Rule and CAMR.

The utility emissions input into CMAQ were developed from the Integrated Planning Model (IPM). The IPM is a model of the U.S. electric power sector that can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of pollutants, including mercury. EPA has used the IPM in rulemakings since the mid 1990's. As part of that process, EPA takes comments on the underlying assumptions of the model and makes changes as a result. For its Clean Air Interstate Rule and CAMR analyses, EPA used IPM to estimate base case and future year national inventories of unit-specific mercury emissions under different control scenarios.

IPM uses equations (emission modification factors) to estimate utility emissions given the chemical composition of the coal being burned as well as various operating characteristics of the utility unit (e.g., type of control technology installed). These equations were based on various coal composition and emissions testing data collected during a 1999 Information Collection Request and more recent testing conducted by EPA, the Department of Energy, and industry participants.

While extensive data have been collected on mercury emissions from coal-fired utilities, some data and science gaps still exist with respect to understanding the effectiveness of specific controls in reducing mercury emissions from coal. As noted in the EPA Office of Research and Development's February 18, 2005,

[3] Mercury speciates into three basic forms: elemental, ionic, and particulate. Estimating the amount of speciated mercury emissions is important since the type of mercury emitted impacts how effectively it is captured by control technologies, and how it will react when emitted into the atmosphere. Differences in atmospheric reactions impact the amount and location of the mercury's deposition.

update of its study on control of mercury emissions, data and science gaps exist with respect to existing controls that are intended to reduce emissions of other pollutants with the co-benefit of reducing mercury, as well as emerging technologies specifically designed to reduce mercury emissions. The impact of these uncertainties on EPA's estimates of mercury emissions in base case and future years is qualitatively discussed in Agency documents but has not been quantified. The uncertainties could impact the accuracy of the estimated utility emissions input into CMAQ and CMAQ's resulting deposition estimates.

CMAQ Model Uncertainties and Limitations

CMAQ is useful for predicting regional and national patterns of deposition, but it has limitations that need to be carefully considered when used for modeling small areas of localized deposition and, thus, identifying hotspots. When emissions data are fed into CMAQ, the model averages the data over an area known as a "grid cell." CMAQ can predict deposition results over grid cells of various sizes (or resolutions) as specified by the modeler.

For CMAQ, EPA used a 36 kilometer (km) grid resolution (36 km x 36 km) for its Clean Air Interstate Rule and CAMR modeling, which equates to a surface area approximately 22 miles wide by 22 miles long, or approximately 484 square miles. The model provides one average concentration for the entire area. For example, if there is only one power plant in the corner of a grid square, that plant's emissions are averaged over the entire 36 km x 36 km area. Averaging over grid cells may result in a smoothing out of areas of high and low deposition. EPA acknowledges this limitation in its *Effectiveness Technical Support Document:*[4]

> *CMAQ immediately dilute[s] simulated emissions into the entire grid volume in which they are released. This causes an artificially fast dilution and under-represents direct deposition from air to surfaces near emission sources . . .*

When looking for hotspots, the ability to identify areas of localized deposition is important. Using the CMAQ model at 36 km x 36 km, in the opinion of some EPA officials we interviewed, was too coarse a resolution to be able to pinpoint small areas of localized deposition. Some EPA officials stated that use of a finer resolution, such as 12 km grid size, is possible in CMAQ. However, at very fine resolutions – for instance, a 4 km grid size – the meteorological components of the model probably fall apart and may introduce greater uncertainties in model results. EPA outlines three reasons for using a 36 km grid square size in its *Effectiveness Technical Support Document.* First, the larger grid size would account for mercury deposition that enters a watershed through groundwater

[4] *Methodology to Generate Deposition, Fish Tissue Methylmercury Concentrations, and Exposures for Determining Effectiveness of Utility Emission Controls (Effectiveness Technical Support Document).* U.S. EPA, March 15, 2005.

inflow and runoff, as opposed to a smaller grid size that may only account for direct inputs to surface water. Second, in larger waterbodies where there is substantial fishing activity, the fish species consumed by humans are likely migratory and the accumulation of mercury in these fish will come from deposition over a larger area. Third, many anglers may catch fish from a variety of waterbodies in a watershed, thus a larger grid size would account for this fishing pattern.

Study Finds Different Rates of Atmospheric Chemical Reactions

The Mechanisms of Mercury Removal Study developed information on the rates of atmospheric chemical reactions involving mercury that is different than rates used by EPA in its CAMR hotspots analysis. The study was published in June 2005 after EPA issued CAMR. Rate constants, which quantify the speed or rate of chemical reactions, are the most important inputs affecting modeling results. The accuracy of rate constants can affect the accuracy of modeling results. Oxidation is an atmospheric process that makes mercury more reactive and is the most important reaction associated with mercury deposition. The mercury oxidation rate affects how quickly mercury is deposited and influences its properties and behavior. For example, oxidation makes elemental mercury more water soluble and more quickly deposited; if mercury emitted from a source comes out already oxidized, it can be immediately deposited near the source (depending on meteorological conditions and other factors).

Results of the Mechanisms of Mercury Removal Study regarding mercury reactions and associated rates suggest that emissions from global sources potentially account for less mercury deposition in the United States than previously believed. This means that the contribution of global sources to U.S. deposition may have been overestimated in EPA's analysis and the impact from domestic sources underestimated. According to the Agency scientist responsible for developing mercury capabilities in CMAQ, if the study's results about rate constants are accurate, then chemical formulations currently used in all other atmospheric simulation models, including CMAQ, could be incorrect (when modeling mercury deposition).

Uncertainties Noted with Methylation and Bioaccumulation

Assumptions about methylation and bioaccumulation directly impact the resulting predictions about mercury fish tissue concentrations after implementation of CAMR. Mercury methylation is a complex process that occurs in the environment when oxidized mercury is transformed into highly toxic methylmercury, which bioaccumulates (builds up) in fish tissue. Some of the important factors affecting methylation rates and bioaccumulation were not fully accounted for in EPA's analysis. Also, a lack of knowledge about some factors used in EPA's analysis is a source of uncertainty in EPA's conclusions about mercury fish tissue concentrations.

Methylation. Transformation of mercury to methylmercury occurs at varying speeds in different waterbodies, and EPA's analysis did not fully account for this variation. Methylation occurs when mercury enters waterbodies and bacteria transform it to methylmercury, a highly toxic and bioaccumulative form of mercury. Methylation of mercury occurs in waterbodies at highly variable speeds depending on various ecosystem-specific factors, including: the bacteria in the waterbody, the type of land surrounding the waterbody, the quantity of certain substances such as sulfate and carbon in the waterbody, and the pH (chemistry) of the waterbody. Thus, two adjacent waterbodies with equal mercury deposition can have different concentrations of mercury in fish.

EPA's analysis did not address individual differences between waterbodies, or the time it takes for different waterbodies to adjust to changes in atmospheric deposition. The modeling assumed that the environmental factors affecting the formation of methylmercury remain constant. EPA acknowledges that a lack of knowledge about methylation is "a major contributor to overall uncertainty" in its analysis; however, the effect of this uncertainty on the Agency's ability to inform mercury control policies is highly variable. An EPA official stated that variance in methylation rates was taken into account because actual methylmercury fish tissue measurements, which reflect varying methylation rates among different waterbodies where measurements were obtained, were used in the "utility-attributable" hotspot analysis. As explained in the next section, we found that concerns remain about these fish tissue measurements, which call into question how well they address methylation uncertainties.

Bioaccumulation. EPA's analysis did not fully account for the highly variable ways that mercury bioaccumulates in fish. When mercury deposition to a waterbody changes because of reductions in emissions, it can take time for those changes to be reflected in fish tissue methylmercury concentrations. Fish absorb methylmercury from their food and directly from water as it passes over their gills. To predict levels of methylmercury in fish tissue, CMAQ deposition results for a given area were input into a model that assumed a proportional relationship between declines in atmospheric mercury deposition and declines in mercury fish tissue concentrations. For example, a 50-percent decrease in mercury deposition rates was projected to lead to a 50-percent decrease in mercury concentrations in fish. However, drawing conclusions and making comparisons between different fish types is limited in that mercury bioaccumulates in highly variable ways among fish, both between species and within individual fish of a species. To establish a 2001 baseline estimate of methylmercury fish tissue concentrations, EPA used data from the National Listing of Fish Advisories and the National Lake Fish Tissue Survey:

> *For included locations, samples for the same species are averaged across all available years (post 1998), and then the highest averaged per species concentration is used to represent the methylmercury concentration for that*

sample location. For example, if there are two species at a location, walleye and pike, with three sampling dates for each species, we would first average over the three sample dates for each species, and then select walleye if the average for walleye is highest, or select pike if the average for pike is highest. . . . Assignment of the maximum average species concentration recognizes the greater risk to an individual consuming species with higher accumulation of mercury while respecting the fact that each sample for an individual species is only an estimate of the true mean concentration in that species.

According to EPA staff, the adequacy of current fish tissue data is sparse – it is patchy, non-standardized from State to State, and only identifies potential problems where data were actually collected. Regarding EPA's fish tissue data, an Agency official said, "The data does not support the conclusion that CAMR will not cause hotspots." In its *Effectiveness Technical Support Document*, EPA states that, among other limitations, the model it used to estimate changes in methylmercury fish tissue concentrations does not account for the time lag between a reduction in mercury deposition and a reduction in methylmercury concentrations in fish tissue. However, the document stated that EPA is unaware of any other tool for performing a national-scale assessment of the change in fish methylmercury concentrations resulting from reductions in atmospheric deposition of mercury.

Study Shows Significant Deposition from Local Sources

Results from the Steubenville Study,[5] a multiyear study in the Ohio River Valley, found that approximately 70 percent of mercury wet deposition at Steubenville, Ohio in 2003 and 2004 was attributable to local/regional coal combustion sources, predominantly from utility boilers.[6] The results of the Steubenville Study suggest that additional monitoring is necessary to ensure that EPA's CAMR analysis has properly estimated the contribution of local and regional mercury deposition. For example, while CMAQ results do not provide an estimate of mercury wet deposition for Steubenville specifically (due to its 36 km x 36 km grid cell area), it estimated for 2001 that 44 percent of the wet deposition in the grid cell containing Steubenville was from coal-fired utilities. Spatial and temporal differences[7] between the Steubenville Study and EPA's CAMR analysis do not allow for their results to be fully comparable; however, data from other monitoring sites further suggest that monitoring is needed to ensure that CMAQ

[5] A peer review of the Steubenville Study was completed in late December 2005 and it was submitted for publication in a scientific journal in February 2006.

[6] The Steubenville Study results have an uncertainty bound of approximately 15 percent. This uncertainty bound does not follow a normal distribution pattern but is positively skewed, i.e., the upper bound of the 95 percent confidence interval extends further from the estimate than the lower bound.

[7] The Steubenville Study wet deposition results are for 2003 and 2004 and (1) represent the wet deposition for a specific monitoring location; (2) include wet deposition for all coal-combustion sources; and (3) have quantified estimates of uncertainty. Conversely, the CMAQ results are for the year 2001 and (1) represent an estimate for a much larger area (i.e., a 36 km x 36 km grid cell); (2) represent deposition from coal-fired utilities only; and (3) do not quantify uncertainty.

has not underestimated wet deposition in some locations. An Agency scientist noted that:

> *. . .CMAQ runs conducted using 2001 emissions data for CAMR modeling showed that there are areas in the U.S. where domestic sources create large areas of enhanced deposition (e.g., up to 60% of wet mercury deposition in some areas originated from domestic coal combustion sources). The Steubenville measurements are consistent with these projections. As an example of uncertainties related to CMAQ . . . the University of Michigan has run a network of event-based mercury monitoring sites in the Midwest and Vermont and the 2001 CMAQ model runs systematically underestimate the deposition observed at these sites (in some cases by over a factor of 2).*

Senior Office of Air and Radiation officials told us that the Steubenville area is known to have higher-than-average deposition from coal-fired utilities, and that the preliminary monitoring results were not unexpected. OAQPS noted that for grid cells neighboring the Steubenville grid cell, the CMAQ model predicted that a higher percentage of mercury deposition was attributable to utility coal combustion (i.e., 57 to 71 percent). Preliminary results of the Steubenville Study were made available to Agency officials shortly after EPA's promulgation of CAMR and the *Revision of December 2000 Regulatory Finding* in March 2005, but were not available for consideration by the Agency during its promulgation of these rules. The Agency noted that they analyzed a number of scientific studies in developing CMAQ, but our evaluation did not consider all of the scientific evidence EPA used in developing CMAQ. As noted in Appendix A, we did not evaluate all the inputs and assumptions associated with EPA's mercury hotspots analysis. Additional limitations of our evaluation are listed in Appendix A.

Uncertainties Underscore Need for Mercury Monitoring Plan

In the preamble to the *Revision of December 2000 Regulatory Finding*, EPA stated that although it believed the likelihood of a "utility-attributable" hotspot occurring to be "remote," it intended to closely monitor the potential for hotspots, continue to advance the state of the science of mercury fate and transport, and take appropriate action if the possibility of a "utility-attributable" hotspot arose after implementation of CAMR. However, at the time we completed our field work, EPA had not yet developed a plan for monitoring hotspots. Given the uncertainties associated with the inputs to the CMAQ model and the results of recent studies as noted, it is important for EPA to have a plan to monitor mercury deposition. Mercury monitoring data could assist the Agency in determining "utility-attributable" hotspots, and in evaluating and improving the accuracy of its mercury fate and transport models. Without a mercury monitoring plan, "utility-attributable" hotspots could potentially occur after implementation of CAMR but be less likely to be identified due to a lack of deposition data or reliable modeling techniques to identify mercury sources.

Field measurement of mercury deposition could improve EPA's ability to conduct source apportionment studies to help to determine whether a hotspot was "utility-attributable." To assess whether CAMR results in "utility-attributable" hotspots, EPA must have mercury deposition data that enable it to identify the mercury source. Source-apportionment studies, such as that conducted by EPA in Steubenville, are designed to accomplish this task. Such studies estimate a source's contribution to mercury deposition and require the collection of deposition samples and measurements of trace elements in addition to mercury. Trace elements are elements that are co-emitted with mercury from particular sources, and help identify from which source(s) the deposited mercury originally came. For example, sulfur and selenium are trace elements associated with coal combustion. When these elements are in samples of deposited mercury, they indicate the mercury came from coal combustion sources. By employing a monitoring plan that incorporates more studies of this nature, EPA can better assess the impact that utilities have on mercury deposition and resulting fish tissue concentrations.

Mercury deposition data would also help EPA improve its current understanding of mercury fate and transport, and allow the Agency to validate and improve mercury deposition estimation models and techniques. Model performance can be assessed by comparing model predictions to actual field data. While mercury deposition data are available through the Mercury Deposition Network (MDN), these data have important limitations for model evaluation, particularly modeling designed to identify mercury hotspots:

- The MDN measures only wet deposition because there is no adequate field methodology currently available for dry deposition.

- The MDN does not generally provide deposition monitoring data for areas expected to be of greatest concern for deposition from local emissions sources. This is because MDN monitoring sites are generally located in rural locations that do not have local sources of emissions.

- There are large areas of the nation with few or no MDN monitoring sites.

- The MDN collects deposition samples on a weekly basis, so it does not accurately measure the impacts of individual events, such as rain or snowfall.

- The MDN sites do not collect trace element data, such as sulfur and selenium data for coal combustion, which is needed to conduct source apportionment modeling.

Due to the limitations associated with available data from the current mercury deposition monitoring network, EPA is currently unable to fully assess the accuracy of CMAQ's mercury deposition predictions against actual field

measurements. Agency officials told us that the EPA Office of Research and Development's National Exposure Research Laboratory was already implementing a research plan for mercury monitoring, but recent budget reductions have halted the program.

Conclusion

EPA has acknowledged uncertainties and limitations in its analysis of the potential for "utility-attributable" hotspots. The results from two studies – the Mechanisms of Mercury Removal Study and the Steubenville Study – illustrate uncertainties about some of the key assumptions used in CMAQ and the deposition results projected by the model. Further consideration of uncertainties could alter EPA's conclusions about the potential for "utility-attributable" mercury hotspots. EPA indicated it will closely monitor hotspots, continue to advance mercury science, and take appropriate actions if hotspots arose. To accomplish this, the Agency needs to establish a monitoring plan to conduct source-apportionment studies to measure the impact of CAMR and to assist in evaluating the accuracy of its model predictions against actual field data.

Recommendation

We recommend that the Acting Assistant Administrator for Air and Radiation:

2-1 Work with the Assistant Administrator for the Office of Research and Development to develop and implement a mercury monitoring plan, including milestones and responsible program offices for implementing each component of the plan, to: (1) assess the impact of CAMR, if adopted, on mercury deposition and fish tissue; and (2) evaluate and refine, as necessary, mercury estimation tools and models. This effort should consider the suitability of the Office of Research and Development's mercury research plan for addressing these objectives.

Agency Comments and OIG Evaluation

The Agency generally agreed with the recommendation in Chapter 2 of the report. However, the Agency expressed concern with our characterization of some scientific issues in the report and offered clarification on three specific issues. We accepted the Agency's technical clarifications and have made changes to the final report as appropriate. The Agency also provided us with additional concerns not specifically addressed in its written response to our draft report. We met with the Agency to discuss these concerns, and made changes to the final report as appropriate. In response to our recommendation, the Agency stated that the Office of Air and Radiation and Office of Research and Development will continue to work together to ensure that they are using the best possible information to assess the transport, transformation, deposition, and fate of mercury emissions in the United States. We support the Agency's commitment to

using the best possible information to assess the impact of mercury emissions in the United States, and continue to recommend the Agency develop a monitoring plan to better ensure that this happens. The Agency's formal written response is in Appendix C.

Chapter 3
EPA Needs to Clarify Conditions Under Which CAMR Performance Standards Can be Tightened

EPA does not clearly explain how the "utility-attributable" hotspot definition affects the Agency's ability to revise performance standards under CAMR. When CAMR is read in conjunction with the *Revision of December 2000 Regulatory Finding,* we believe the CAMR could be interpreted to preclude EPA from taking action to mitigate a mercury hotspot (such as tightening the cap or utilities' performance standards) unless it first determined that the hotspot was solely "utility-attributable." If this were the case, such a prerequisite could limit EPA's ability to reduce methylmercury fish tissue concentrations below acceptable levels, and thus address public health hazards that are being caused predominantly (but not "solely") by utilities. This could also impact EPA's ability to reduce the number of waterbodies with fish consumption advisories.

EPA Provides "Utility-Attributable" Hotspot Definition

In its *Revision of December 2000 Regulatory Finding,* EPA defined a "utility-attributable" hotspot[8] as:

> *". . . a waterbody that is a source of consumable fish with Methylmercury tissue concentrations, attributable solely to utilities, greater than the EPA's Methylmercury water quality criterion of 0.3 mg/kg."*

This definition only considers the contribution of one source (utilities) on environmental problems that could threaten human health, and would only consider a hotspot to be "utility-attributable" if the utility emissions alone caused methylmercury in fish tissue to exceed 0.3 mg/kg.

According to the preamble of the *Revision of December 2000 Regulatory Finding,* EPA adopted this definition based on its interpretation of Clean Air Act Section 112(n), which directed the Agency to ". . . study hazards to public health reasonably anticipated to occur as a result of emissions by electric utility steam generating units." EPA interpreted the language "as a result of" to mean that utility emissions must be the *sole* cause of a health hazard, and not just contribute to causing a hazard, to be regulated under Section 112. Using EPA's methylmercury water quality criterion of 0.3 mg/kg in fish tissue as the one

[8] EPA uses the terms "hotspot," "hot spot," "utility hot spot," and "utility-attributable hotspot" interchangeably throughout the *Revision of December 2000 Regulatory Finding* when referring to a waterbody that is a source of consumable fish with methylmercury tissue concentrations, attributable solely to utilities, greater than the EPA's methylmercury water quality criterion of 0.3 mg/kg.

measure for "hazards to public health," EPA adopted the "utility-attributable" hotspots definition to determine whether such utility hotspots would remain after implementation of the Clean Air Interstate Rule and CAMR. Based on the analysis described in Chapter 2 of this report, EPA stated that it did not believe that "utility-attributable" mercury hotspots would exist after implementing these rules, therefore supporting the Agency's decision that utilities did not need to be regulated under Section 112 of the Clean Air Act.

"Utility-Attributable" Definition Could be Interpreted to Limit EPA's Ability to Mitigate Hotspots

The "utility-attributable" definition could be interpreted to limit EPA's ability to address waterbodies with elevated levels of mercury unless utility emissions were the sole cause of the problem. This could in turn limit EPA's ability to reduce the number of waterbodies with fish consumption advisories where there is a health risk due to the combined impact of mercury from all sources, including air emissions.

As discussed in its December 1997 *Mercury Study Report to Congress*, EPA stated that there is "clearly" a need to address the combined impacts of mercury originating from all sources, including air emissions, wherever the combination of sources have been related to unacceptably high mercury levels in fish. Further, in its *December 2000 Finding,* EPA recognized concerns about the potential local impact of mercury trading programs and acknowledged that:

> . . . *approaches that involve economic incentives must be constructed in a way that assures that communities near the sources of emissions are adequately protected.*

Within CAMR and the *Revision of December 2000 Regulatory Finding*, EPA specifies several actions it might take to mitigate the effects of a hotspot in the event one should be identified. However, our analysis of the revision and CAMR suggests that the Agency may be precluded from taking any of those actions unless the hotspot first meets the criteria of a "utility-attributable" hotspot. EPA officials told us that this was not the intent of the rule, but agreed that the rule could be clearer.

CAMR and Revision Must be Read Together

Based on our reading of CAMR and the *Revision of December 2000 Regulatory Finding,* we conclude that the definition of a hotspot presented in the revision is intended to apply to CAMR. CAMR and the revision were issued on the same day and address the same subject matter. In addition, the preamble to the CAMR restates EPA's conclusion from the revision, but refers to it as part of "this action":

> *As stated elsewhere in this action EPA does not believe that utility-attributable hot spots will be an issue after implementation of CAIR [Clean Air Interstate Rule] and CAMR.*

Because "utility-attributable" hotspots are not discussed "elsewhere" within CAMR, we conclude that "this action" refers to the other, closely related action published by EPA on the same day. This action, the *Revision of December 2000 Regulatory Finding*, defines "utility-attributable" hotspots and also explains that EPA may address hotspots under "other authorities under the CAA [Clean Air Act]," should they occur. However, the only mechanism to which EPA refers in order to addresses potential future hotspots – and the only mechanism presently promulgated – is CAMR. The revision cites the following ways it could address "utility-attributable" hotspots:

> *. . . if in the future we determine that utility-attributable hotspots exist and that those hotspots occur as the result of Hg emissions from coal-fired Utility Units, we may promulgate a tighter section 111 standard of performance, provided we determine the technology can achieve the contemplated reductions. We could revise the standard of performance by adjusting the cap-and-trade program to limit trading by high-emitting Utility Units. . . . Thus, although we cannot conclude today which statutory authority we would implement to address utility attributable hotspots because that determination necessarily hinges on the facts associated with the identified hotspots, we do conclude that were such a situation to occur, we believe that EPA has adequate authority to address any such situation that may arise in the future.*

When read together, these regulatory actions suggest that a finding of a solely "utility-attributable" mercury hotspot is necessary to initiate Agency action to mitigate hotspots under CAMR. If this were the case, EPA would be precluded from requiring additional mercury reductions from the utility industry, even if it were determined that utilities were significantly contributing to a hotspot, if the utilities were not the sole cause of the hotspot. For example, if methylmercury fish tissue concentrations for a waterbody were at 0.32 mg/kg, EPA's water quality criterion of 0.3 mg/kg would be exceeded. If, in this hypothetical case, utility mercury emissions were causing 0.3 mg/kg or less of the total methylmercury, under the requirement as written, utilities would be excluded from any additional reductions to help mitigate the problem.

We discussed our interpretation with Office of Air and Radiation officials. These officials confirmed that the "utility-attributable" hotspot definition in the revision applies to the CAMR. However, these officials told us that this definition does not establish a criterion for when the Agency can adjust the performance standards under CAMR. They noted that under Section 111, performance standards are to be reviewed every 8 years, and can be adjusted for various reasons.

Conclusion

The two rules related to controlling mercury emissions from coal-fired utilities were issued on the same day and refer to and are consistent with each other. Thus, it appears that they are intended to be read together. Further, the "utility-attributable" definition in the *Revision of December 2000 Regulatory Finding* applies to the discussion of hotspots in CAMR, and this definition establishes a criterion for when the CAMR can be adjusted to address a potential health hazard. If this were the case, tighter performance standards for utilities contributing to a hotspot could not be promulgated unless it was first determined that the hotspot was solely "utility-attributable." Although not the intent of the rulemaking, EPA officials agreed that the rule could be clearer. We believe CAMR, if adopted, should be clarified to avoid any possible misinterpretation of how the "utility-attributable" definition affects EPA's ability to modify utility performance standards.

Recommendation

If EPA decides to adopt CAMR after the rule reconsideration process, to better ensure protection of public health and the environment, we recommend that the Acting Assistant Administrator for Air and Radiation:

3-1 Explain in CAMR that the "utility-attributable" hotspot definition found in the revision does not establish a prerequisite for making future changes to the performance standards under CAMR.

Agency Comments and OIG Evaluation

The Agency's response did not specifically address our analysis and conclusion that CAMR could be interpreted to use the "utility-attributable" hotspot definition as a prerequisite for future changes to CAMR. The Agency commented that, while information regarding "utility-attributable" hotspots would be relevant to future possible revisions to CAMR, such hotspots are not a prerequisite to the Agency making changes to performance standards under CAMR. We believe the Agency's intent should be made clear in the final rule. Accordingly, we revised our final report to recommend that EPA, to better ensure protection of public health and the environment, explain in the CAMR that the "utility-attributable" hotspot definition set forth in the revision is not a prerequisite for making changes to the CAMR. After submitting its formal written response to the draft report the Agency also suggested clarifying language to parts of Chapter 3. We accepted some of the suggestions and incorporated them into the final report. The Agency's formal written response is in Appendix C.

Appendix A

Details on Scope and Methodology

We conducted interviews with staff from the following EPA offices:

- Office of Air and Radiation, including its Office of Air Quality Planning and Standards and Office of Atmospheric Programs.
- Office of Research and Development, including its National Exposure Research Laboratory and National Center for Environmental Research.
- Office of Policy, Economics, and Innovation.
- Office of Water.

We also interviewed officials from the following external organizations: the National Oceanic and Atmospheric Administration, including its Air Research Laboratory; the Northeast States for Coordinated Air Use Management; and the Clean Air Task Force.

To understand the variables associated with mercury fate and transport modeling and, specifically, CMAQ, we reviewed and/or discussed with the above officials selected reports and studies, including:

- Mechanisms of Mercury Removal by O_3 and OH in the Atmosphere. Calvert Jack G.; Lindberg Steve E. *Atmospheric Environment*, Volume: 39, Number: 18, Page: 3355-3367, June 5, 2005.
- The National Oceanic and Atmospheric Administration's September 2005 (draft) report by Cohen, et al, *Report to Congress: Mercury Contamination in the Great Lakes.*
- EPA's *Regulatory Impact Analysis of the Final Clean Air Mercury Rule*, March 2005.
- EPA's *Mercury Study Report to Congress*, December 1997.
- A slide presentation on EPA's Steubenville, Ohio, study, *Preliminary Results from Steubenville Hg Deposition Source Apportionment Study*, April 27, 2005.
- The most recent peer review of CMAQ, *Final Report: Second Review of the CMAQ Model.*
- *Technical Support Document: Methodology Used to Generate Deposition, Fish Tissue Methylmercury Concentrations, and Exposure for Determining Effectiveness of Utility Emission Controls. Analysis of Mercury from Electricity Generating Units*, March 17, 2005 (revised).
- *Technical Support Document for the Final Clean Air Mercury Rule: Air Quality Modeling*, March 2005.
- *Emissions Inventory and Emissions Processing for the Clean Air Mercury Rule*, March 2005.

To gain an understanding of State and environmental groups' concerns related to EPA's analysis of potential "utility-attributable" hotspots under CAMR, we reviewed the following selected comments:

- The December 19, 2005 comments submitted *In Reconsideration of: Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units and the Removal of Coal- and Oil-Fired Electric Utility Steam Generating Units from the Section 112(c) List 70 Fed. Reg. 62200 (Oct. 28, 2005); and Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units 70 Fed. Reg. 62213 (Oct. 28, 2005). Comments Submitted by: The States of New Jersey, California, Connecticut, Delaware, Illinois, Maine, Massachusetts, Minnesota, New Hampshire, New Mexico, New York, Pennsylvania, Rhode Island, Vermont, and Wisconsin*, Docket No. OAR-2002-0056.

- The December 19, 2005 comments submitted regarding the *"Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units and the Removal of Coal- and Oil-Fired Electric Utility Steam Generating Units From the Section 112(c) List: Reconsideration," 70 Fed. Reg. 62,200 (October 28, 2005). Comments of: Clean Air Task Force, Izaak Walton League of America, Natural Resources Council of Maine, Ohio Environmental Council, U.S. Public Interest Research Group, Natural Resources Defense Council, Chesapeake Bay Foundation, Waterkeeper, Aroostook Band of Micmac Indians, Houlton Band of Maliseet Indians, Penobscot Indian Nation, The Passamaquoddy Tribe at Indian Township.*

To gain an understanding of EPA's definition of "utility-attributable" hotspots and the basis for that definition, we reviewed the following regulatory actions:

- *Regulatory Finding on the Emissions of Hazardous Air Pollutants From Electric Utility Steam Generating Units*, December 20, 2000.
- *Proposed National Emission Standards for Hazardous Air Pollutants; and, in the Alternative, Proposed Standards of Performance for New and Existing Stationary Sources: Electric Utility Stream Generating Units; Proposed Rule*, January 30, 2004.
- Final Rule – Preamble - *Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units*, March 15, 2005.
- Final Rule – Regulatory Text - *Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units*, March 15, 2005.
- Final Rule - *Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants from Electric Utility Steam Generating Units and the Removal of Coal- and Oil-fired Electric Utility Steam Generating Units from the Section 112 (c) List*, March 15, 2005.
- *Reconsideration: Revision of December 2000 Regulatory Finding on the Emissions of Hazardous Air Pollutants from Electric Utility Steam Generating Units and the Removal of Coal- and Oil-fired Electric Utility Steam Generating Units from the Section 112 (c) List*, October 21, 2005.
- *Reconsideration: Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units*, October 21, 2005.

Prior Coverage

In a prior EPA OIG report, *Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities* (2005-P-00003), dated February 3, 2005, we cited concerns about EPA's limited assessment of the potential for mercury hotspots resulting from its (then proposed) cap-and-trade program under CAMR. In that report, we recommended that EPA further assess the risk of hotspots and, if necessary, identify how the Agency would reassess the hotspot issue. In response to our recommendation, EPA stated that it did not believe utility emissions would result in hotspots based on additional analyses it had performed, particularly after implementation of the Clean Air Interstate Rule and CAMR, but it would monitor the situation and take action if necessary. For this current review, we evaluated EPA's analysis of hotspots, its conclusion that there will be no "utility-attributable" hotspots after implementation of the Clean Air Interstate Rule and CAMR, and plans the Agency may have in place to continue to monitor the issue. Details on what we found, including recommendations, are in Chapters 2 and 3 of this current report.

Internal Controls

Government Auditing Standards require that auditors obtain an understanding of internal control significant to the audit objectives and consider whether specific internal control procedures have been properly designed and placed in operation. This evaluation was a limited-scope assessment of certain analyses pertaining to a rulemaking. Thus, we determined whether the Agency's hotspots analysis and conclusions were peer reviewed, and if the key model used in this analysis was separately peer reviewed. Peer review is a key internal control for ensuring the acceptability of scientific data and processes. We found that CMAQ, the main model used by EPA in its hotspots analysis, was peer reviewed; however, we found no evidence that the Agency's overall hotspots analysis, described in the document *Methodology to Generate Deposition, Fish Tissue Methylmercury Concentrations, and Exposures for Determining Effectiveness of Utility Emission Controls,* was peer reviewed. The Agency's *Ecosystem Scale Modeling for Mercury Benefits Analysis*, part of the Regulatory Impact Analysis for the CAMR, was peer reviewed. The benefits analysis was similar to the hotspots analysis, but it assessed the impact of CAMR on a national scale, as opposed to identifying localized hotspots or local-scale impacts.

Limitations

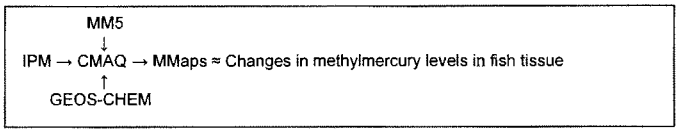
Our work had several limitations. Specifically, we did not:

- Review every model that contributed to EPA's analysis of the potential for "utility-attributable" hotspots under CAMR.
- Evaluate all of the inputs and assumptions associated with EPA's mercury hotspots analysis.
- Evaluate the adequacy of EPA's water quality criterion to protect human health.

Appendix B

Models Used in CAMR Analysis

The following diagram depicts how data from each model were used in EPA's hotspot analysis. Details on each model follow the diagram.



Model	Purpose	Contribution to Hotspot Analysis
Integrated Planning Model (IPM)	• To analyze future cost and emissions impacts of proposed environmental regulations upon utilities.	Estimates mercury emissions from utilities after implementation of Clean Air Interstate Rule and CAMR.
Mesoscale Model (MM5)	• To provide meteorological information, such as wind, temperature, precipitation, and sea level pressure.	Simulates weather patterns, which affect where mercury deposits.
Goddard Earth Observing System-CHEMistry (GEOS-CHEM) Global Model	• To provide a global three-dimensional model of atmospheric chemistry driven by meteorology.	Uses global chemistry and transport information to provide global/background mercury concentrations.
Community Multiscale Air Quality (CMAQ) Model	• To estimate mercury deposition. • To simulate various chemical and physical processes thought to be important in the atmospheric transformation and distribution of mercury.	Estimates amount of mercury deposition occuring within 36 km^2 grid cells after implementation of Clean Air Interstate Rule and CAMR.
Mercury Maps (MMaps)	• To relate changes in mercury air deposition rates to changes in mercury fish tissue concentrations on a national scale.	Uses CMAQ deposition data to estimate fish tissue concentrations of methylmercury based on the assumption of a 1-to-1 ratio between reductions in air deposition and reductions in average methylmercury fish tissue concentrations.

Appendix C

Agency Response to Draft Report

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

Bill Roderick, Acting Inspector General
Office of the Inspector General
Office of Program Evaluation
1301 Constitution Ave. NW (2400 T)
EPA West Building
Washington, DC 20004

Dear Mr. Roderick:

Thank you for the opportunity to comment on the draft Office of the Inspector General (OIG) report entitled ***"Monitoring Needed to Assess Impact of EPA's Clean Air Mercury Rule on Potential Hotspots."*** In reviewing the draft report, we acknowledge your acceptance of the majority of the issues we identified in our earlier review. We have also recently supplied your office with additional written comments pertaining to the modeling analyses associated with the Steubenville project. We believe that the collective scientific and engineering expertise within EPA's Offices of Air and Radiation (OAR) and Research and Development (ORD) puts our offices in a unique position to assess the current state-of-the-science with respect to mercury transport, deposition, and fate, and its impact on the creation of utility-attributable hotspots.

We continue to have concerns about the portrayal of some scientific issues in the report, and note three areas where we would like to provide clarifying remarks. First, with respect to the potential changes in the atmospheric reaction rates within the Community Multiscale Air Quality (CMAQ) model (see pages 9 and 10), such changes would be made uniformly in **all** mercury transport/deposition models, not just CMAQ. Thus, the enhancements would create different results in any assessment using these numerical simulation technologies. Second, regarding our need to improve ambient monitoring (see page 13), the report should acknowledge that the Mercury Deposition Network (MDN) currently measures only wet deposition because there is no adequate field methodology available for dry deposition.

Finally, in terms of how EPA addressed the uncertainties in methylation and bioaccumulation rates between different fresh water bodies, our supporting health benefits assessment materials describe in great detail our complete understanding of these processes. You are correct to point out, and we clearly acknowledge in our documents, the uncertainties associated with mercury transport, deposition, and effects. At the same time, it should be acknowledged that the magnitude of uncertainties and their effect on our ability to inform mercury control policies is highly variable. We believe we have clearly explained the science and the uncertainties and provided a solid foundation for the Clean Air Mercury Rule (CAMR).

In your draft report, you recommend two specific follow-up actions for the Agency. Below we address each of these recommendations.

Recommendation 2-1: ***Work with the Assistant Administrator for the Office of Research and Development to develop and implement a mercury monitoring plan, including milestones and responsible program offices for implementing each component of the plan, to: (1) assess the impact of CAMR, if adopted, on mercury deposition and fish tissue, and, (2) evaluate and refine, as necessary, mercury estimation tools and models. This effort should consider the suitability of the Office of Research and Development's mercury research plan for addressing these objectives.***

EPA currently operates the MDN, which is located predominantly in the eastern U.S. and monitors only wet deposition. In the technical support documents supporting CAMR, EPA has continually highlighted the need for and the willingness to support additional ambient monitoring, including the development of dry deposition monitoring, to enhance our ability to assess the numerical accuracy of our sophisticated simulation tools – e.g., the CMAQ model. As you are aware, ORD has been heavily involved over the past decade in developing the CMAQ model, and is actively engaged in utilizing ambient data and the latest scientific information to update the model to reflect the best possible chemistry and physics. OAR and ORD will continue to work together to ensure that we are using the best possible information to assess the transport, transformation, deposition, and fate of mercury emissions in the U.S.

Recommendation 3-1: ***If EPA decides to adopt CAMR after the rule reconsideration process, we recommend that the Acting Assistant Administrator for Air and Radiation: Specifically explain what role the "utility-attributable" hotspot definition has in determining whether to make any future changes to the performance standards under CAMR.***

EPA has explained to your staff that while information regarding utility-attributable hotspots would be relevant to future possible revisions to CAMR, such hotspots are not a prerequisite. CAMR controls are based on the new source performance standards (NSPS) as set forth in section 111 of the Clean Air Act. To this end, the Agency is required by law to review and revise, as necessary, these limits every eight years. In conducting such a review,

we will analyze and evaluate the availability of new mercury control technologies installed since the previous review, and to the extent they provide additional cost-effective control, the Agency can move to change the existing NSPS limits. Additionally, the Agency continues to update its understanding of the science associated with mercury emissions, transport, transformation, and deposition, both from ambient data collection and monitoring and through continued enhancements to our analytical tool box. Thus, we feel that OAR and ORD are uniquely positioned to monitor this situation and provide the best possible solution for the protection of public health and the environment.

In closing, we direct the OIG staff to the numerous technical documents supporting the final CAMR, particularly the benefits assessment materials in which we outline in detail the variability associated with methylation and bioaccumulation rates in different water bodies. In these documents, EPA has demonstrated that the conclusions reached in the CAMR are based firmly in sound scientific principles, utilizing the best information available. If your staff have additional questions in researching these documents, our scientists, engineers, and modelers would be happy to assist them.

Sincerely,

William Wehrum
Acting Assistant Administrator
Office of Air and Radiation

George Gray
Assistant Administrator
Office of Research and Development

Appendix D

Distribution

Office of the Administrator
Acting Assistant Administrator for Air and Radiation
Assistant Administrator for Research and Development
Deputy Assistant Administrator for Air and Radiation
Acting Deputy Assistant Administrator for Science, Office of Research and Development
Acting Deputy Assistant Administrator for Management, Office of Research and Development
General Counsel
Agency Followup Official (the CFO)
Agency Followup Coordinator
Audit Followup Coordinator, Office of Air and Radiation
Audit Followup Coordinator, Office of Research and Development
Associate Administrator for Congressional and Intergovernmental Relations
Associate Administrator for Public Affairs
Director, Office of Air Quality Planning and Standards
Deputy Director, Office of Air Quality Planning and Standards
Audit Liaison, Office of Air Quality Planning and Standards
Acting Inspector General

United States General Accounting Office

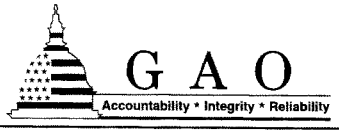
GAO

Report to Congressional Requesters

August 2003

CLEAN AIR ACT

EPA Should Use Available Data to Monitor the Effects of Its Revisions to the New Source Review Program



GAO-03-947

GAO

Highlights

August 2003

CLEAN AIR ACT

EPA Should Use Available Data to Monitor the Effects of Its Revisions to the New Source Review Program

What GAO Found

Consistent with agency guidance, EPA used a limited screening analysis that relied on staff's professional judgment and public comments from earlier reform proposals to conclude that the final rule would decrease emissions and health risks and not impose significant costs. EPA determined that neither the rule's benefits nor its costs would exceed a $100 million threshold that triggers requirements to conduct a more comprehensive assessment. EPA issued the rule to streamline the NSR permitting process and provide flexibility to industry. For example, the rule provides a mechanism for companies to develop plantwide emissions limits, which would allow them to make changes in one part of a facility's operations as long as they offset emissions increases with decreases elsewhere within the facility. While OMB agreed with EPA's conclusion that the rule would not have significant economic effects, it determined that the rule was significant for policy reasons. Therefore, OMB asked EPA if it could better quantify the rule's potential impacts, but the agency lacked the necessary data to do so. EPA lacked comprehensive data on the program's economic impacts, and could not predict how many facilities would use the rule's optional provisions. Several states and environmental groups disagree with EPA's conclusions, claiming that it will enable facilities to increase their emissions. These parties have filed suit against EPA challenging the rule and also have petitioned EPA to reconsider the rule. We did not identify any comprehensive assessments that contradicted or supported EPA's conclusions or the assertions of those who oppose the rule. Because of the data limitations, it was not possible to verify EPA's conclusions about the rule's effects.

Because it lacked comprehensive data, EPA relied on anecdotes from the four industries it believes are most affected by NSR to conclude that the NSR program (prior to the rule) discouraged some energy efficiency projects, such as upgrades to industrial boilers, including some that would have decreased emissions. Because the information is anecdotal, EPA's findings do not necessarily represent the program's effects across the industries subject to the program. Several environmental groups disputed EPA's findings. One such group said that factors other than NSR, such as economic downturns, discouraged the projects. Furthermore, EPA's conclusion that some projects would have decreased emissions assumed that facilities would not increase production after performing the projects. However, according to EPA and the executive director of an industry group, companies often expand production after implementing energy efficiency projects because it is advantageous to maximize production at the most efficient facilities. Such expansions could increase emissions and related health risks, although EPA asserts that this would be offset by decreased production and emissions at less efficient facilities.

Contents

Letter		1
	Results in Brief	3
	Background	5
	EPA's Economic Analysis of the Final Rule Complied with EPA and OMB Cost-Benefit Analysis Requirements, but Some Stakeholders Have Sought to Have EPA Reconsider the Rule	10
	EPA Relied Primarily on Anecdotes from Industries Most Affected by NSR to Conclude That it Discouraged Some Energy Efficiency Projects	16
	Conclusions	24
	Recommendations for Executive Action	25
	Agency Comments	25
Appendix I	**Objectives, Scope, and Methodology**	27
Appendix II	**GAO Contacts and Staff Acknowledgments**	29
	GAO Contacts	29
	Acknowledgments	29
Table		
	Table 1: Chronology of the New Source Review Program	8
Figure		
	Figure 1: Percentage of Total U.S. Emissions Released by Industrial, Transportation, and Other Sources in 2001	6

United States Government Accountability Office

GAO

Report to Congressional Requesters

February 2005

CLEAN AIR ACT

Observations on EPA's Cost-Benefit Analysis of Its Mercury Control Options



GAO-05-252

GAO

Highlights

February 2005

CLEAN AIR ACT

Observations on EPA's Cost-Benefit Analysis of Its Mercury Control Options

Why GAO Did This Study

What GAO Found

GAO identified four major shortcomings in the economic analysis underlying EPA's proposed mercury control options that limit its usefulness for informing decision makers about the economic trade-offs of the different policy options. First, while Office of Management and Budget (OMB) guidance directs agencies to identify a policy that produces the greatest net benefits, EPA's analysis is of limited use in doing so because the agency did not consistently analyze the options or provide an estimate of the total costs and benefits of each option. For example, as seen in the table, EPA analyzed the effects of the technology-based option by itself, but analyzed the effects of the cap-and-trade option alongside those of another proposed rule affecting power plants, the Clean Air Interstate Rule (the interstate rule), without separately identifying the effects of the cap-and-trade option. As a result, EPA's estimates are not comparable and are of limited use for assessing economic trade-offs. EPA officials said they analyzed the cap-and-trade option alongside the interstate rule because the agency views the two proposed rules as complementary. Nonetheless, to provide comparable estimates, EPA would have to analyze each option alone and in combination with the interstate rule.

Estimated Annual Economic Impacts of EPA's Proposed Mercury Policy Options in 2010 (1999 dollars, in billions)

Policy option	Annual costs	Annual benefits	Annual net benefits
Technology-based option	2	15 or more	13 or more
Cap-and-trade option	Not estimated	Not estimated	Not estimated
Technology-based option and the interstate rule	Not estimated	Not estimated	Not estimated
Cap-and-trade option and the interstate rule	3 to 5 or more	58 to 73 or more	55 to 68 or more

Source: EPA.

Second, EPA did not document some of its analysis or provide information on how changes in the proposed level of mercury control would affect the cost-and-benefit estimates for the technology-based option, as it did for the cap-and-trade option. Third, EPA did not estimate the value of the health benefits directly related to decreased mercury emissions and instead estimated only some secondary benefits, such as decreased exposure to harmful fine particles. However, EPA has asked for comments on a methodology to estimate the benefits directly related to mercury. Fourth, EPA did not analyze some of the key uncertainties underlying its cost-and-benefit estimates.

What GAO Recommends

Contents

Letter

		1
	Results in Brief	3
	Background	5
	EPA's Economic Analysis Is of Limited Use for Informing Decision Makers about the Economic Trade-offs of Different Policy Options	8
	Conclusions	15
	Recommendations for Executive Action	16
	Agency Comments	16

Appendixes

Appendix I:	**Objectives, Scope, and Methodology**	20
Appendix II:	**Comments from the Environmental Protection Agency**	21
Appendix III:	**GAO Contacts and Staff Acknowledgments**	23
	GAO Contacts	23
	Staff Acknowledgments	23

Table

Table 1:	Estimated Annual Economic Impacts of EPA's Proposed Mercury Policy Options in 2010	9

Abbreviations

CAA	Clean Air Act
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
IPM	Integrated Planning Model
MACT	Maximum Achievable Control Technology
OMB	Office of Management and Budget
UMRA	Unfunded Mandates Reform Act

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.

United States Government Accountability Office

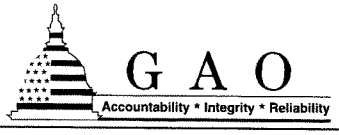
GAO

Report to Congressional Requesters

June 2006

CLEAN AIR ACT

EPA Should Improve the Management of Its Air Toxics Program



GAO-06-669

GAO

Highlights

Highlights of GAO-06-854, a report to congressional requesters

Why GAO Did This Study

The Environmental Protection Agency's (EPA) most recent data indicate that 95 percent of all Americans face an increased likelihood of developing cancer as a result of breathing air toxics—pollutants such as benzene and arsenic that may cause cancer or other serious health problems. Sources of air toxics include large industrial facilities, smaller facilities such as dry cleaners, and cars and trucks. The 1990 Clean Air Act Amendments required EPA to regulate the pollutants from these sources through a multifaceted regulatory program. While EPA issues federal standards, state and local agencies generally administer these standards, and some develop their own rules to complement the federal standards. In this context, GAO was asked to assess (1) EPA's progress and challenges in implementing the air toxics program, (2) available information on the program's costs and benefits, and (3) practices of state and local air toxics programs.

What GAO Recommends

GAO recommends that EPA develop a plan for improving the management of its air toxics program, including a reevaluation schedule, timeframe, and estimates of resources needed to meet its statutory obligations. EPA agreed, in part, with our conclusions and recommendations, and provided clarifications on these statements in the report.

www.gao.gov/cgi-bin/getrpt?GAO-06-854

To view the full product, including the scope and methodology, click on the link above. For more information, contact John Stephenson at (202) 512-3841 or stephensonj@gao.gov.

June 2006

CLEAN AIR ACT

EPA Should Improve the Management of Its Air Toxics Program

What GAO Found

While EPA has made some progress in implementing its air toxics program mandated by the 1990 Clean Air Act Amendments, most of its regulatory actions were completed late and major aspects of the program have still not been addressed. Most of EPA's progress relates to issuing emissions standards for large stationary sources, although EPA completed these standards about 4 years behind schedule. However, many of the unmet requirements pertain to limiting emissions from small stationary and mobile sources, which collectively account for most emissions of air toxics. The agency faces continuing implementation challenges stemming from the program's low priority relative to other programs and related funding constraints. To this end, the agency lacks a comprehensive strategy for completing the unmet requirements or estimates of resources necessary to do so. Senior EPA officials said the program's agenda is largely set by external stakeholders who file litigation when the agency misses deadlines. As a result of EPA's limited progress, the agency has not addressed health risks from air toxics to the extent or in the time frames envisioned in the Clean Air Act. Senior EPA officials said that issuing standards for large stationary sources had addressed the greatest risks from air toxics and that other clean air programs also control air toxics as a side benefit. However, EPA does not have reliable data on the degree of risk reduction achieved through its regulations. Furthermore, the data that are available suggest that the agency has substantial opportunities to reduce emissions from mobile and small stationary sources.

Available information on EPA's efforts to control air toxics is not sufficiently comprehensive to measure the program's total costs and benefits. Specifically, EPA has not comprehensively estimated the national economic costs of all air toxics standards and lacks the data necessary to assess the benefits of these standards, such as decreased incidence of cancer. Information on these impacts would help the agency assess the overall net benefits (total benefits minus total costs) of the air toxics program and compare these effects with those generated by higher-priority clean air programs, such as those intended to address smog. Data on other indicators of the program's effectiveness, such as changes in emissions, concentrations of air toxics in the (ambient) outdoor air, and data on compliance with air toxics standards are also limited and inconclusive.

The state and local programs we reviewed use practices that could potentially help EPA enhance the effectiveness of its air toxics program. For example, several state programs have systematic approaches for identifying and prioritizing new pollutants that could inform EPA's efforts to meet the act's requirement to review and update the list of regulated pollutants.

Contents

Letter		1
	Results in Brief	4
	Background	8
	EPA Has Made Limited Progress in Addressing the Clean Air Act's Requirements for Air Toxics and Faces Significant Implementation Challenges	15
	Available Information on Costs and Benefits Is Not Sufficient to Measure the Program's Effectiveness	25
	State and Local Programs Employ Practices That Could Potentially Help EPA Enhance the Effectiveness of the Federal Air Toxics Program	33
	Conclusions	41
	Recommendations for Executive Action	42
	Agency Comments	43
Appendix I	**Status of EPA's Efforts to Respond to Recommendations in the National Academies' Report on Air Quality**	47
Appendix II	**Objectives, Scope, and Methodology**	48
Appendix III	**Profiles of State and Local Air Toxics Programs**	52
	California	53
	New Jersey	53
	Oregon	54
	Wisconsin	54
	Louisville, Kentucky	55
Appendix IV	**Comments from the Environmental Protection Agency**	56
	GAO comments	63
Appendix V	**GAO Contact and Staff Acknowledgments**	65

Tables

Table 1: The Five Most Commonly Emitted Air Toxics, 2002 10
Table 2: Overview of the Risk Assessment Process 12
Table 3: Number of Air Toxics Actions Required under the 1990 Clean Air Act Amendments 14
Table 4: EPA Progress in Meeting Air Toxics Requirements 16
Table 5: Timeliness of MACT Emission Control Standards for Major Source Categories 17
Table 6: EPA Funding for Air Toxics Program as a Percentage of Funding for All Clean Air Programs, Fiscal Years 2000 through 2005 20
Table 7: Percentage of Estimated Total Air Toxics Emissions by Source Type, 1993, 1999, and 2002 22
Table 8: Issues Rated by Stakeholders as Challenges to a Large or Great Extent 24
Table 9: Summary of Annual Costs Imposed by the 1990 Clean Air Act Amendments 26
Table 10: Key Steps in Estimating the Benefits of Controlling Air Toxics 28
Table 11: Results of Inspections at Facilities Regulated by Air Toxics Standards, 2003 and 2004 33
Table 12: Selected State and Local Air Toxics Programs 52

Figures

Figure 1: Common Sources of Air Toxics Emissions 9
Figure 2: EPA Air Toxics Regulatory Framework for Major Stationary Sources 13
Figure 3: Emission Points at an Industrial Facility Emitting Air Toxics 38

October 3, 2017

Dear Senator:

On behalf of our millions of members, Earthjustice, the League of Conservation Voters, the Natural Resources Defense Council and the Sierra Club oppose the nomination of William Wehrum to be the Assistant Administrator for the Office of Air & Radiation for the United States Environmental Protection Agency. We are national nonprofit organizations dedicated to improving the quality of the human environment, protecting public health and safeguarding the nation's natural resources.

Mr. Wehrum has a long record of working to weaken public health and clean air protections for Americans. While he served in senior leadership positions with the EPA air program, courts held the agency in violation of the federal Clean Air Act 30 times. In private practice with corporate law firms, Mr. Wehrum has represented industrial interests in nearly 35 lawsuits that sought to weaken or void EPA clean air and public health safeguards. Americans deserve better for the nation's chief clean air official. Senators should not confirm him.

A Record of Lawbreaking

Mr. Wehrum was a political appointee in the Bush EPA's Office of Air & Radiation from 2001 to 2007. He served as chief legal counsel to the head of the air program for nearly 5 years and as acting assistant administrator of that program for almost 2 years.

During Mr. Wehrum's tenure, federal courts found that EPA violated the Clean Air Act repeatedly and egregiously. In fact, federal courts found EPA in violation of the Clean Air Act while Mr. Wehrum was serving in these senior legal and leadership capacities more often than in any other administration before or since. Courts determined that EPA violated the Clean Air Act an astonishing 30 times, according to data compiled by EPA's Office of General Counsel for Congress.[1] Of these, 27 losses in court involved retreats from the law's protections for clean air and Americans' health, and unlawful exemptions and amnesty for regulated pollution sources. *Id.*

Few of EPA's court losses during Mr. Wehrum's tenure involved procedural or analytic transgressions. Instead, federal courts found again and again that EPA contradicted and violated the "plain language" of the Clean Air Act. This is the most egregious way for agencies to violate congressionally-enacted laws and repudiate their requirements. For example, the D.C. Circuit Court of Appeals found at least *three* times that EPA air pollution rules contradicted the plain

[1] Letter from U.S. EPA General Counsel, Roger Martella, to the Honorable Henry Waxman (April 18, 2008), with attached spreadsheet (both attached here as Attachments 1 & 2).

meaning of the statutory term, "any."[2] Exasperated judges took to quoting Lewis Carroll to criticize the upside-down, "Humpty Dumpty" legal arguments advanced by the EPA air program under Mr. Wehrum.[3] In a 2007 decision late in Mr. Wehrum's tenure, irritated D.C. Circuit judges reproached EPA for violating the same congressional command and ignoring plain statutory language in three prior D.C. Circuit decisions, reminding EPA how our constitutional system of laws works.[4]

In 2006, while Mr. Wehrum was the acting head of EPA's air program, a federal court found that EPA's implementation of key air toxics requirements in the Clean Air Act had been "grossly delinquent."[5] The court found that, "EPA ... currently devotes substantial resources to discretionary rulemakings, many of which make existing regulations more congenial to industry, and several of which since have been found unlawful." *Id.* The judge ordered EPA to issue long overdue air toxic regulations by 2009, denying the agency's request for a 2012 deadline. *Id.*

Mr. Wehrum also played a key role in defending the Bush EPA's refusal to act on the carbon pollution that drives dangerous climate change. The Bush EPA air program fought the plain language of the Clean Air Act for more than seven years, disputing that the law characterizes carbon pollution as an "air pollutant." The Supreme Court decisively rejected that position in 2007 in *Massachusetts v. EPA*, ruling that carbon dioxide and other greenhouse gases are "air pollutants," just like carbon monoxide or sulfur dioxide, and that the Clean Air Act gives EPA the authority and responsibility to regulate them all.[6]

Mr. Wehrum departed the agency one month after the Supreme Court's decision. By the end of the Bush administration, EPA still had done nothing to regulate the carbon pollution that drives dangerous climate change.

---

[2] *See, e.g., New Jersey v. EPA*, No. 05-1097 *et al.* (Feb. 8, 2008), http://caselaw.findlaw.com/us-dc-circuit/1236563.html; *Natural Resources Defense Council v. EPA*, No. 04-1385 *et. al* (June 8, 2007), http://caselaw.findlaw.com/us-dc-circuit/1024879.html; & *New York v. EPA*, 443 F.3d 880 (D.C. Cir. 2006), https://casetext.com/case/new-york-v-epa.

[3] In one case, DC Circuit federal appellate judges wrote that EPA's explanation "deploy[ed] the logic of the Queen of Hearts, substituting EPA's desires for the plain text of" the law. In another decision, judges rejected EPA's arguments and cited Carroll's "Through the Looking Glass," writing "[o]nly in a Humpty Dumpty world would Congress be required to use superfluous words while an agency could ignore an expansive word that Congress did use. We decline to adopt such a world-view."

[4] *Sierra Club v.* EPA, 03-1202 (March 13, 2007), https://www.cadc.uscourts.gov/internet/opinions.nsf/3DE6EA395F4B40A685257440004537C7/$file/03-1202a.pdf.

[5] *Judge blasts EPA's efforts. He denies request for later deadline, says agency is 'foot dragging' on air standards*, San Francisco Chronicle (Aug. 4, 2006), http://www.sfgate.com/green/article/Judge-blasts-EPA-s-efforts-He-denies-request-2514695.php

[6] No. 05-1120 (April 2, 2007), https://www.law.cornell.edu/supct/pdf/05-1120P.ZO.

A Record of Harming Americans' Health and Air Quality

Undermining National Health Standard for Fine Particulate Matter

During Mr. Wehrum's tenure leading EPA's air office, the agency issued a watered-down air pollution standard for deadly fine particulate matter, $PM_{2.5}$. The Clean Air Act requires that standard to protect the health of children, elders, and people with heart and lung ailments. Mr. Wehrum contradicted the unanimous recommendation of EPA's external science advisors that a more protective health standard was needed based on overwhelming medical science. The D.C. Circuit Court of Appeals found this rule arbitrary, capricious and unlawful because it inadequately protected Americans' heath and air quality.[7]

Rolling Back Hazardous Air Pollution Controls for Dirty Power Plants

Mr. Wehrum's actions in the Bush EPA delivered an illegal, 8-year amnesty period to dirty power plants for their emissions of mercury and over seven dozen hazardous air pollutants, like lead and arsenic. EPA illegally evaded the protective Clean Air Act safeguards requiring deep and timely reductions in all toxic air pollution from each of the nation's coal-burning power plant generating units.

When EPA released its controversial proposal in 2004, it was discovered that industry attorneys—from Mr. Wehrum's former law firm—had drafted key language that EPA included verbatim in the proposal to let power plant companies off the hook.[8] Then, an explosive 2005 report by EPA's Office of Inspector General found that "EPA senior management" had instructed staff to work backward from a pre-determined political outcome, "instead of basing the standard on an unbiased determination of what the top performing units were achieving in practice," essentially sabotaging the standards that the Clean Air Act required.[9] The Inspector General also faulted EPA for "not fully analyzing the cost-benefit of regulatory alternatives and not fully assessing the rule's impact on children's health."[10]

Mr. Wehrum's air office then developed a "cap-and-trade" approach for mercury, a potent neurotoxin that affects local populations and thus is inappropriate for regional emissions trading. His regulation exempted more than seven dozen other hazardous air pollutants emitted by power plants, including other neurotoxins such as lead, and carcinogens such as arsenic, benzene and

---

[7] *American Farm Bureau Federation v. EPA*, No. 06-1410 *et al.* (Feb. 24, 2009), http://caselaw.findlaw.com/us-dc-circuit/1209595.html.

[8] Eric Pianin, *Proposed Mercury Rules Bear Industry Mark*, Washington Post (Jan. 31, 2004), https://www.washingtonpost.com/archive/politics/2004/01/31/proposed-mercury-rules-bear-industry-mark/028e1379-0026-4bcb-b7ce-192bbae7b4c6/?utm_term=.c0cd6bb0d656.

[9] U.S. EPA, Office of Inspector General, *Additional Analyses of Mercury Emissions Needed Before EPA Finalizes Rules for Coal-Fired Electric Utilities* (Feb. 3, 2005), at 11, https://www.epa.gov/sites/production/files/2015-12/documents/20050203-2005-p-00003.pdf.

[10] *Id.*, at 3.

dioxins.[11] The cap-and-trade program even allowed individual power plants to *increase* their mercury emissions.[12] EPA emails uncovered through a Freedom of Information Act request revealed that agency officials pressured states into participating in the mercury trading program, by threatening to disapprove state programs that adopted more stringent mercury safeguards—despite the Clean Air Act's legal guarantee that states may adopt standards more protective than federal ones.[13]

The Clean Air Act requires coal-burning and oil-burning power plants to install and operate modern pollution controls to reduce *all* their hazardous air pollutants. The law required EPA to adopt those standards no later than 2004 and ensure compliance no later than 2007. Due to Bush EPA lawbreaking led by Mr. Wehrum, however, EPA flouted this schedule. Following a federal court ruling that invalidated the Bush EPA's lawbreaking,[14] the Obama EPA adopted the legally required standards in 2012. Thus, EPA lawbreaking fostered by Mr. Wehrum meant that coal- and oil-burning power plants did not end up complying with the Clean Air Act until 2015 to reduce their dangerous hazardous air pollution.

In 2012, EPA projected that by 2016 the Obama-issued standards would avoid up to 11,000 premature deaths and 130,000 asthma attacks *every year.*[15] The net health benefits to Americans are over $80 billion annually. *Id.* And each year, the Obama EPA standards are reducing coal-burning power plants mercury emissions by 90%, acid gas emissions by 88% and sulfur dioxide emissions by 41% beyond what other regulations would have required.[16] The illegal rollback by Mr. Wehrum and the Bush EPA denied Americans the totality of these health, environmental and economic benefits *for eight years.*

Rolling Back Hazardous Air Pollution Controls for All Other Industries

Mr. Wehrum also pushed a clean air rollback in early 2006 that would have allowed oil refineries, chemical plants and other industrial facilities to increase emissions of lead, mercury,

---

[11] U.S. EPA, Clean Air Mercury Rule (March 15, 2005), https://archive.epa.gov/mercuryrule/web/html/rule.html, & Mercury Delisting Rule (March 15, 2007), https://archive.epa.gov/mercuryrule/web/pdf/camr_final_regfinding.pdf.

[12] U.S. EPA, *Regulatory Impact Analysis of the Final Clean Air Mercury Rule*, EPA-452/R-05-003 (March 2005), https://www3.epa.gov/ttnecas1/regdata/RIAs/mercury_ria_final.pdf.

[13] Testimony of John Walke, NRDC, *The Overturning of EPA's "Clean Air Interstate Rule": Consequences and Opportunities* (July 29, 2008), at 7-8, https://www.epw.senate.gov/public/_cache/files/6/e/6e18496c-3193-4f13-85d4-c79a947f4020/01AFD79733D77F24A71FEF9DAFCCB056.walketestimonyoncair72908.pdf.

[14] *See supra note 2, New Jersey v. EPA.*

[15] U.S. EPA, FACT SHEET: MERCURY AND AIR TOXICS STANDARDS FOR POWER PLANTS, https://www.epa.gov/sites/production/files/2015-11/documents/20111221matssummaryfs.pdf.

[16] U.S. EPA, Regulatory Impact Analysis for the Final Mercury and Air Toxics Standards, EPA-452/R-11-011 (Dec. 2011), https://www3.epa.gov/ttnecas1/regdata/RIAs/matsriafinal.pdf.

arsenic, benzene and other hazardous air pollutants by many thousands of pounds each.[17] Officials in 9 of 10 EPA regional offices criticized Mr. Wehrum's plan, calling it "detrimental to the environment" and a "drastic change in interpretation" of clean air regulations. *Id.* The draft rollback claimed that even if corporations were given legal permission to save money by increasing hazardous air pollution, they would not do so, voluntarily, "to avoid negative publicity and to maintain their appearance as responsible businesses." *Id.* Following public and congressional outcries, EPA dropped this air toxics rollback plan.

Rolling Back Need for Modern Pollution Controls That Apply to Increases in Harmful Air Pollution

The Clean Air Act requires industries to install modern pollution controls when they build new facilities, or modify existing ones, in ways that lead to significantly higher annual emissions. Mr. Wehrum tried to make regulatory changes in 2002-2003 that would have dramatically weakened this clean air program.[18] In a 2004 report, the U.S. General Accounting Office reported that 27 of 44 state official surveyed "expected the [EPA] rule to increase emissions of harmful air pollutants, thereby hindering areas' efforts to meet air quality standards and potentially creating or exacerbating public health risks."[19] Thirty "of the officials expected their agency's workload would increase." *Id.*

The D.C. Circuit was so concerned that it issued a judicial stay of this EPA rollback rule two days before it was to take effect.[20] Such stays are very rare. The judges subsequently held that the rollback, once again, violated the plain language of the Clean Air Act. *Id.* Parties had presented evidence to the court that the rollback was so drastic, it would have eliminated the requirement to install pollution controls at one power plant increasing harmful emissions, like smog-forming nitrogen oxides, by over *21,000 tons per year*.[21]

---

[17] *E.P.A. Emissions Plan Is Criticized as Harmful to the Environment*, N.Y. Times (April 4, 2006), http://query.nytimes.com/gst/fullpage.html?res=9C06E3D61330F937A35757C0A9609C8B63.

[18] U.S. EPA, Prevention of Significant Deterioration (PSD) and Non-Attainment New Source Review (NSR): Equipment Replacement Provision of the Routine Maintenance, Repair and Replacement Exclusion (Oct. 27, 2003), https://www.federalregister.gov/documents/2003/10/27/03-26320/prevention-of-significant-deterioration-psd-and-non-attainment-new-source-review-nsr-equipment.

[19] U.S. GAO, *Key Stakeholders' Views on Revisions to the New Source Review Program*, GAO-04-274 (Feb. 2004), at 2 https://www.gao.gov/assets/250/241349.pdf

[20] *See New York v. EPA*, No. 03-1380 (March 17, 2006), at 6 (noting judicial stay of rule in December 2003), https://www.cadc.uscourts.gov/internet/opinions.nsf/DD611C38CF556DD6852574400044D637/$file/03-1380a.pdf.

[21] Opening Brief of Environmental Petitioners and Intervenors, *State of New York v. EPA*, No. 03-1380 *et al.* (Sept. 8, 2005), at 14-15. For comparison, this amount is nearly one-and-a-half times the total amount of nitrogen oxides emissions annually by *all* sources located in the District of Columbia. *State Emissions Totals* (NEI 1999 v3), www.emissionsonline.org/nei99v3/state/stindex.htm.

Undermining Clean Air Act Enforcement

Even the Bush EPA's own enforcement office protested Mr. Wehrum's 2003 rollback of these new source review regulations, finding that an astonishing "88 percent of [EPA's] pending enforcement cases" against coal-burning power plants would have been impossible under the expansive amnesty that the rollback conferred.[22] The political appointee heading EPA's enforcement office argued internally that these rollbacks would "eviscerate the air enforcement program," particularly as it impacts coal-fired utilities.[23]

A subsequent politically appointed head of the Bush EPA enforcement office related that the goal of Mr. Wehrum's air program clean air rollbacks "was to prevent any enforcement case from going forward. Some people thought the [agency's power plant enforcement initiative] should never have been brought. [The air program's] reform was really designed to thwart our ability to do it."[24] As noted, the D.C. Circuit subsequently stayed, then vacated, the rollback unanimously.[25]

Undermining States' Rights to Regulate Motor Vehicle Greenhouse Gas Emissions

As acting administrator of the EPA air office, Mr. Wehrum recommended against granting California's Clean Air Act Section 209 waiver to regulate greenhouse gas emissions from vehicles.[26] This decision had negative implications for a third of the nation's vehicle market, and represented the first and only time EPA has denied a waiver since California was granted pre-emption authority in 1967.

A Record of Advancing a Polluting Agenda for Industries

EPA lawbreaking during Mr. Wehrum's tenure in the Bush administration advanced an industry agenda to increase harmful air pollution and weaken clean air protections for all Americans. Mr. Wehrum has continued to pursue that agenda in his role as a corporate attorney representing industry.

---

[22] EPA, Office of the Inspector General, *New Source Review Rule Change Harms EPA's Ability to Enforce Against Coal-fired Electric Utilities*, Evaluation Report No. 2004-P-00034 (Sept. 30, 2004), at 18 ("2004 NSR OIG Report").

[23] *Id.*, at 11.

[24] Joel A. Mintz, *'Treading Water': A Preliminary Assessment of EPA Enforcement During the Bush II Administration*, 34 ELR 10933, 10937-40 (Oct. 1, 2004) (quoting J.P. Suarez).

[25] *See supra* note 20.

[26] Richard Simon & Janet Wilson, *EPA staff turned to former chief on warming*, L.A. Times (Feb. 27, 2008) (discussing email in which Wehrum argued against granting the waiver as far back as 2006). http://articles.latimes.com/2008/feb/27/nation/na-waiver27; *Global Warming Waiver Documents Show "An Environmental Protection Agency in Crisis* (Feb. 26, 2008), https://www.epw.senate.gov/public/index.cfm/press-releases-democratic?ID=5688A360-802A-23AD-4441-77F52C3C17B6.

As a private attorney, Mr. Wehrum has represented corporations and trade associations in *34 lawsuits* involving the EPA. Attachment 3 to this letter lists these cases.[27] The clear majority of the cases were lawsuits against EPA to weaken or overturn clean air and health protections. A few cases involved intervening on EPA's side to defend weak requirements that the petitioners believed the law requires to be strengthened.

We have not identified any case in which Mr. Wehrum represented a client that sought to strengthen clean air protections. Mr. Wehrum even sued the Occupational Health and Safety Administration opposing workplace exposure safeguards for dangerous respirable silica.[28]

Mr. Wehrum's conflicts of interest letter to EPA's Designated Agency Ethics Official indicates no intention to recuse himself from the large number of Clean Air Act matters that he is currently suing to overturn or weaken on behalf of industry clients.[29] Mr. Wehrum does not have an open mind about these standards and the legal, scientific and policy elements that contradict his private clients' positions and interests. Moreover, Mr. Wehrum's letter indicates an intention to recuse himself for only a limited duration from actual litigation against EPA in which he has participated personally and substantially. *Id.* If he is confirmed, Mr. Wehrum should recuse himself permanently from all future aspects of EPA Clean Air Act standards that are the subject of all his lawsuits against EPA on behalf of private clients.

A Mixed Record of Improving Public Health and Air Quality

EPA's air program did achieve some important air pollution reductions during Mr. Wehrum's tenure. The Bush EPA continued the Clinton administration's successful diesel emissions work, and launched their own efforts to control previously unregulated diesel engines. Building on interstate pollution reductions for smog-forming nitrogen oxides in the Clinton administration, and acting in response to petitions by frustrated downwind states, the Bush EPA's Clean Air Interstate Rule accomplished significant reductions in deadly sulfur dioxide and nitrogen oxides emissions from coal-burning power plants in the eastern U.S. A unanimous D.C. Circuit did find this rule unlawful, however, after concluding that the Clean Air Act requires power plants to make more reductions in these pollutants than the rule accomplished, in order to help downwind states like North Carolina.[30] Mr. Wehrum and the Bush EPA deserve credit for these achievements, even though the law required, and the Obama administration delivered, deeper pollution reductions.

---

[27] The list in Attachment 3 is limited to cases in the federal appellate courts in which Mr. Wehrum represented a party. It does not include any cases in federal district courts or state courts in which he may have participated. In addition, the list exceeds 34 EPA cases, because some of the cases were consolidated into a single case. This reduces the 68 listed cases involving EPA to 34 overall cases.

[28] *See* Attachment 3; https://www.hunton.com/en/people/william-wehrum.html.

[29] Letter from William Wehrum to Kevin Minoli, Designated Agency Ethics Official, U.S. EPA (undated), https://www.eenews.net/assets/2017/09/15/document_pm_04.pdf.

[30] *North Carolina v. EPA*, http://caselaw.findlaw.com/us-dc-circuit/1336309.html.

A Record of Damning Government Investigations

During Mr. Wehrum's tenure at EPA, there was an explosion of critical investigations and reports by independent watchdogs in the agency's Office of Inspector General (OIG) and by the Government Accountability Office. These government auditors directed sharp criticism at the harmful and frequently illegal clean air rollbacks overseen by Mr. Wehrum. Some of these examples include:

- The General Accounting Office's 2003 report, *EPA Should Use Available Data to Monitor the Effects of Its Revisions to the New Source Review Program*, determined that EPA's justifications for 2002 rollbacks to a clean air program were based on self-serving, unsubstantiated anecdotes submitted by industry, rather than on reliable data.[31]
- The EPA Office of the Inspector General's 2004 report, *New Source Review Rule Change Harms EPA's Ability to Enforce Against Coal-fired Electric Utilities*, found that a 2003 clean air rollback shepherded by Mr. Wehrum had "seriously hampered [EPA enforcement office] settlement activities, existing enforcement cases, and the development of future cases."[32] The OIG related that "[t]hree of nine utilities in ongoing active litigation with EPA [had] asserted that enforcement actions should cease or be significantly reduced" because their alleged violations would be acceptable under the rollback. *Id.* Soon after the rollback was made public, "a major utility ceased negotiations with EPA" and "[n]o new enforcement actions [were] taken against coal-fired utilities alleged to have violated the [old rule] due to the new rule's adverse impact on [the EPA enforcement office's] leverage in settlements or court remedies." *Id.* at ii-iii. As noted above, a federal court stayed and subsequently vacated the 2003 rollback.[33]
- The Government Accountability Office's 2005 report, *Observations on EPA's Cost-Benefit Analysis of Its Mercury Control Options*, identified major shortcomings in the economic analysis for EPA's proposed mercury cap-and-trade program.[34] For example, EPA examined the costs and benefits of the trading approach, but not the actual Clean Air Act requirement that EPA chose to roll back. This skirted examining which approach produced the greatest net benefits, leading GAO to conclude, "EPA's estimates are not comparable and are of limited use for assessing economic trade-offs." *Id.*
- The Government Accountability Office's 2006 report, *EPA Should Improve the Management of Its Air Toxics Program*, strongly criticized EPA for failing to act on scores of specific toxic air pollution control measures that Congress required the agency to complete years earlier.[35] GAO concluded that "as a result of EPA's limited progress, the agency has not addressed health risks from air toxics to the extent or in the time frames envisioned in the Clean Air Act." *Id.*
- The Government Accountability Office's 2006 report, *Particulate Matter: EPA Needs to Make More Progress in Addressing the National Academies' Recommendations on Estimating Health Benefits*, found EPA had failed to fully apply 26 recommendations by

---

[31] GAO-03-947 (Aug. 2003), at 4-5, 16-25, http://www.gao.gov/assets/240/239346.pdf.
[32] 2004 NSR OIG Report, *supra* note 22, at ii.
[33] *See supra* note 20, *New York v. EPA.*
[34] GAO-05-252 (Feb. 2005), http://www.gao.gov/new.items/d05252.pdf.
[35] GAO-06-669 (June 2006), https://www.gao.gov/assets/260/250607.pdf.

the National Academies for improving its benefits analysis for the national health standards for particulate matter pollution.[36]

CONCLUSION

Mr. Wehrum has dedicated his career to rolling back EPA health and clean air protections for Americans, both while at EPA and in service of industry clients. His record does not show the necessary dedication to achieving the Clean Air Act's imperative to "protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of the population."[37]

During Mr. Wehrum's prior tenure in EPA's air office, the agency's accomplishments were overshadowed by extraordinarily harmful rollbacks and delays, and frequent court losses and rebukes from judges. He left Americans to suffer from dangerous and unlawful air pollution for many years after his tenure ended.

Mr. Wehrum is a knowledgeable air pollution attorney, but he is not fit for the job as the nation's chief air quality official. We respectfully urge Senators not to confirm him to this position.

Sincerely,

Center for Biological Diversity
Earthjustice
Friends of the Earth
League of Conservation Voters
National Parks Conservation Association
NRDC
Save EPA
Sierra Club
Voices for Progress

[36] GAO-06-992T (July 2006), http://www.gao.gov/assets/120/114447.pdf.

[37] 42 U.S.C. § 7401(b).

CLEAN AIR TASK FORCE

October 4, 2017

Senator John Barrasso, Chairman
Senate Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC. 20510

Senator Thomas Carper, Ranking Member
Senate Committee on Environment and Public Works
465 Dirksen Senate Office Building
Washington, DC. 20510

RE: Opposition to the Nomination of William L. Wehrum as Assistant Administrator for the U.S. Environmental Protection Agency's Office of Air & Radiation

Dear Chairman Barrasso and Ranking Member Carper:

On behalf of Clean Air Task Force (CATF), we write you in opposition to the nomination of William L. Wehrum to be the Assistant Administrator in the Office of Air & Radiation of the United States Environmental Protection Agency (EPA or Agency). CATF is a non-profit organization, whose lawyers, scientists, policy analysts and engineers work towards public health improvements under the Clean Air Act, including safeguarding against the worst impacts of climate change, through the rapid global development and deployment of low carbon energy and other climate-protecting technologies.

Since our founding in 1996, it has generally been CATF's policy not to comment on, endorse, or oppose nominees for agency posts. We are breaking with our general practice in this instance, due to Mr. Wehrum's long history of opposition to protections for public health and welfare, both during his previous tenure at the Agency and in his subsequent representation of industrial and commercial clients. These issues are well documented by the Natural Resources Defense Council in their September 19, 2017 letter to you, and we will not repeat them here. We note however that when Mr. Wehrum served in senior leadership positions with the EPA air program during the George W. Bush administration, courts held the Agency in violation of the federal Clean Air Act 30 times, and while in private practice, Mr. Wehrum has represented private interests opposed to Clean Air Act regulation. Furthermore, Mr. Wehrum's August 28, 2017 letter on file with the Agency's Designated Ethics Official does not provide sufficient commitment to recuse himself to eliminate the appearance of conflict, given Mr. Wehrum's ongoing activity representing clients against the Agency.

The evidence suggests that Mr. Wehrum will not act in the best interests of American breathers, nor in the interests of environmental improvement, including taking steps to safeguard against the worst impacts of climate change, if he is appointed to the post to which he has been nominated. He should not be confirmed to lead the Office of Air & Radiation.

Thank you for your consideration,



For:

Armond M. Cohen, Executive Director
Ann Brewster Weeks, Legal Director
Conrad Schneider, Advocacy Director

Clean Air Task Force
114 State Street, 6th floor
Boston, MA 02109
617-624-0234

CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

September 19, 2017

Dear Chairman Barrasso and Ranking Member Carper:

The Center for Science in the Public Interest writes to strongly oppose the nomination of Michael Dourson to lead the Office of Chemical Safety and Pollution Prevention at the U.S. Environmental Protection Agency.

For decades, Dourson has consistently underestimated the health impacts of food chemicals, typically while he or his organization acted as a consultant, expert witness, or paid researcher for the food and chemical industries. In particular, Dourson or his firm's employees underestimated the potential harm of acrylamide (a carcinogen), diacetyl (a cause of lung disease), and perchlorate (which poses developmental risks), as well as pesticides linked to cancer or neurodevelopmental effects.

For example, after conducting a safety review of acrylamide, Dourson proposed a safety estimate that, according to the Center for Public Integrity and InsideClimate News, was *10 times less protective* of the public's health than the standard developed by EPA scientists. The study was funded by major food companies, including Burger King, Frito-Lay, KFC, and McDonald's.

Dourson's firm also sought to weaken the safety estimate for diacetyl, which can cause a fatal lung disease in workers, after receiving funding from a consortium of food companies, including Cargill, Coca-Cola, ConAgra, Frito-Lay, General Mills, J.M. Smucker, Land O'Lakes, Procter & Gamble, and Unilever. Employees of Dourson's firm proposed an occupational exposure limit of 200 parts per billion, which is *40 times less protective* than the standard recommended by the National Institute for Occupational Safety and Health.

Moreover, in April 2016, Dourson testified for Croplife, the pesticide trade association. And, unlike the EPA staff scientists he would oversee (but consistent with the views of this administration's political appointees), he argued in favor of the continuing use of current levels of chlorpyrifos, a pesticide linked to brain damage. Dourson also proposed weak safety estimates for breakdown products of alachlor and acetochlor, two herbicides linked to cancer and banned in the European Union.

In light of his long record of seeking to weaken chemical safety protections on behalf of chemical industry clients, Michael Dourson should never have been nominated to lead that industry's primary regulator. I strongly urge you to reject his nomination.

Sincerely,

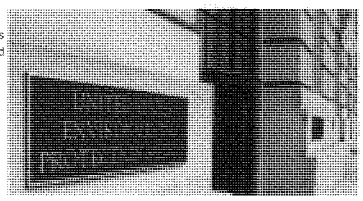
Peter G. Lurie, MD, MPH
President

1220 L Street, NW, Suite 300 • Washington DC 20005-4053 • tel 202-332-9110 • fax 202-265-4954 • www.cspinet.org

United Farm Workers

TAKE ACTION: Dourson is a toxic candidate to head the EPA Office of Chemical Safety and Pollution Prevention

The Trump Administration has nominated Michael Dourson to head the EPA Office of Chemical Safety and Pollution Prevention (OCSPP), the office charged with reviewing and ensuring the safety of chemicals, including pesticides like chlorpyrifos and many others.



Alarmingly, Dourson has spent much of his professional career receiving payment from chemical companies and their trade associations to publish papers and studies that undermine existing science and concerns about toxic chemicals, and call for weaker regulations on chemicals.

On chlorpyrifos specifically, Dourson was paid by Dow Agrosciences to downplay concerns about the chemical and cast doubt on a Columbia university study linking prenatal exposures to chlorpyrifos to irreversible neurodevelopmental problems in children. In other words, to hide the fact that chlorpyrifos is dangerous to kids. Really dangerous.

In a nutshell, Dourson is a threat to the health and safety of children and farm workers across the country.

This Wednesday, the Senate Environment and Public Works Committee will hold a hearing on his nomination. **Join us in telling your senators to oppose Michael Dourson.**

To get started, enter your zip code below and click 'Participate'

Participate



AMERICAN
SUSTAINABLE
BUSINESS
COUNCIL

September 19, 2017

The Honorable John A. Barrasso
Chairman
Environment and Public Works Committee
United States Senate
410 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
Environment and Public Works Committee
United States Senate
456 Senate Dirksen Office Building
Washington, DC 20510

RE: Nomination of Michael Dourson, Environmental Protection Agency's Office of Chemical Safety And Pollution Prevention

Dear Chairman Barrasso and Ranking Member Carper:

The American Sustainable Business Council (ASBC), with a national network of members representing over 250,000 businesses, strongly opposes the nomination of Michael Dourson to lead the Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention.

As the head of the industry-funded Toxicology Excellence for Risk Assessment, or TERA, Mr. Dourson repeatedly sought to weaken standards to protect families from dangerous chemicals, including chemicals linked to cancer, brain damage, and reproductive harm. Thirty to forty percent of TERA's funding came from the chemical industry to produce studies favoring weaker safety standards, and industry-funded studies made up more than half of the studies peer-reviewed by TERA since 1995.

The office Mr. Dourson has been nominated to head will be responsible for the risk evaluation and subsequent regulation of chemicals under the updated Toxic Substances Control Act, which Mr. Dourson sought to dramatically weaken after receiving funding from members of the chemical industry.

At a time when many businesses are successfully producing non-toxic products and consumers want stricter protections against harmful products and pesticides, Dourson has consistently argued for weaker standards and helped companies avoid liability for damages resulting from chemical pollution. Weaker standards for harmful chemicals not only increase risk of exposure, but the absence of meaningful safety standards also undermines consumer confidence across the spectrum of industries affected.

Given the funding that he has received over the years to produce studies on behalf of the chemical industry, we do not believe that Mr. Dourson would be independent in leading EPA's regulation of chemicals and pesticides. We encourage you to reject his nomination.

Respectfully submitted,

David Levine

David Levine, CEO

TEL: 202.595.9302
1001 G STREET NW, SUITE 400E
WASHINGTON DC 20001-4559
ASBCOUNCIL.ORG

September 26, 2017 *VIA EMAIL*

The Honorable John Barrasso
Chair
Comm. on Environment and Public Works
410 Dirksen Senate Office Building
Washington, D.C., 20510

Senator Thomas R. Carper
Ranking Member
Comm. on Environment and Public Works
456 Dirksen Senate Office Building
Washington, D.C., 20510

Dear Senators Barrasso and Carper:

As organizations committed to protecting reproductive rights, health, and justice, we are writing to express our concerns regarding the nomination of Michael Dourson to head the Office of Chemical Safety and Pollution Prevention at the Environmental Protection Agency (EPA). Mr. Dourson has long worked with corporations and industry groups to downplay or dismiss the harmful health effects of chemical industry products and, in particular, the risks these products pose to reproductive health.

Mr. Dourson has sought to weaken chemical safety standards on behalf of industry clients, yet he has been nominated to a position charged with establishing government safety standards for those very chemicals. Specifically, he has argued for weaker safety standards for chemicals linked to harm to individuals' reproductive health, such as 1-Bromopropane, TCE, and flame retardant chemicals. If confirmed, Dourson would be charged with establishing government safety standards for these chemicals, all of which are slated for EPA action in the next few years. Mr. Dourson also has a long record of proposing weaker safety standards for pesticides, many of which can interfere with the developing brain of children who were exposed to the chemicals in utero or as infants or toddlers. And the chemicals Mr. Dourson would be charged with regulating have been linked to a host of reproductive harms, including infertility, cancer, and even the early onset of puberty.

While all people can be harmed by dangerous chemicals, the risks are not shared equally. People of color and people who are struggling to make ends meet are more likely to be exposed to hazardous chemicals or conditions, including chemical spills and disasters, than other groups. People of color also are more likely to work in industries in which they are exposed to toxic chemicals. Migrant farm workers, who are consistently exposed to dangerous pesticides, are overwhelmingly Latinx. Nail salon workers, who are overwhelmingly women and a majority of whom are women of color, are exposed to products that contain a host of toxic chemicals that may cause reproductive harm and cancers. And women – especially Black women – are more likely to be exposed to toxic chemicals in personal care products.

The EPA is supposed to protect our families from chemicals that can harm our health. Mr. Dourson's record of seeking to weaken chemical safety standards, however, raises serious concerns about his ability to vigorously protect the public. We urge you to carefully consider the impacts of chemical safety on reproductive health as you make the critical decision of whether Mr. Dourson is fit to head the office of Chemical Safety and Pollution Prevention.

Sincerely,

Black Women's Health Imperative

Center for Reproductive Rights

If/When/How

In Our Own Voice: National Black Women's Reproductive Justice Agenda

National Asian Pacific American Women's Forum

National Council of Jewish Women

National Health Law Program

National Institute for Reproductive Health

National LGBTQ Task Force Action Fund

National Latina Institute for Reproductive Health

National Organization for Women

National Partnership for Women & Families

National Women's Health Network

National Women's Law Center

PAI

Physicians for Reproductive Health

Planned Parenthood Federation of America

Sexuality Information and Education Council of the United States

URGE: Unite for Reproductive & Gender Equity

September 19, 2017

The Honorable John Barrasso
Chairman
Committee on Environment and Public Works
410 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
Committee on Environment and Public Works
456 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Barasso and Carper:

We write to urge you to oppose the nomination of Michael Dourson to be Assistant Administrator of EPA's Office of Chemical Safety and Pollution Prevention. Dourson has spent decades playing down concerns about toxic chemicals for his industry clients—chemicals tied to cancer, infertility, severe lung damage, developmental impairment and other serious health concerns.

From his work on tobacco to his work defending chemicals like PFOA, TCE, chlorpyrifos, and 1,4-dioxane that are impacting communities across the country, Dourson has proven to be a reliable ally for industry clients rather than someone who will work to protect public health and the environment, as this position requires.

The position Dourson would hold at the helm of EPA's toxics office is of critical importance to public health and the environment. If confirmed, Dourson would oversee implementation of the newly amended Toxic Substances Control Act (TSCA). The reforms made last year to TSCA provide a significant opportunity to better ensure that chemicals used in products and materials we encounter every day in our homes, schools and workplaces are safe. Critical decisions about the implementation of the reformed law will fall to the current EPA and to the person leading this office.

Dourson would also lead the EPA program charged with ensuring the safety of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In light of the controversial decision made by Administrator Scott Pruitt to reject the recommendations of EPA scientists to ban chlorpyrifos, the credibility of the pesticide review process cannot afford to be further compromised.

Unfortunately, Michael Dourson is the wrong man for this job. Over the last two decades, Dourson has worked as a toxicologist-for-hire, with his firm Toxicology Excellence for Risk Assessment (TERA), recently migrated into a center at the University of Cincinnati. Contrary to TERA and the center's claims of "independence," they have deep financial ties to the chemical industry, tobacco industry, and other major corporations and industry groups—many of the same entities he would now be charged with regulating.

In fact, Dourson or his firm have been paid by dozens of chemical companies or trade associations to work on dozens of different chemicals. Those chemicals include several that are right now under active review by the very office Dourson has been nominated to lead, including trichloroethylene (TCE), 1,4-dioxane and chlorpyrifos.

Compounding the concern is that Dourson's firm routinely played down health concerns about the chemicals his clients produced or used. As multiple news articles have documented, Dourson and his firm have been the go-to firm for companies seeking to lessen or muddy concerns and press for less health-protective standards.

His work for industry went beyond science issues to include developing and running the website "kids+chemicalsafety.org" that was funded by the main chemical industry trade association. While it promised information about "chemical hazards and safe use of chemicals around children," the website actually delivered chemical industry spin that shifted the burden of protection onto parents and consumers, for example, by suggesting that parents concerned about toxic chemicals in toys ensure that children keep the toys out of their mouths and wash their hands after playing with them.

Such a long record of downplaying concerns about toxic chemicals means that Dourson should not be entrusted with protecting our children and families from toxic chemicals. Please reject Michael Dourson's nomination.

Sincerely,

Center for Biological Diversity
Clean Water Action
Earthjustice
Environmental Defense Action Fund
Environmental Working Group
Friends of the Earth
Green For All
Hip Hop Caucus
League of Conservation Voters
Moms Clean Air Force
Physicians for Social Responsibility
Power Shift Network
Public Citizen
Save EPA
Sierra Club
Union of Concerned Scientists

CC: Members of the Committee on Environment and Public Works

Center for Progressive Reform | CPR

Board of Directors

John Applegate
Alyson Flournoy
Robert Glicksman
Alice Kaswan
Alexandra Klass
Thomas McGarity
Sidney Shapiro
Amy Sinden
Robert R.M. Verchick

Advisory Council

Patricia Bauman
Frances Beinecke
Eula Bingham
W. Thompson Comerford, Jr.
Sally Greenberg
John Passacantando
Henry Waxman
Robert Weissman

September 19, 2017

Chairman Barrasso
410 Dirksen Senate Office Building
Washington, D.C. 20510

Ranking Member Carper
456 Dirksen Senate Office Building
Washington, D.C. 20510

Re: Nomination of Michael Dourson for Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention

Chairman Barrasso, Ranking Member Carper, and Members of the Committee:

We urge you to oppose the nomination of Dr. Michael Dourson to head EPA's Office of Chemical Safety and Pollution Prevention (OCSPP). Our concerns about his fitness for the position arise out of research conducted by the Center for Progressive Reform concerning his work with the consulting firm Toxicology Excellence for Risk Assessment (TERA).

Cozying Up: How Manufacturers of Toxic Chemicals Seek to Co-opt Their Regulators, the report based on that research, is attached.

Key findings from the report most relevant to your committee's review of Dr. Dourson's nomination include:

- When state regulators in Wisconsin began to consider limits on the chemical byproducts produced when two widely used herbicides break down in the environment, the manufacturers of the herbicides hired TERA to convene an expert panel to develop a "reference dose" (RfD) for the chemicals. (An RfD is an estimate of the daily oral exposure to a chemical that will not result in adverse health effects.) The result was an article co-authored with government scientists that advocated drinking water limits up to 280 times higher than the limit Wisconsin regulators had set.

- Significant amounts of TERA's funding derived from corporations (e.g., Boeing, Alcoa) and government agencies (e.g.,

Department of Defense) that could reduce compliance and cleanup costs if risk assessment policies and findings by regulatory agencies do not meet the bold public health goals Congress set in our toxic chemicals, clean air, and clean water laws.

- Chemical manufacturers have taken advantage of agency scientists' interest in professional development by fostering the growth of organizations like ILSI and TERA, which blur the lines between professional development and policy advocacy. For instance, after National Academy of Sciences' National Research Council published the Silver Book, TERA set up a committee (the affiliated Alliance for Risk Assessment's Beyond Science and Decisions) to partner with agency scientists in order to increase their influence over future federal agency risk assessment practices. Government scientists' participation in such activities undermines EPA's independence and objectivity.

Based on Dr. Dourson's past work with TERA, we have serious concerns about his potential biases in favor of regulated industry over EPA's public health mission, as well as the likelihood that he will pursue partnerships with outside organizations in a way that gives undue influence to regulated parties.

We urge you to oppose Dr. Dourson's nomination and insist that President Trump nominate someone for this important position who will put public health and environmental safety first.

Sincerely,

Alejandro E. Camacho
Professor of Law and Director, Center for Land, Environment, and Natural Resources
University of California, Irvine School of Law

David M. Driesen
University Professor
Syracuse University

Carmen G. Gonzalez
Professor of Law
Seattle University School of Law

Alice Kaswan
Professor of Law
University of San Francisco School of Law

Mary L. Lyndon
Professor
St. John's University School of Law

Martha McCluskey
Professor
University at Buffalo, SUNY

Thomas O. McGarity
Professor of Law
University of Texas School of Law

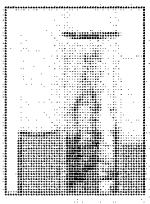
Joel A. Mintz
Professor of Law
Nova Southeastern University College of Law

Sidney A. Shapiro
Frank U. Fletcher Chair in Administrative Law
Wake Forest University

Karen C. Sokol
Associate Professor of Law
Loyola University New Orleans College of Law

Rena I. Steinzor
Edward M. Robertson Professor of Law
University of Maryland Francis King Carey School of Law

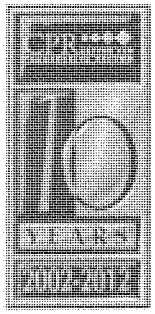
**** Affiliations are listed for identification purposes only.***



Cozying Up:

How the Manufacturers of Toxic Chemicals Seek to Co-opt Their Regulators

by CPR Member Scholar Rena Steinzor
and Policy Analyst Wayland Radin



CENTER FOR
PROGRESSIVE REFORM
WHITE PAPER #1211

September 2012

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization comprising a network of scholars across the nation dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation, and improved public access to information. The Center for Progressive Reform is grateful to the John Merck Fund and the Johnson Family Foundation for their support of our toxics work.

[illegible]

For more information about the authors, see page 17.

www.progressivereform.org

For media inquiries, contact Matthew Freeman at mfreeman@progressivereform.org
or Ben Somberg at bsomberg@progressivereform.org.

For general information, email info@progressivereform.org.

© 2012 Center for Progressive Reform.

Acknowledgments

The Center for Progressive Reform is grateful to the John Merck Fund and the Johnson Family Foundation.

Cover photo: ©Horia Varlan.

Deceptive Partnerships

Given the charged debate in Washington over proposals to impose environmental or health and safety restrictions on industry, Americans might reasonably assume that toxic chemicals undergo rigorous, independent testing before they enter the stream of commerce. The reality of chemical regulation is disturbingly different and far less protective of public health and the environment. When Congress passed the 1976 Toxic Substances Control Act (TSCA)—one of the most important federal statutes to regulate potentially dangerous chemical products—tens of thousands of chemicals were "grandfathered," meaning they were allowed to remain on the market without additional tests to prove their safety.[1] The tens of thousands of new chemicals that have come on the market over the last 35 years undergo a perfunctory, 90-day "pre-manufacture review" by the Environmental Protection Agency (EPA), which under even the best circumstances must rely on a comparison of the chemical structure of the new chemical to the structures of existing chemicals and whatever information the manufacturer has chosen to submit regarding the chemical. This "hear no evil, see no evil" system means that the hazards of chemical exposure are often revealed long after a chemical is pervasive in the environment. Bisphenol A is still used in a host of consumer products despite the fact that scientific studies link it to increased susceptibility to prostate and breast cancers, reproductive system defects and abnormalities, hormonal imbalances, brain development abnormalities, gender confusion, heart disease, and diabetes.[2]

When Congress passed the 1976 Toxic Substances Control Act (TSCA), tens of thousands of chemicals were "grandfathered," meaning they were allowed to remain on the market without additional tests to prove their safety.

As troubling, when the toxic effects of exposure to an untested chemical emerge, regulators must depend on "best available" science in order to decide whether to restrict the ways the chemical is marketed and used.[3] This approach gives manufacturers strong incentives to generate their own studies exonerating their products in an effort not only to keep chemicals on the market without restrictions but also to avoid liability for injuries caused by past exposures.

Because research by a chemical's producer is often the primary resource available to regulators who make crucial public health decisions, independent experts have examined whether industry-sponsored studies produce different results than comparable government-funded work. These analyses cover a wide range of adverse effects, but they all reveal that industry sponsorship makes it significantly more likely that these studies reach conclusions more favorable to the sponsors than would research conducted by neutral scientists. An empirical review of 1,140 biomedical studies determined that "industry-sponsored studies were significantly more likely to reach conclusions that were favorable to the sponsor than were non-industry studies."[4] Concerned by these findings, but unwilling to reject industry-sponsored science out of hand, the world's most prestigious scientific journals require authors to disclose the source of their work so that potential biases are evident to readers.[5] These disclosures alert readers to the need to scrutinize study design, implementation, and findings more carefully.

Chemical manufacturers have long chafed under these restrictions because they know that once a study is labeled as an industry work product, most people are unwilling to

take its conclusions at face value, and some will find them unconvincing on any level. This discomfort has generated a search for ways to make industry research appear more credible. One of the most effective methods of doing so is to recruit government scientists as co-authors for journal articles about the chemical in question. A second strategy is to obtain the active participation of government officials in industry-sponsored efforts to formulate "consensus" policy pronouncements regarding research design and risk assessment. These deliberations rarely include representatives from independent scientific organizations or public interest organizations, and government officials are typically a small minority of participants in comparison to scientists employed or largely funded by chemical manufacturers. Although their industry sponsors claim that such efforts represent "partnerships" that are balanced and therefore persuasive, in fact the limited number of participating government scientists do not and cannot rehabilitate the credibility of these fundamentally biased discussions.

The International Life Sciences Institute (ILSI) and Toxicology Excellence for Risk Assessment (TERA) are the most effective and active leaders in this intensifying effort to convert industry research into the result of an "industry/government partnership." Both are self-styled "tripartite" organizations that purport to represent a broad consensus among scientists from industry, government, and academia. ILSI is primarily funded by large agribusiness and TERA receives substantial financial support from chemical manufacturers and their customers. Both firms are structured as non-profit corporations. They rarely produce their own research, but rather compile and assess the research performed by other industry-sponsored scientists.

For example, ILSI has a subsidiary, the Health and Environmental Sciences Institute (HESI), which has convened the "Risk Assessment in the 21st Century Technical Committee" (RISK21). Its purpose is to create and advocate risk assessment policies that would result in far more lenient controls on toxic chemicals by federal and state regulators. Similarly, when state regulators in Wisconsin began to consider limits on the chemical byproducts produced when two widely used herbicides break down in the environment, the manufacturers of the herbicides hired TERA to convene an expert panel to develop a "reference dose" (RfD) for the chemicals. (An RfD is an estimate of the daily oral exposure to a chemical that will not result in adverse health effects.[6]) The result was an article co-authored with government scientists that advocated drinking water limits up to 280 times higher than the limit Wisconsin regulators had set.

Government scientists have a commendable interest in developing their professional skills and judgment by participating in scientific dialogues sponsored by the private sector. They make mistakes when they lend their names to industry-sponsored articles or committee deliberations designed to influence regulatory policy. Not only do such activities undermine the independence of their government employers, they undermine public confidence in regulatory agencies. Disclaimers to the effect that a government scientist is speaking in her "personal" capacity do little to restore public confidence.

Empirical Evidence of Industry Bias

Because industry-generated science is so influential with respect to public policy, researchers have conducted empirical reviews to determine the extent to which a project's funding source influences its outcome. Those studies revealed that industry-sponsored research is significantly more likely to produce results that exonerate chemicals and other products than studies funded by government or other entities.[7] In addition to the survey of studies conducted in the biomedical field described above, the industry influence on scientific research has been documented in research regarding second-hand smoke, nutrition, and chemical exposures. For instance, a study of review articles about second-hand smoke found that 94 percent of articles authored by researchers affiliated with the tobacco industry determined that the smoke posed no health risk.[8] A survey of articles regarding the potential health effects of the controversial chemical bisphenol A revealed that 94 of the 104 government-funded studies reported adverse effects at low doses but none of the 11 industry-funded studies did.[9] In the nutrition and food science arena, a review of articles regarding the risks and benefits of several beverages, including soft drinks, found that studies funded by soda manufacturers were four to eight times more likely to reach conclusions that were favorable to the sponsors than non-industry studies.[10] An empirical analysis of studies concerning the health effects of several widely used toxic chemicals found that 60 percent of studies conducted by non-industry scientists concluded that the chemicals were hazardous, but only 14 percent of industry-sponsored studies arrived at the same conclusion.[11]

A survey of articles regarding the potential health effects of the controversial chemical bisphenol A revealed that 94 of the 104 government-funded studies reported adverse effects at low doses but none of the 11 industry-funded studies did.

As these studies suggest, industry funding affects scientific outcomes and thus suggests that there is substantial corporate control over the construction of these studies, including the methods, data collection, analysis, and publication of the study results.[12] Study sponsors are even able to define the scope of the research and methodology used in the lab in order to minimize the possibility that this work will uncover adverse effects.[13] Sponsors may also reserve their authority to rewrite the article or block its publication entirely. Policies that require authors and organizations to disclose conflicts of interest are critically important because they suggest how the users of such research should evaluate it. For instance, if a research article includes full disclosures of authorship rights and responsibilities, critical readers can look for evidence that the researchers' sponsors used contracts or other mechanisms to establish control over outcomes or messaging.

The Structure and Funding of ILSI and TERA

ILSI is one of the oldest and most prominent organizations established by the chemical industry to influence scientific conclusions about agencies' risk assessment policies. Founded in 1978 by Coca-Cola, Pepsi Cola, General Foods, Kraft, and Procter & Gamble, ILSI focuses on science policy decisions that may affect the food, agriculture, and pharmaceutical industries. ILSI's membership remains limited to large corporations active in the food and drug industries.[14] It is governed by a board of trustees, half of whom are drawn from member companies, including Coca-Cola, Monsanto, and other large international corporations.[15] ILSI functions as the parent organization for 14 worldwide branches that are active in science policy in their respective regions and a Research Foundation. ILSI also supervises its separately chartered sister organization, the Health and Environmental Sciences Institute (HESI).

HESI organizes conferences and committees that publish reports on policies that run the gamut of risk assessment practice, from hazard identification to dose-response modeling to exposure science. Representatives from the chemical industry chair many of HESI's committees.[16] Committee members include academics and even government scientists who work on regulatory programs that affect ILSI-HESI corporate funders.[17] The HESI-sponsored interactions between government scientists and the entities that they regulate occur outside of the established regulatory process, potentially giving regulated entities exceptional influence over government policies. Industry often claims that the products of these interactions represent a scientific "consensus" even when independent academics and scientists from public interest organizations are conspicuously absent.[18]

In 2010 ILSI North America brought in $3.4 million in revenue, HESI received another $3.5 million and ILSI itself received $3.2 million.[19] (This financial information was drawn from publically available IRS documents that do not require, and thus did not provide, any information about which organizations provided the funding.) ILSI's lack of clear disclosure of funding sources is problematic because the bulk of its funding presumably comes from its corporate members, which can lead to the sponsorship bias issues described above.

TERA was founded in 1995 and primarily focuses on conducting risk assessments for its clients, which include chemical manufacturers, their customers, and a handful of government agencies. TERA also operates the Alliance for Risk Assessment (ARA), a closely related organization that has organized conferences and workshops regarding new risk assessment methods.[20] ARA recently convened a series of workshops to address the suggestions regarding the future of risk assessment the National Research Council made in its 2009 *Science and Decisions: Advancing Risk Assessment* document (a.k.a. the "Silver Book").[21] EPA and other government agencies are among sponsors that include chemical manufacturers and industry trade groups but do not include public interest groups or independent science organizations.[22]

TERA is governed by a ten-person board that includes industry representatives and academics. Directors serve three-year terms with the exception of Michael Dourson, founder and president, who is a perpetual member of the board. Prior to founding TERA, Dr. Dourson spent 15 years at EPA where he worked on several toxics projects, including the creation of EPA's Integrated Risk Information System. Dr. Dourson has also worked with the National Academy of Sciences and is a member of both EPA's and California's science advisory boards.

TERA had gross revenue of about $2.4 million in 2010, 32 percent of which came directly from industry.[23] Government agencies, including EPA, the Food and Drug Administration, and the National Institute for Occupational Safety and Health accounted for approximately 40 percent. "Non-profit" sources, including the affiliated ARA, represented approximately 30 percent.[24] Those non-profit sources are often dependent upon chemical manufacturer support. For example, TERA convened a panel regarding the carcinogenicity of hexavalent chromium that was funded by the non-profit Aerospace Industries Association (AIA). AIA is in turn funded by corporations that rely extensively on hexavalent chromium in their manufacturing, including Boeing and Alcoa. Additionally, at least some of TERA's government funding has come not from EPA or other agencies charged with protecting public health, but from agencies like the Department of Defense, which relies on toxic chemicals and has millions of dollars of potential liabilities arising out of those uses.[25]

Some of TERA's government funding has come from agencies like the Department of Defense, which relies on toxic chemicals and has millions of dollars of potential liabilities arising out of those uses.

Two case studies of recent ILSI and TERA advocacy make clear the goals and implications of their advocacy of science policies that favor their corporate sponsors.

Alachlor, Acetochlor and the Weakening of State Protection

Alachlor and acetochlor are popular herbicides used to control weeds on millions of acres of American farmland, particularly in corn, wheat, and soybean fields. Both chemicals are banned in the European Union but their use is on the rise in the United States because the broadleaf weeds and grasses they target are developing resistances to other herbicides.[26] Alachlor is the second most used herbicide in the United States.[27] The resurgence of these chemicals, as well as their prevalence in the drinking water supplies of agricultural states, has led some state agencies to institute tighter regulations on the herbicides and the chemicals they become as they break down in the environment. While the states were developing improved safety standards to protect public health and the environment, Dow and Monsanto, the manufacturers of these chemicals, funded a panel of scientists to review toxicological studies and derive their own "safe" levels of exposure.

Acetochlor and Alachlor are banned in the European Union but their use is on the rise in the United States.

The panel was organized through TERA and included scientists employed by government agencies tasked with ensuring pesticide and herbicide safety.[28] The panel consisted of five TERA employees, including its president and director, three government scientists, and a professor. The government scientists were from EPA, the Maine Department of Agriculture, and the California Environmental Protection Agency, while the professor was from the University of Florida. The representatives from Maine and EPA refused the travel expenses and honoraria offered by TERA.[29] The University of Florida professor and representative from the California Environmental Protection Agency accepted the offered funds.

In addition to being effective herbicides, alachlor and acetochlor pose environmental and human health hazards. Acute exposures, like those suffered by farmworkers who spread the chemicals or work in the fields after they have been applied, can cause skin and eye irritation. People who live near agricultural lands are similarly exposed because wind disperses the herbicides before they are absorbed into the soil or washed off into nearby waterways that serve as sources of drinking water. Chronic exposure to the chemicals can lead to cancer or endocrine disruption. Scientists have linked long-term exposures to liver, kidney, and spleen damage.[30]

Both chemicals are also toxic to animals. Acetochlor, for instance, affects development cycles in aquatic species, resulting in accelerated metamorphosis in amphibians and changes in gene expression and brain function of minnows.[31] Changes in the mortality of species lower on the aquatic food chain can rapidly accelerate up the chain and disrupt entire ecosystems.

To make matters worse, both acetochlor and alachlor break down into degradates that are also toxic to human health and the environment. The degradates alachlor-ESA, alachlor-OXA, acetochlor-ESA, and acetochlor-OXA are even more prevalent in water supplies than their parent chemicals and are cause for significant concern for some scientists and regulators because of their potential health effects. A 1994 study of acetochlor and similar herbicides in 12 Midwestern states found alachlor-ESA in all 104 surface water samples tested.[32] That same study detected alachlor-ESA in almost two thirds of groundwater samples.

EPA has set some regulatory limits on alachor and acetochlor, but it has also allowed new and increased uses of acetochlor, and has decided not to regulate their degradates. These decisions at the federal level, along with the pervasiveness of the degradates in drinking water in agricultural states and emerging research concerning toxicity and carcinogenicity of the parent chemicals, spurred Minnesota and Wisconsin to establish their own limits on some of the degradates. (See text box). In 2009, shortly after these states began regulating, TERA's subsidiary ARA organized a panel of scientists to review toxicological data and existing studies to derive their own reference doses for the chemicals. Monsanto and Dow provided direct financial support to the panel and also paid TERA for organizing the panel and facilitating the workshop.

Pesticide Regulations at the State Level

The Minnesota Department of Health established drinking water standards limiting acetochlor ESA and OXA. Wisconsin's Natural Resources Defense Board successfully established a limit for alachlor-ESA in groundwater in 2007 after an earlier effort was scuttled by a legislative committee for failing to acquiesce to Monsanto's demand that they be allowed to hand-pick and exclude their own study in the regulatory process. Wisconsin's regulatory limit ended up relying on Monsanto-sponsored research despite there being one of the few entities that has studied the degradates at all. While both states were ultimately successful in setting standards for degradates, the herbicide manufacturers thwarted Minnesota's 2007 attempt to set its surface water standard for acetochlor. At the end of the rulemaking process, the regulatory limit had been raised to more than double the initial proposal and was based on at least three studies conducted by Monsanto. Dow and Monsanto strongly opposed the states' pursuit and implementation of these standards because they will ultimately restrict how much of the herbicides can be used, and thus sold, in regulating states.

The TERA panel reviewed several studies that suggested degradates pose serious health risks, including the Monsanto drinking water study that Wisconsin regulators used to set the state's standard for alachlor-ESA. However, the panel ultimately recommended Reference Doses (RfDs) for alachlor-ESA and -OXA that were based on more recent studies conducted by Monsanto that administered the chemical in the animals' food. The panel's rationale was that the more powerful adverse effects noticed in the drinking water study could be attributed to dehydration. The panelists, as well as the industry authors of the drinking water studies, speculated that the animals were dehydrated because they found the dosed water unpalatable.[33] So, instead of the drinking-water studies, the panelists used feed-based studies, including two conducted by Central Toxicology Laboratory, to recommend RfDs for acetochlor-ESA and –OXA. Using just these four industry-sponsored dietary studies, the TERA panel developed RfDs that would lead to drinking water standards significantly higher than those the states deemed adequately protective of human health. The panel recommended RfDs of 5600ppb for alachlor-ESA and 1400ppb for both acetochlor-ESA and –OXA. Wisconsin adopted a standard of 20ppb for alachlor-ESA while Minnesota set standards for acetochlor-ESA and –OXA at 300ppb and 100ppb, respectively. The TERA panel's recommendations were published in *Regulatory Toxicology and Pharmacology*, a journal with strong industry ties.[34]

Table 1: The TERA Panel's Recommended Values Far Exceed Those Set by States

	Alachlor	Alachlor ESA	Alachlor OXA	Acetochlor	Acetochlor ESA	Acetochlor OXA
EPA	2ppb	None	none	Restrictions on crop types.	None	None
Wisconsin		20ppb		7ppb		
Minnesota		70ppb (Risk Assessment Advice)		3.6ppb	300ppb	100ppb
North Carolina		0.4ppb				
TERA		5600ppb[35]	5600ppb		1400ppb	1400ppb

When EPA's standard RfD to drinking water conversion is applied to the panel's recommendations it becomes clear that those recommendations are significantly less protective of public health than the standards adopted by the states.[36] The panel's recommendation for alachlor-ESA, for instance, is 280 times higher than the standard Wisconsin adopted.

Risk21 and the Co-optation of the National Academies' Silver Book

Drug licensing, pesticide registration, and toxic chemical regulation are shaped by the complex science of toxicological risk assessment. As just one example of the complications involved in the practice of risk assessment, scientists can use a variety of methods to account for uncertainties when they extrapolate chemicals' potential low-dose effects on humans from high-dose studies conducted with animals. Depending on the method used, regulatory decisions about how best to protect the public can vary widely. In order to address these sorts of problems and with an eye toward protecting human health, government risk assessors use standard assumptions and guidelines that they develop through public processes and with the advice of experts from academia, private industry, NGOs, and other government agencies. ILSI has a history of trying to preempt government-driven policy development through establishment of its own "tripartite" committees.

A recent example of an ILSI-HESI committee that is working to reshape federal risk assessment policies by building close relationships with government scientists is the ongoing Risk Assessment in the 21st Century Technical Committee (RISK21). Highlighted by a well-attended conference in January 2011, RISK21 has brought together more than 100 scientists and regulators, the majority of whom are representatives from the chemical industry.[37] RISK21 is co-chaired by Syngenta's principal scientist and Dr. Alan Boobis, a professor at the Imperial College London who was previously a member of ILSI's board of trustees and has authored numerous industry-sponsored articles. Pesticide Action Network Europe (PANE) extensively researched Dr. Boobis' publishing history and ties to ILSI, and concluded that he is clearly biased toward the chemical industry, stating: "Alan Boobis was chair of the ILSI board of trustees and a fierce defender of industry's agenda in his work."[38] PANE further determined that a list of his "publications reads like a list of ILSI opinions and ILSI meeting reports," which "gives the impression that Boobis is a ghost writer for ILSI."[39]

In addition to 19 chemical manufacturers and affiliated organizations RISK21 participants include the Consumer Product Safety Commission, the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, and the National Institutes of Health.[40] RISK21 has four sub-teams working on agendas that are closely related to important and controversial areas in the development of risk assessment practice.

- ***The Exposure Science Sub-team***: Accurately determining the extent to which certain populations are exposed to toxic chemicals is of critical importance to both risk assessment and risk management, particularly in terms of protecting those that might be more susceptible to toxic effects, such as children and the elderly. The RISK21 exposure team, led by a representative from the National Institutes of Health working closely with a scientist from Arysta, a large chemical manufacturer, works to characterize exposure to chemicals with an emphasis on "real-world" exposures and a "data-driven" approach. An exclusive emphasis on existing exposures is minimally protective of

human health because it fails to account for potential new or unpredicted exposure scenarios.[41] Choosing whose "real-world" exposures are relevant to regulatory decisions is also an important exercise, given the problem of toxic hot spots near Superfund sites, power plants, and chemical facilities.

- ***The Dose-Response Sub-team:*** Dose-response science attempts to determine the relationship between exposure to a chemical and specific toxic effects. Most toxicological research involves dosing animals with a chemical, measuring the response, and then extrapolating from that data human-relevant dose-response curves. The relationship is governed by complex biological processes and is one of the most important aspects of risk assessment. The RISK21 dose-response team, led by representatives from Dow and University of Nebraska, aims to quantitatively incorporate dose-response information into risk assessments with a strong focus on mode of action analysis.[42] Focusing solely on mode of action analysis has the potential to over-emphasize certain obvious chemical effects in the body while losing sight of the overall toxic effects caused by exposure and highly complex biological processes.[43]

- ***The Integrated Evaluation Strategies Sub-team:*** "Integrated evaluation strategies" is a catch-all for HESI's push away from current risk assessment practices, including animal testing, and toward a heavy reliance on *in vitro* testing and rapid assessments of individual chemicals. Other expert organizations, like the National Academies' National Research Council have acknowledged that the new techniques are not yet reliable and are "at least a decade away."[44] An EPA scientist and a former Syngenta scientist lead the RISK21 team, which is developing a framework that relies on new technologies for evaluating the toxicity of chemicals that is "more accurate and utilizes fewer resources than the current paradigm."[45] Forcing a reliance on these technologies to save time and resources would result in potentially drastic adverse effects on human health and the environment because they can oversimplify the biological processes that are affected by the chemicals' toxic effects.[46]

- ***The Cumulative Risk Sub-team***: One of the most important, and most frequently overlooked, aspects of risk assessment, cumulative risk science attempts to account for the wide variety of factors that contribute to the toxic effects that result from chemical exposure. The RISK21 team is led by scientists at ExxonMobil and the University of Milan and focuses on creating a method for assessing health risks of combined exposures to multiple chemicals in the context of other stressors. The RISK21 team downplays scientists' ability to determine whether multiple stressors combine at levels relevant to humans. In contrast, the NAS recommends that EPA "draw on other approaches, including those from ecologic risk assessment and social epidemiology, to incorporate interactions between chemical and nonchemical stressors in assessments."[47] Congress recognized the importance of cumulative exposures, requiring EPA to consider cumulative risk when determining pesticide tolerances under the Food Quality Protection Act.[48]

Current HESI Committee Leadership

Current HESI Project Committees

Distinguishing Adverse from Non-Adverse/Adaptive Effects
sanofi-aventis, Dow, Colorado State

Animal Alternatives in Environmental Risk Assessment
Procter & Gamble, L'Oreal

Development of Methods for a Tiered Approach to Assess the Bioaccumulation of Chemicals
Dow, USEPA

Biomarkers of Nephrotoxicity
Pfizer, Newcastle University, John Moores University, sanofi-aventis

HESI Project Committee on Imaging for Translational Safety Assessment
Duke University, GlaxoSmithKline

The Relevance and Follow-Up of Positive Results in In Vitro Genetic Toxicity (IVGT) Testing
Dow, sanofi-aventis

Vaccines and Adjuvants Safety
Sanofi, Medicines Evaluation Board (CBG-MEB)

Evaluating Causality in Epidemiologic Studies Subcommittee
Dow, USEPA

Frameworks for Alternative Chemical Assessment and Selection of Safer, Sustainable Alternatives
Dow

Current HESI Technical Committees

Cardiac Safety
GlaxoSmithKline Safety Assessment, College of Veterinary Medicine, Cornell University, U. S. Food and Drug Administration, Data Sciences International (DSI), Lilly Research Laboratories, AstraZeneca

HESI Global Developmental and Reproductive Toxicology (DART)
Sanofi, AstraZeneca

HESI Application of Genomics to Mechanism-Based Risk Assessment
Pfizer, National Institute of Environmental Health Sciences

HESI Immunotoxicology Technical Committee (ITC)
Pfizer, Amgen

Protein Allergenicity Technical Committee (PATC)
E.I. DuPont de Nemours and Company, Syngenta, Academic Medical Center, Amsterdam University

Risk Assessment in the 21st Century
Syngenta, Imperial College London

Government scientists' participation in these committees and meetings allows HESI to make claims to scientific consensus where none actually exists. Government scientists' involvement with HESI and its members is inappropriate because they are engaging in potentially far-reaching policy discussions without the public notice and transparency that would attend similar discussions if pursued according to the rules that exist to govern these kinds of interactions and protect the public—for example, the Federal Advisory Committee Act, which places great emphasis on open meetings, public involvement, and reporting of committee activities.[49] Because the interactions between government

scientists and industry representatives fostered by groups like ISLI-HESI and TERA-ARA generally occur before any Notice of Proposed Rulemaking, they are not recorded on any docket and are thus not made known to the public. Even more troubling is that government scientists, to the extent to which they are influenced by their interactions with industry in these pre-decisional discussions, may be unduly predisposed to favor industry during the actual rulemaking process.

Recommendations

EPA policies designed to protect against individual bias on the part of agency employees should be revised to incorporate stronger protections against undue industry influence.

The Obama Administration has repeatedly reaffirmed its commitment to running a clean and transparent government. President Obama's 2009 scientific integrity memorandum states his aspirations for protecting government science from undue influences.[50] Shortly after its publication, EPA Administrator Lisa Jackson published her own memorandum pledging transparency with respect to scientific analysis at the Agency.[51] Unfortunately, the administration's initiatives have had mixed success. As this report indicates, serious problems can occur when EPA scientists interact with industry scientists in circumstances that industry spokespeople characterize as "partnerships" with government. Portraying such discussions as balanced collaboration appears to be an attempt to whitewash ends-oriented deliberations that have as their primary goal the weakening of controls on toxic chemicals.

So that it can attract and retain the best scientists, the government should encourage agency scientists to participate in events organized by private sector scientific organizations that do not attempt to influence government policy in ways that favor their industry financial supporters. Such events allow government scientists to remain current on the latest developments in research and interact with other scientists in their field without exploiting their status as civil servants to make any recommendations seem less biased. For instance, the American Association for the Advancement of Science hosts a yearly forum on Science & Technology Policy.[52]

Chemical manufacturers have taken advantage of agency scientists' interest in professional development by fostering the growth of organizations like ILSI and TERA, which blur the lines between professional development and policy advocacy. For instance, after NAS published the Silver Book both ILSI and TERA set up committees (RISK21, ARA's Beyond Science and Decisions) to partner with agency scientists in order to increase their influence over future federal agency risk assessment practices. Government scientists' participation in such activities undermines EPA's independence and objectivity.

Government scientists need not turn to industry and its affiliates for professional development. Professional societies and organizations such as the American Association for the Advancement of Science provide numerous opportunities to engage with colleagues in relevant fields.[53] And EPA policies designed to protect against individual bias on the part of agency employees should be revised to incorporate stronger protections against undue industry influence when agency employees are pursuing professional development opportunities.[54]

Guaranteeing Transparency, Eliminating Conflicts, Balancing for Bias

The Federal Advisory Committee Act (FACA) sets out the basic legal framework that safeguards the integrity of federal agencies' consultation with outside experts.[55] FACA's findings declare that "the public should be kept informed with respect to ... [the] purpose, membership, [and] activities."[56] Although FACA only applies to committees established or controlled by government agencies, the principles it sets forth indicate the huge gap between what can rightly be called a collaboration among stakeholders and the biased processes that ILSI and TERA sponsor. Those principles include:

- Committee membership must be balanced for bias, taking into account "a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and function of the advisory committee."[57]
- Before accepting appointment, potential committee members should fully disclose their other affiliations.[58]
- FACA committee members are subject to federal ethics and conflict of interest laws.[59]
- Committee meetings must be open to the public.

The National Academies endorse similar principles in the rules governing their committees.[60] The international health community has also taken steps to preserve the integrity of its committee deliberations. The World Health Organization (WHO) requires disclosures to be made before scientists can participate in meetings and places great emphasis on disclosing the relationship between the administrative unit or organization with which a scientist is interacting and any commercial entities.[61] WHO committees foster transparency by inviting neutral outside scientists to observe the committee proceedings. WHO also requires disclosures to be made before scientists can participate in advisory meetings, including "any interests that could constitute a *real, potential or apparent* conflict of interest, with respect to his/her involvement in the meeting or work, between a) commercial entities and the participant personally, and b) commercial entities and the administrative unit with which the participant has an employment relationship." (emphasis added)[62] The stipulation that scientists must avoid potential or apparent conflicts of interest is critical. The ILSI and TERA activities described above do not meet this appropriately rigorous standard, much less the threshold requirements of balancing advisory panels for bias and conducting committee deliberations in public.

The stipulation that scientists must avoid potential or apparent conflicts of interest is critical.

We urge EPA and other agencies to take steps to put an immediate end to these collaborations that benefit industry and undermine trust in government. Specifically:

- EPA and other government agencies should withdraw their employees from participation in activities sponsored by ILSI and TERA immediately.
- Government agencies should adopt ethics rules that:
  - Prohibit government scientists from co-authoring articles with industry-sponsored experts regarding matters that may be considered by their respective agencies, including individual toxicological risk assessments;
  - Prohibit government employees from participating in private sector activities that are designed to influence a decision under the jurisdiction of the employer agency if such expert will be asked to endorse the final work product produced by the group.
- Government agencies should establish programs to ensure that these ethics standards are being met, including review by trained ethics officers of individual requests to undertake extracurricular activities; limits on the time spent on such activities; and affirmative recommendations regarding appropriate private sector organizations. In formulating lists of qualified organizations, agencies should take into consideration standards for balance, transparency, and conflict of interest used by professional societies when they accredit entities that provide continuing education in their respective fields.

Endnotes

[1] Prior to enacting TSCA (15 USC §§ 2601-2692), Congress passed the Federal Hazardous Substances Act (FHSA) (15 USC §§1261–1278) to regulate "any substance or mixture of substances … [that] may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." FHSA, however, explicitly exempted pesticides, food, drugs, and cosmetics.

[2] *See* Protecting the Public from BPA: An Action Plan for Federal Agencies, Center for Progressive Reform, 2012, http://www.progressivereform.org/articles/BPA_Action_Plan_1202.pdf.

[3] Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(3)(A)(i).

[4] Justin E. Bekelman, Yan Li, & Cary P. Gross, "Scope and Impact of Financial Conflicts of Interest in Biomedical Research," *JAMA* 289 (2003): 454.

[5] *See, e.g.*, International Committee of Medical Journal Editors, http://www.icmje.org/ethical_4author.html.

[6] EPA Risk Assessment Glossary, http://www.epa.gov/risk/glossary.htm#r.

[7] For a full discussion of the "funding effect," *see* Thomas McGarity & Wendy Wagner, Bending Science: How Special Interests Corrupt Public Health Research 24, Harvard U. Press (2008).

[8] Deborah E. Barnes & Lisa A. Bero, "Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions," *JAMA* 279 (1998): 1566.

[9] Frederick S. vom Saal & Claude Hughes, "An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment," Environmental Health Perspectives 113 (2005): 926.

[10] Leonard I. Lesser et al., "Relationship between Funding Source and Conclusion among Nutrition-Related Scientific Articles," *PLoS Medicine* 4 (2007): 5.

[11] Rosenstock L, Lee LJ. Attacks on science: The risks to evidence based policy. Am J Public Health 2002;92:14-8; Fagin D, Lavelle M. Center for Public Integrity. Deception: how the chemical industry manipulates sciences, bends the law and threatens your health. Seacaucus, NJ: Birch Lane Press, 1997:57.

[12] Bending Science, *supra* note 7.

[13] The ways in which study sponsors influence the outcomes of studies are often entirely legal which has led some commentators to propose an independent coordinating organization that would control study design and parameters. David C. Volz and Kevin C. Elliott, *Mitigating Conflicts of Interest in Chemical Safety Testing, Environ. Sci. Technol.* (July 27, 2012). http://pubs.acs.org/doi/full/10.1021/es302826b.

[14] ILSI Q&A, http://www.ilsi.org/Pages/ILSI_QA.aspx ("ILSI members are companies from the food, agricultural, chemical, pharmaceutical, and biotechnology and supporting industries."). *See also*, ILSI North America 2010 IRS Form 990, http://www.guidestar.org/organizations/52-2337019/ilsi-health-environmental-sciences-institute.aspx?jsReportSection=Status.

[15] The full list of companies represented on the ILSI board as of 2011: Nestle, Kraft Foods, sanofi-aventis, Coca-Cola, Archer Daniels Midland, Kelloggs Europe, Monsanto, Lotte Company, Kikkoman corporation, Pepsico, Groupe Danone, General Mills, and Planitox, http://www.ilsi.org/Features/ILSI_AR_2010_Web.pdf.

[16] *See*, e.g., HESI Project Committees, http://www.hesiglobal.org/itia/pages/index.cfm?pageid=3206.

[17] *Id.*

[18] *See, e.g.* HESI's Agricultural Chemical Safety Assessment (ACSA) Technical Committee: "The mission of the HESI Agricultural Chemical Safety Assessment (ACSA) Technical Committee was to develop a consensus across sectors (government, academia, and industry) on a credible and viable testing approach for assessing the safety of crop protection chemicals." (http://www.hesiglobal.org/itia/pages/index.cfm?pageid=3461).

[19] ILSI North America 2010 IRS Form 990, http://www.guidestar.org/organizations/52-2337019/ilsi-health-environmental-sciences-institute.aspx?jsReportSection=Status.

[20] ARA Membership document, available at http://www.allianceforrisk.org/ARA%20Membership.doc.

[21] Alliance for Risk Assessment, Beyond Science and Decisions: From Problem Formulation to Dose-Response Assessment, http://www.allianceforrisk.org/ARA_Dose-Response.htm.

[22] Alliance for Risk Assessment, Dose Response Sponsors, http://www.allianceforrisk.org/ARA_Dose-Response_Sponsors.htm.

[23] TERA 2010 Annual Report, http://tera.org/about/2010%20Annual%20Report.pdf; TERA Funding Sources, http://tera.org/about/FundingSources.html.

[24] *Id.*

[25] *See* TERA's work on Perchlorate, http://www.tera.org/src/Perchlorate/index.html.

[26] EU Phase-out for Acetochlor: http://news.agropages.com/News/NewsDetail---6107.htm.

[27] Delaware Health and Social Services, Department of Public Health, Frequently Asked Questions: Alachlor, http://dhss.delaware.gov/dph/files/alachlorfaq.pdf.

[28] Report of a Peer Workshop on Toxicological Assessment and Development of Reference Doses for Acetanilide Degradates, http://www.tera.org/ARI/Degradates/AcetanilideMeeting%20Report.pdf.

[29] Bernard Gadagbui, Andrew Maier, Michael Dourson, Ann Parker, Alison Willis, John P. Christopher, Lebelle Hicks, Santhini Ramasamy, & Stephen M. Roberts, Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation, *Regulatory Toxicology and Pharmacology*, Volume 57, Issue 2, 220-234.

[30] EPA, Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Acetochlor, http://www.epa.gov/oppsrrd1/REDs/acetochlor_red.pdf.

[31] Li, et al., Effects of Exposure to Acetochlor on the Expression of Thyroid Hormone Related Genes in Larval and Adult Rare Minnow (Gobiocypris rarus), http://www.ncbi.nlm.nih.gov/pubmed/19577411.

[32] Aga, D.S., Thurman, E.M., and Pomes, M.L., 1994, Determination of alachlor and its ethane-sulfonic acid metabolite in water by solid-phase extraction and enzyme-linked immunosorbent assay: Analytical Chemistry, v. 66, no. 9, p. 1495–1499.

[33] Derived Reference Doses (RfDs) for the Environmental Degradates of the Herbicides Alachlor and Acetochlor: Results of an Independent Expert Panel Deliberation, *supra*, note 29.

[34] *Id.*; Letter from Center for Science in the Public Interest, *Re: Regulatory Toxicology and Pharmacology*, November 19, 2002, http://www.cspinet.org/new/pdf/final_letter_academic_press_rtp.pdf.

[35] Lebelle Hicks, Maine Board of Pesticides Control, Presentation, http://www.nwwa.org/wp-content/uploads/2011/09/AgriculturalPesticidesGWContamination-Hicks-web.pdf.

[36] EPA assumes that the average person weighs 70kg and drinks 2 liters of water a day. EPA also assumes that drinking only accounts for 20 percent of an individual's exposure. Using TERA's alachlor-ESA RfD as an example:

.8mg/kg-day x 70kg = 56mg/day
56 / 2L = 28mg/liter
28 x .2 = 5.6 mg/liter or 5600ppb

EPA, 2012 Edition of the Drinking Water Standards and Health Advisories, http://water.epa.gov/action/advisors/drinking/upload/dwstandards2012.pdf.

[37] HESI – Risk Assessment in the 21st Century, http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3492.

[38] Pesticide Action Network Europe, A Toxic Mixture? Industry bias found in EFSA working group on risk assessment for toxic chemicals. http://www.pan-europe.info/Resources/Reports/PAN%20-%20A%20Toxic%20Mixture%20-%20Industry%20bias%20found%20in%20EFSA%20working%20group%20on%20risk%20assessment%20for%20toxic%20chemicals.pdf.

[39] *Id.*

[40] RISK21 2011-2012 Participating Organizations: Applied Pharmacology & Toxicology, Inc., BASF, Bayer CropScience, Chemical Regulation Directorate, Craig Barrow Consulting, CXR Biosciences, Dow Corning Corporation, DuPont, European Commission, Joint Research Center, European Center for the Validation of Alternative Methods, ExxonMobil Biomedical Sciences, Inc., Gradient Corporation, Hamner Institutes of Health Sciences, Health Canada, Humane Society of the United States, Imperial College London, Indiana University School of Medicine, Johns Hopkins University, L'Oréal Corporation, Medical College of Wisconsin, Michigan State University, Monsanto Company, National Center for the Replacement, Refinement, and Reduction of Animals in Research (NC3Rs, UK), National Institutes of Health, Pacific Northwest National Laboratory, Parker Doe Partnership, Radboud University Nijmegen, Swiss Federal Office of Public Health, Syngenta, Ted Simon Toxicology, The Coca-Cola Company, The Dow Chemical Company/Dow AgroSciences, The Procter & Gamble Company, University of Aarhus, University of Basel, University of California, Los Angeles, University of Florida, University of Guelph, University of Kansas, University of Michigan, University of Milan, University of Nebraska Medical Center, University of Ottawa, University of Texas Houston, University of Washington Medical Center, US Consumer Product Safety Commission, US Department of Agriculture, US Environmental Protection Agency, US Food and Drug Administration, Utrecht University, and Virginia Commonwealth University. http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3492.

[41] RISK Assessment for the 21st Century Exposure Subteam Update, http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/SargentPrez.pdf.

[42] RISK21, http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/CollectPrez.pdf.

[43] *See* comments by Richard Denison at *Systems Biology-Informed Risk Assessment*, National Academies, Emerging Science for Environmental Health Decisions (June 15, 2012) http://dels-sites.org/emergingscience/workshop/omics-informed-risk-assessment/systems-biology-informed-risk-assessment-presentations/.

[44] NAS, Science and Decisions (Silver Book), at 4.

[45] HESI Workshop Synopsis, http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/Risk21WkshpSynopsis.pdf.

[46] *Id.*

[47] RISK Assessment for the 21st Century (RISK21): Cumulative Risk Assessment Sub-Group, http://www.hesiglobal.org/files/public/Committees/Risk21/Jan_2011_Workshop/MeetingPrez.pdf; NAS, Science and Decisions (Silver Book), at 286.

[48] Food Quality Protection Act of 1996, Public Law 104-70, § 405.

[49] Federal Advisory Committee Act (FACA) of 1972, Public Law 92-463, 5 U.S.C. App. 2.

[50] President Obama, Scientific Integrity, March 9, 2009, http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09.

[51] Administrator Lisa Jackson, Memo to EPA Employees: Transparency in EPA's Operations, April 23, 2009, http://blog.epa.gov/administrator/2009/04/23/memo-to-epa-employees-transparency-in-epas-operations/.

[52] AAAS Forum on Science & Technology Policy, http://www.aaas.org/spp/rdf/forum/.

[53] The American Association for the Advancement of Science, http://www.aaas.org/.

[54] *See, generally*, Standards of Ethical Conduct for Employees of the Executive Branch, 5 CFR 2635. (Restrictions on receipt of gifts and compensation for outside activities); U.S. Environmental Protection Agency Scientific Integrity Policy, http://www.epa.gov/osa/pdfs/epa_scientific_integrity_policy_2012_20115.pdf.

[55] Federal Advisory Committee Act, *supra*, note 49.

[56] 5 USC Appendix - Federal Advisory Committee Act § 2, 01/02/01, http://www.gpo.gov/graphics/cgi/cgi-bin/getpage.cgi?dbname=2001_register&page=1&position=all&id=byJ_0Z5RDZ-13sK-pR.gfoc.

[57] The Federal Advisory Committee Act (FACA) Brochure, General Services Administration, http://www.gsa.gov/portal/content/101010.

[58] *Id.*

[59] *See, e.g.*, 18 USC § 203 ("Whoever, otherwise than as provided by law for the proper discharge of official duties, directly or indirectly—

(1) demands, seeks, receives, accepts, or agrees to receive or accept any compensation for any representational services, as agent or attorney or otherwise, rendered or to be rendered either personally or by another— . . .

(B) at a time when such person is an officer or employee . . . in any agency of the United States,

in relation to any proceeding, application, request for a ruling or other determination, contract, claim, controversy, charge, accusation, arrest, or other particular matter in which the United States is a party or has a direct and substantial interest, before any department [or] agency.")

[60] The National Academies, Policy On Committee Composition And Balance And Conflicts Of Interest For Committees Used In The Development Of Reports May 12, 2003, http://www.nationalacademies.org/coi/bs_coi_form-0.pdf.

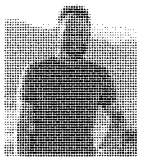
[61] Declaration of Interests for WHO Experts, www.who.int/occupational_health/declaration_of_interest.pdf.

[62] *Id.*

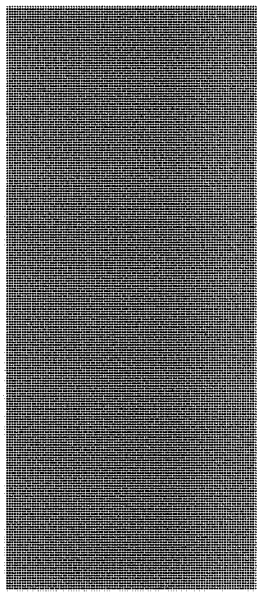
About the Authors



Rena Steinzor is a Professor of Law at the University of Maryland School of Law, with a secondary appointment at the University of Maryland Medical School Department of Epidemiology and Preventive Medicine. Among the courses she teaches are risk assessment, critical issues in law and science, and a survey of environmental law. Professor Steinzor received her B.A. from the University of Wisconsin and her J.D. from Columbia Law School. She joined the Maryland faculty in 1994 from the Washington, D.C. law firm of Spiegel and McDiarmid. From 1983 to 1987, Steinzor was staff counsel to the U.S. House of Representatives' Energy and Commerce Committee's subcommittee with primary jurisdiction over the nation's laws regulating hazardous substances. She is the President and a Director of the Center for Progressive Reform.



Wayland Radin is a Policy Analyst at the Center for Progressive Reform, providing research, drafting, coordination, and other staff assistance to CPR's Toxics and Climate Mitigation issue groups.



To see more of CPR's work or to contribute,

visit CPR's website at www.progressivereform.org.

455 Massachusetts Avenue, NW

 # 150-513

Washington, DC 20001

202-747-0698 (phone/fax)

CPR CENTER FOR PROGRESSIVE REFORM

RETURN UNDELIVERABLES TO:

Center for Progressive Reform

455 Massachusetts Avenue, NW

 # 150-513

Washington, DC 20001

September 29, 2017

The Honorable John Barrasso
Chair
Committee on Environment and Public Works
U.S. Senate
Washington, DC 20510

The Honorable Thomas Carper
Ranking Member
Committee on Environment and Public Works
U.S. Senate
Washington, DC 20S10

Dear Chairman Barrasso and Ranking Member Carper:

On behalf of the undersigned organizations committed to improving maternal and child health across our Nation, we are writing to urge you to ensure the Director of the Environmental Protection Agency's Office of Chemical Safety and Pollution Prevention (OCSPP) vigorously upholds the mission of the office to protect individuals, families, and the environment from potential risks from pesticides and toxic chemicals.[i]

Our organizations are dedicated to the advancement of women's and children's health and improved health outcomes. The ideal outcome of pregnancy is not simply a healthy newborn, but a human being optimally programmed for health across the lifespan. Harmful chemicals can cross the placenta, and in some cases can accumulate in the fetus, resulting in disproportionate fetal exposure. Robust scientific evidence has emerged over the past several years demonstrating that preconception and prenatal environmental exposures can have a profound and lasting impact on health across the life course. In addition, as infants and children grow and mature, their unique physiologic, developmental, and behavioral differences make them especially vulnerable to chemical exposures during critical windows of development.

It is with these concerns in mind that we propose the following joint principles that the Director of OCSPP should pledge to follow:

- Prioritize the protection of vulnerable populations, including pregnant women, infants, and children;
- Demonstrate an unimpeachable commitment to the health of the public over the interests of industry;
- Implement fully and promptly the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law No. 114-182), consistent with congressional intent; and
- Defend existing pesticide and toxic chemical safety standards that protect the public health.

The Director of OCSPP holds immense responsibility for the protection of the public's health. The Committee on Environment and Public Works has the duty of thoroughly vetting the nominee, and we encourage you to carefully evaluate the nominee to ensure his or her willingness and fitness to undertake and uphold the standards of the office.

We hope that careful consideration will be given to our concerns, and that the health of vulnerable populations is uppermost during the nomination process. For any questions please contact Ami Gadhia, American Academy of Pediatrics, at agadhia@aap.org, Rachel Tetlow, American Congress of Obstetricians and Gynecologists, at rtetlow@acog.org, and Jaimie Vickery, March of Dimes, at jvickery@marchofdimes.org.

Sincerely,

Fernando Stein, MD, FAAP
President
American Academy of Pediatrics

Haywood L. Brown, MD, FACOG
President
American Congress of
Obstetricians and Gynecologists

Stacey D. Stewart
President
March of Dimes

[i] Environmental Protection Agency. About the Office of Chemical Safety and Pollution Prevention (OCSPP). https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp Accessed September 14, 2017.

Over 100 Organizations Across the US Oppose Michael Dourson for EPA

October 3, 2017

Dear Chairman Barrasso and Ranking Member Carper:

On behalf of our millions of members and the American people, the undersigned 109 organizations urge you to stand up for our health and environment by opposing the nomination of Dr. Michael Dourson for the position of Assistant Administrator for Chemical Safety and Pollution Prevention of the Environmental Protection Agency.

The job of the Assistant Administrator is to lead the office whose mission is to protect American families and the environment from the potential risks of pesticides and toxic chemicals. This position will shape the way that the United States manages its environmental and chemical programs and thus will have a significant effect on the lives of millions of Americans. In particular, the next Assistant Administrator will be responsible for implementing and enforcing the laws designed to safeguard our health from toxic chemicals. This includes the Toxic Substances Control Act (TSCA), recently updated and amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The new law was signed on June 22, 2016 with the intention and hope that the updated requirements would be a beacon for change in the management of toxics and chemical safety.

Implementation of the 2016 TSCA amendments is a significant and challenging task. It must be undertaken by someone who not only demonstrates through their actions and accomplishments a commitment to human and environmental health, but also by someone who is committed to implementing and enforcing the law as written without influence from the regulated industries that may have an interest in seeing the law weakened or poorly enforced. Dr. Dourson's background indicates that he is not the person for this job.

Dr. Dourson's work consulting for the chemical industry during the last few decades raises significant concerns. First, he has a history of serving the interests of big business and industry dating back to the inception of the non-profit he founded and directed, Toxicology Excellence for Risk Assessment (TERA). Examples of TERA's questionable bias include:

- In 1997, Dr. Dourson was hired by the Center for Indoor Air Research, which was later disbanded by a judge who found it to be a tool to bolster the credibility of tobacco products, to produce a report on the effects of secondhand smoke, which is

known to cause cancer even in people who don't smoke. The report downplayed the effects by reporting that nonsmokers in the workplace have minimal exposures to secondhand smoke.

- In 2002, DuPont sought out Dr. Dourson's firm TERA to recommend to West Virginia's Department of Environmental Protection a "safe" level for perfluorooctanoic acid (PFOA), a chemical made by DuPont and linked to cancer, thyroid disease, and obesity. His firm recommended a level that, as reported in The Intercept, was "150 times higher than the maximum safety level DuPont's own scientists had determined in 1988 —1 [part per billion] — based on internal company research showing that PFOA was toxic to both workers and lab animals." The EPA later conducted its own assessment which determined a level that was thousands of times more protective than TERA's recommended level. PFOA has also contaminated rivers and drinking water in Ohio, Michigan, New York, North Carolina, Pennsylvania, Vermont, West Virginia and other communities around the country.

- An email revealed in The Intercept demonstrates how chemical companies hire Dr. Dourson to "bless" their dangerous chemicals:

  > While everyone had a few names to offer, the common theme that emerged was that TERA (i.e. Mike Dourson) was the leading choice. TERA had "a very good reputation among the folks that are still in the business of blessing criteria," [DuPont employee Timothy] Bingman explained, going on to describe the company's ability to "assemble a package and then sell this to EPA, or whomever we desired."
  >
  > -"Trump's EPA Chemical Safety Nominee Was in the 'Business of Blessing' Pollution", The Intercept, July 21, 2017.

- In 2013 Dr. Dourson was hired by Koch Industries to produce a study that found no adverse health effects to residents in Chicago who were concerned about piling amounts of petroleum coke (petcoke) from Koch subsidiary KCBX Terminals. Dr. Dourson's findings were based on soil studies and use of KCBX air monitors showing that petcoke soil is no different in the neighboring community than baseline levels in the rest of Chicago, and that the level of air contaminants are not likely to cause health effects. However, research by the city of Chicago and residents' own documentation of petcoke on their properties contradicted Dr. Dourson's findings. A class action lawsuit was ultimately settled for $1.4 million.

- Dr. Dourson also published a report in 2014 entirely funded by a polluting company to study 1,4 dioxane, one of the first ten chemicals being reviewed under the revised TSCA by the office he has been nominated to lead. PPG Industries, responsible for discharging the chemical and contaminating Ohio's waterways, hired Dr. Dourson to publish a paper on the chemical. The paper argued for an acceptable level of 1,4 dioxane that is 1,000 times higher than EPA's drinking water guidelines. The methodology Dr. Dourson used in his assessment of 1,4 dioxane was rejected by a panel convened by the state of Michigan.

We are not only concerned about Dr. Dourson's ties to the chemical and tobacco industries, but by the role he played in presenting industry-biased science in a seemingly neutral manner to alleviate concerns about their products. For example, Dr. Dourson administered a website designed for parents called "Kids + Chemical Safety" that minimized the concern of chemical risks using chemical industry talking points. Another example of downplaying concerns about chemical risks includes the "Tox Topics" webpage of the Toxicology Education Foundation, led by Dourson and funded by companies like Chevron, ExxonMobil, 3M, and the chemical industry's trade association.

The importance of this job is best defined by the imperative to protect our health. This is made clear by tragic personal stories including the West Virginia residents who lost their drinking water due to the 2014 Elk River Spill; the parents in Flint, MI worrying about the effects of the lead in their water on the IQ and brain development of their children; the farmworkers in Bakersfield, CA poisoned by chlorpyrifos; and the family of 18-year-old Jonathan Welch who died on the job from exposure to methylene chloride. Whether and how potentially dangerous chemicals enter the marketplace is a matter of life and death. We can't leave those decisions to someone with Dr. Dourson's history of close ties to the chemical industry.

As organizations committed to the health of the American people, we are deeply concerned with the nomination of Dr. Dourson as the Assistant Administrator.

We need and deserve an Assistant Administrator for EPA's toxics office who will put public health first, without favoring the industry that the office is charged with regulating. We urge you to oppose the nomination of Mr. Dourson and insist on a nominee with an unblemished record of defending the health of the American people from the hazards of toxic chemicals.

Sincerely,

5 Gyres

Alaska Community Action on Toxics

Alliance of Nurses for Healthy Environments

As You Sow

Asbestos Disease Awareness Organization

Blue Green Alliance

Breast Cancer Action

Breast Cancer Prevention Partners

Build A Better Planet

Cape Fear River Watch

Capital District Against Fracking

Catskill Mountainkeeper

Center for Environmental Health

Center for Health, Environment & Justice

Central California Environmental Justice Network

Citizens' Environmental Coalition

Clean and Healthy New York

Clean Production Action

Clean Water Action

Clean Water Action California

Clean Water Action Connecticut

Clean Water Action Massachusetts

Clean Water Action Minnesota

ClimateMama

Coalition for Clean Air

Collaborative on Health and the Environment

Coming Clean

Comit Civico del Valle

Communications Workers of America

Community Food and Justice Coalition

Conservation Minnesota

Conservation Voters for Idaho

Cook Inletkeeper

Del Amo Action Committee

Democracy Initiative

Earthjustice

Ecology Center

Empire State Consumer Project

Environmental Advocates of New York

Environmental Health Strategy Center

Environmental Justice and Health Alliance

Environmental Working Group

Farmworker Association of Florida

Farmworker Justice

Food & Water Watch

Fresnans against Fracking

Friends of the Earth

Global Alliance for Incinerator Alternatives (GAIA)

Grassroots Environmental Education

Great Neck Breast Cancer Coalition

Green Inside and Out

Greenaction for Health and Environmental Justice

GreenFaith

Greenpeace

Headwater LLC

Health Care Without Harm

Health Professionals and Allied Employees

Healthy Building Network

Healthy Legacy Coalition

Healthy Schools Network

Hillsborough Clean Investment Coalition

Hip Hop Caucus

Huntington Breast Cancer ACTION Coalition, Inc

International Center for Technology Assessment

League of Conservation Voters

Learning Disabilities Association of America

Learning Disabilities Association of Georgia

Learning Disabilities Association of Illinois

Learning Disabilities Association of Maine

Learning Disabilities Association of New Jersey

Learning Disabilities Association of South Carolina

Learning Disabilities Association of Tennessee

Lenape Indian Tribe of Delaware

Los Jardines Institute

Marin City Parent Academy

Natural Resources Defense Council

NC Child

Nontoxic Certified / Made Safe

North Carolina Conservation Network

Northwest Atlantic Marine Alliance

Oregon Environmental Council

Organize Florida

People for Clean Air & Water of Kettleman City

Pesticide Action Network

Physicians for Social Responsibility

PODER

Safer Chemicals Healthy Families

Safer States

San Francisco Firefighters Cancer Prevention Foundation

Science and Environmental Health Network

Sierra Club

Stupid Cancer, Inc.

Texas Campaign for the Environment

Texas Environmental Justice Advocacy Services (TEJAS)

The Alliance for Appalachia

The Environmental Justice Coalition for Water

The Institute of Neurotoxicology and Neurological Disorders (INND)

The Progressive Hub, Saratoga

Toxic-Free Future

Toxics Action Center Campaigns

Tri-County Watchdogs

Tri-Valley CAREs

United Steelworkers

Utility Workers Union of America

Vermont Conservation Voters

Vermont Public Interest Research Group (VPIRG)

WE ACT for Environmental Justice

West Berkeley Alliance for Clean Air and Safe Jobs

Women's Voices for the Earth

Why signatories oppose Michael Dourson's nomination:

"Dourson has a long history of working for the interests of the chemical industry rather than for the health of communities affected by devastating pollution from these industries. This is a clear conflict of interest with the important mission of EPA to protect the environment and public health. His nomination must be rejected."
-**Pamela Miller**, Executive Director, Alaska Community Action on Toxics

"The implementation of the updated TSCA rule will have health implications for years to come. We need a leader who will put public health first when addressing toxic chemicals and Mr. Dourson is not that leader. As nurses, we strongly oppose his nomination for Assistant Administrator."
-**Katie Huffling**, Executive Director, Alliance of Nurses for Healthy Environments

"Dr. Dourson's work consulting for the chemical industry during the last few decades raises significant concerns. The job of the Assistant Administrator is to lead the office whose mission is to protect American families and the environment from the potential risks of pesticides and toxic chemicals. We are sure that there are more qualified candidates for this position."
-**Andrew Behar**, CEO, As You Sow

"Profoundly unqualified."
-**Linda Reinstein**, President, Asbestos Disease Awareness Organization

"Involuntary chemical exposures are linked to increased risk of breast cancer and other diseases and disorders. The OCSPP's mission is to protect the public 'from potential risks from pesticides and toxic chemicals' and 'prevent pollution before it begins'. Mr. Dourson's industry links threaten to undermine the use of ""sound science as a compass"" in pursuit of this mission and his track record shows he will put corporate profit before public health. Protect the safety of our food, air, and personal care and other consumer products by opposing Mr. Dourson's nomination and insisting on a nominee who will stand up for public health."
-**Karuna Jaggar**, Executive Director, Breast Cancer Action

"OCSPP must be led by an individual free from any conflict of interest with the chemical industry. Based on his record, Michael Dourson is not that person."
-**Jeanne Rizzo**, R.N., President and CEO, Breast Cancer Prevention Partners

"Dr. Dourson's ties to the chemical industry can pose a significant conflict of interest. His concerns should lie with the American people and their health and safety."
Soledad Haren, CEO and Founder, Build A Better Planet

"His history of downplaying the risks of chemicals in drinking water supplies. Testing currently shows 1,4 dioxane and several perfluorinated compounds in our *treated* drinking water."
-**Kemp Burdette**, Riverkeeper, Cape Fear River Watch

"Corporate shill"
-**Collin Thomas**, Co-Founder, Capital District Against Fracking

"Michael Dourson's has a history of working for the chemical and tobacco industries to minimize the health risks of their products. With the EPA poised to finalize chemical safety rules for the next generation, the stakes are too high to install a leader compromised by the industry he is nominated to regulate."
-**Ansje Miller**, Director of Policy and Partnerships, Center for Environmental Health

"He has a strong conflict of interest because he has represented the chemical industry for years rather than the public health interests."
-**Barbara Warren**, Executive Director, Citizens' Environmental Coalition

"We represent 50,000 Californians who want the toxics program to help drive the development and use of safer materials to protect our people, our environment, and yes, our economy!"
-**Andria Ventura**, Toxics Program Manager, Clean Water Action California

"The Environmental Protection Agency should be that - an agency whose priority is protecting the environment, including the people who live in it, and its leadership and staff should be made up of people who embody that mission. Michael Dourson is the opposite. He has consistently worked with the chemical industry to ensure that regulations of chemicals are based on profit motives rather than environment and public health protection. He does not belong in the EPA."
-**Elizabeth Saunders**, Massachusetts Director, Clean Water Action Massachusetts

"He has multiple conflicts of interest."
-**Bill Magavern**, Policy Director, Coalition for Clean Air

"The American public needs someone who will put the health of all families and children before anything else. Michael Dourson is not the person for the job."
-**Karen Wang**, Director, Collaborative on Health and the Environment

"The American People need and deserve a true champion for their health and safety in the office of the EPA, not Michael Dourson, whom the regulated industry has paid time and again to undermine safer chemical policies and regulations, advances, which if adopted, lead us to stronger public health and environmental justice outcomes for all."
-**Judith Robinson**, Executive Director, Coming Clean

"Community Food and Justice Coalition believes we need advocates working on behalf of communities and not industry."
-**Y. Armando Nieto**, Executive Director, Community Food and Justice Coalition

"He's a chemical industry lackey."
-**Bob Shavelson**, Inletkeeper, Cook Inletkeeper

"Industry ties. A person in that position should be a scientist and completely independent of any industry ties."
-**Judy Braiman**, President, Empire state Consumer Project

"He appears to be a nominee that will put public health at risk."
-**Peter M. Iwanowicz**, Executive Director, Environmental Advocates of New York

"Communities living on the frontlines of chemical hazards become even more susceptible to toxins when natural and human-made disasters strike. When we look at Dourson's nomination from environmental justice and chemical security perspectives, it's even more clear that the Trump Administration is prioritizing industry profits over health and safety."
-**Michele Roberts**, Co-Director, Environmental Justice and Health Alliance

"Farmworkers are among the most vulnerable people in our nation today. They are chronically exposed to toxic agricultural chemicals in the work place. Michael Dourson's record of denying the science and cozying up to industry is a threat to the health and safety of farmworkers, and ultimately, to us all."
-**Jeannie Economos**, Pesticide Safety and Environmental Health Project Coordinator, Farmworker Association of Florida

"Michael Dourson is the wrong person for any leadership position at the EPA since his career has been to minimize the true dangers of toxic chemicals in the service of those who manufacture and sell them. Even if he wanted to, he would be unable to change his orientation to firm control of the dangers from these chemicals."
-**Ronald J. Martin**, Fresnans against Fracking

"USEPA appointees should serve to strengthen the mission of the Offices they head. The appointment of Michael Dourson will weaken OCSPP and, as his track record has demonstrated, only serve the best interests of the chemical industry."
Ahmina Maxey, U.S. & Canada Regional Coordinator, Global Alliance for Incinerator Alternatives (GAIA)

"The EPA needs to be strengthened to protect public health and the environment from toxic pollution, not gutted to protect corporate toxic polluters."
-**Bradley Angel**, Executive Director, Greenaction for Health and Environmental Justice

"Mr. Dourson's track record suggests he is ethically compromised and inclined to represent chemical industry giants, rather than the public interest."
-**Charlie Cray**, Senior Research Specialist, Greenpeace

"We need impartiality and scientific leadership in this position. Allowing Michael Dourson to lead this program will put profits in front of scientifically-defensible common-sense health protections."
-**Eric Uram**, Principal Consultant, Headwater LLC

"We are deeply concerned that Mr Dourson has no interest in upholding this office's solemn duty. His history indicates that his priority is to undermine efforts to protect American families and the environment from the potential risks of pesticides and toxic chemicals."
-**Tom Lent**, Policy Director, Healthy Building Network

"Michael Dourson is the wrong person for this job. He has demonstrated throughout his career that his focus is on protecting industry interests, rather than protecting human health and our environment."
-**Kathleen Schuler**, Co-Director, Healthy Legacy Coalition

"distorts the safety of chemicals "
-**Steven G. Gilbert**, Director, The Institute of Neurotoxicology and Neurological Disorders (INND)

"Michael Dourson has a well-documented history of underestimating or ignoring risks to children's health from toxic chemicals. It's critical that we have someone leading the office of Chemical Safety who is on the side of our children and families, not on the side of polluting chemical industries."
-**Patricia Lillie**, President, Learning Disabilities Association of America

"Our toxic environment impacts the neurology of our citizens. This impacts the ability to learn and function on an optimum level. Therefore, Michael Dourson's relationship with and support of the tobacco and chemical industries proves his interest is not in the health and welfare of our families but in corporations that make their money at the cost of people's lives. As a support group for those suffering with learning disabilities and other mental health issues, we do not support his nomination."
-**Dr. Joan K. Teach**, President, Learning Disabilities Association of Georgia

"We must have someone who has a clear understanding of the dangers of toxins in our environment."
-**Bev Johns**, President-Elect, Learning Disabilities Association of Illinois

"Michael Dourson has a history of supporting companies which produce and/or encourage toxic effects on our population. As a mother, grandmother and great-grandmother, I worry about the future generations. We need environmental PROTECTION, not DESTRUCTION!!!!"
-**Theresa Cavanaugh**, Imm. Past-President, Learning Disabilities Association of New Jersey

"As a member of a national LDA coalition, the Healthy Children's Project, we have campaigns that advocate for the banning of toxic chemicals in products used by infants and children that may cause learning disabilities, attention deficit disorder, Autism, and other disorders. Mr. Dourson's background in the chemical industry would not be beneficial as we're trying to ban toxic chemicals, not just lower the 'acceptable' levels."
-**Anne Fogel**, Co-Secretary, Learning Disabilities Association of South Carolina

"He will not make the health of our children a priority."
-**Dr. Joy S. Marsh**, State President, Learning Disabilities Association of Tennessee

"We need someone who will protect our most vulnerable including children, low income and communities of color."
-**Tracy Gregoire**, Healthy Children Project Coordinator, Learning Disabilities Association of Maine

"Dourson's record indicates that if he's confirmed as head of EPA's toxics program, communities already disproportionately impacted by toxins--particularly the millions of people living near chemical facilities--will face even greater risks to their health."
-**Sofia Martinez**, Co-Director, Los Jardines Institute

"The EPA is intended to protect the health and well-being of the general public and thus should not be staffed by people who have made a career of aligning with industry in a way that put profits ahead of people. The American people want and deserve better."
-**Amy Ziff**, Founder & Executive Director, Nontoxic Certified / Made Safe

"Impact of pollutants on the marine environment and health of commercially fisheries is often underestimated. But we know it's really important to sustainable fisheries and ocean ecosystems. And who is responsible for this balance is really critical. Mr. Dourson's history of dismissing issues and facts tells us he is not the right choice for this job."
-**Niaz Dorry**, Coordinating Director, Northwest Atlantic Marine Alliance

"21st century science reveals how critical the environment is to human health. Our well-being and our economy depend upon agency leadership that understands the true value of health-protective policy. Michael Dourson has not exhibited that leadership or understanding."
-**Jennifer Coleman**, Director of Health Outreach, Oregon Environmental Council

"Corporate connections are inappropriate, undermine EPA's mission to protect health and the environment."
-**Kristin Schafer**, Executive Director, Pesticide Action Network

"Sounds like he's against regulation."
-**Sue Scherer**, The Progressive Hub, Saratoga

"Firefighters throughout the United States are faced with highly elevated rates of cancer to do toxic chemical exposures on the job. President Trump has said that he is a great supporter of first responders yet he has recommended an individual that has worked 'hand in hand' with the chemical industry downplaying many of the toxic chemicals that are killing firefighters. The selection of Mr. Dourson is of extreme concern for the men and women of the entire firefighting profession. We cannot let this happen!"
-**Tony Stefani**, President, San Francisco Firefighters Cancer Prevention Foundation

"We oppose the nomination of Dr. Dourson to lead the toxic program at EPA. This is another example of the Trump Administration having the fox protect the henhouse."
-**A. Tianna Scozzaro**, Director, Gender Equity, Sierra Club

"The cancer community at large – 80MM Americans strong – collectively demand that toxic chemicals in our food, air, water and everyday household products be regulated for safety."
-**Matthew Zachary**, Chief Executive Officer, Stupid Cancer, Inc.

"People who have worked for industries should not be running the government initiatives to police their former employers or clients."
-**Robin Schneider**, Executive Director, Texas Campaign for the Environment

"Generally speaking, there exist evidence on numerous pesticides and fertilizers used for agricultural farming in mid-western states that indicate fertilizers and pesticides get into the Mississippi River, as a result of run-offs, and drain into the Gulf, creating what is referred to as a 'Dead Zone'. The science is there to proof those chemicals are causing and extending the dead zone, yet, like in this particular situation, the person being nominated, is not one we would stand by. His past record is a reflection of what we can expect, not reliable."
-**Juan Parras**, Director, Texas Environmental Justice Advocacy Services (TEJAS)

"Mr. Dourson is not a good choice. He has taken public policy positions on behalf of the very industries he will be regulating. The person in this role must protect the most vulnerable, not the companies who will profit from his decisions."
-**Laurie Valeriano**, Executive Director, Toxic-Free Future

"Michael Dourson is a bad choice to run the toxics program because his track record of working for the chemical industry means that the fox will be guarding the henhouse when it comes to critical decisions with widespread impacts on the health of our communities."
-**Sylvia Broude**, Executive Director, Toxics Action Center Campaigns

"Dourson's ties to the chemical and tobacco industries and his past actions in support of those industries lead us to believe he will serve them and not the public health."
-**Katherine King**, Secretary, Tri-County Watchdogs

"Conflict of Interest"
-**Paul Mercurio**, Recording Secretary, USW

"Michael Dourson's support of the toxic chemical industry biases him against the public interest, intent of the law and the EPA mission, and our communities health."
-**Johanna de Graffenreid**, Environmental Advocate, Vermont Public Interest Research Group (VPIRG)

"Mr. Dourson has a history of manufacturing doubt and ignoring science. We need a leader who is willing to stand up against chemicals giants who bury facts in order to gain profit. We need a leader willing to put the health of the nation's vulnerable, our children, and our communities first."
-**Erin Switalski**, Executive Director, Women's Voices for the Earth

POLITICS OCT 3 2017, 6:36 PM ET

Democrats: Trump EPA Nominee Is Toxic Chemical Swamp Creature

by SUZY KHIMM

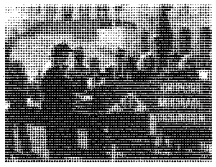
SHARE

WASHINGTON — Sens. Tom Udall, D-N.M., and Richard Blumenthal, D-Conn., rallied chemical exposure victims and public health advocates on Tuesday to oppose President Donald Trump's nominee to become the nation's top chemical regulator.

Michael Dourson, Trump's pick to lead the Environmental Protection Agency's chemical safety program, has sparked fierce opposition from Democrats and public health advocates for spending decades producing industry-funded research that critics say downplays the health risks of chemical substances.

"Instead of draining the swamp, [Trump] has filled it up with some of the swampiest creatures ever. And it keeps getting scarier — Michael Dourson might be the worst yet," Udall said. "Dr. Dourson has made a career of creating junk science for industry."

"We need someone who's going to be a watchdog, not a lapdog for the special-interest chemical industry and other producers of contaminants and substances that can literally kill people, or stunt the growth of children, or make people sick," Blumenthal said.



U.S. Senators Tom Udall (D-N.M.) held a press conference to oppose confirming Michael Dourson to lead the Environmental Protection Agency's (EPA) office, with victims and advocates alongside him, on Oct. 3, 2017 at the U.S. Capitol. Suzy Khimm / NBC News

Dourson, who is scheduled to appear before the Senate at his confirmation hearing on Wednesday, did not respond to a request for comment. The EPA has circulated praise for Dourson from others in the toxicology field.

"Dr. Dourson is a highly qualified scientist, who is a professor at the University of Cincinnati and the founder of a nonprofit," said EPA spokesperson Liz Bowman, citing his leadership positions and awards.

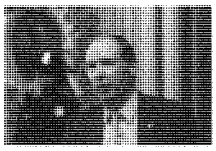
Victims of chemical exposure and their family members shared personal stories of being exposed to substances that Dourson has helped the chemical industry defend, producing research that companies have used to argue for weaker regulations and oversight.

Gwen Young's family lives in Hoosick Falls, New York, where a manufacturing plant contaminated the local drinking water with PFOA, a chemical that's been linked to cancer. Young, 12, said she has the highest PFOA levels in her blood among the children in her community.

"I don't really feel safe anywhere I go," Young said. "I don't want this to have to happen to other kids. I don't think Michael Dourson is cut out to be in the position that he's nominated for."

When DuPont was sued for PFOA exposure in West Virginia, the Dourson helped defend the company in court. DuPont had previously hired Dourson's firm,

Toxicology Excellence for Risk Assessment, to establish a new exposure threshold. The level that Dourson's firm helped establish was 150 times higher than the level DuPont's own scientists had endorsed, and it was thousands of times higher than the level that EPA would ultimately set for drinking water in 2016.



Sen. Tom Udall, D-N.M., leaves the Senate Democrats' weekly policy lunch in the Capitol on Sept. 7, 2016. Bill Clark / CQ Roll Call via AP

"We depend on the EPA, and specifically this position that [Dourson] would be filling, to protect us going forward," said Michael Hickey, another Hoosick Falls resident. "We know that he won't be capable of doing that." Hickey's father died of kidney cancer after working at the Hoosick Falls plant that used PFOA, which is now a federal Superfund site.

Without Republican support, Democrats do not have the votes in the Senate to stop Dourson from being confirmed. But they say that it's especially critical to bring attention to his nomination in light of the sweeping overhaul of the Toxic Substance Control Act, pointing out that the law passed with overwhelming bipartisan support in 2016.

"Many people called it the most significant environmental law in 25 years to pass," Udall said. "Now when you have a good law, the most important thing is implementation. So do you want a guy that's a toxicologist for hire to be doing the implementation?"

SUZY KHIMM

TOPIC CONGRESS

FIRST PUBLISHED OCT 3 2017, 6:15 PM ET

13 WTHR

Indiana mothers take fight over childhood cancer and chemicals to Washington D.C.

Johnson County families spoke out against EPA nominee Michael Dourson in Washington D.C. Tuesday. (Photo: FredWatkins.com)



PUBLISHED: OCT 3RD, 2017 - 8:01PM (EDT)

SANDRA CHAPMAN

WASHINGTON D.C. (WTHR) - Mothers at the center of a 13 Investigates report about childhood cancer are in Washington, D.C. speaking out about sick children in Johnson County and toxic chemicals.

Johnson County moms head to Washington to be 'pillar of strength' for children with cancer

Sarah Bowman, sarah.bowman@indystar.com



Zane Davidson survived childhood cancer and now his family and advocate Kari Rhinehart, whose daughter passed away from childhood cancer, are fighting to find the environmental cause. Michelle Pemberton/IndyStar



Photo: Kari Rhinehart

When Zane Davidson arrived home Sept. 14, his hand was still bleeding.

His palm's pinkish-then-vessel complexion stuck faster than the more than 30 high fives he lorded out earlier that day. Or it might have been the excitement still churning through his veins after ringing the bell.

It's an unassuming bell — not much bigger than an upside down coffee mug with finger pinks wrapping the tiny metal. But its bell never fails to ensure tears, as his sound reverberates down the oncology units' hallways.

Happy mark. Because everyone here knows that you don't get to ring the bell until you've completed treatment and conquered cancer.

"When you are in the oncology wing day in and day out and you walk past that bell, every time you are counting down until when you can ring that bell," said Stacie Davidson, 13-year-old Zane's stepmom.

After three years and three months of chemotherapy to battle a rare form of leukemia, it was Zane's turn.

"It meant he is done with treatment," she said, "and done with cancer."

But Stacie Davidson said that does not mean their wife done with their fight — a fight she and another Johnson County mom are taking to Washington, D.C. today.

'Not one more'

Davidson and Kari Rhinehart — who lost her daughter, Emma Grace Findley, in 2014 from a rare brain tumor — have worked to call attention to the county's rising pediatric cancer cases over the last couple years. With nearly 40 confirmed cases of childhood cancer diagnosed in the county since 2016 — when this put them higher than the state and national average — they begun the grassroots organization "It's Was Your Child."

A small tenant of the group was that more needed to be done to protect not just their children, but those of other communities.

Rhinehart said she knows the diagnoses will continue to come, every day waiting to get worst of another.

"It's a sudden punch every time," said Rhinehart, whose daughter was 13 when she died. "We need to figure out how to address this problem to make this not one more."

They met success in 2016 with the painting of Trevor's Law, which gives local and federal agencies the authority to conduct investigations into potential cancer clusters and their possible links to toxins in the environment — a 35-day bearing advocated for.

Yet when "It's Was Your Child" met with local and state officials and became the first in the nation to call on the law in June, it met unexpected.

"The representatives heard our victory and passed a day, but we haven't been able to utilize it because of red tape," Rhinehart said. "It's tantalizing knowing when we can't use what is already a law."

The problem of that no one has been named a coordinator or director of the law within the U.S. Department of Health and Human Services or its Centers for Disease Control and Prevention, according to the Environmental Defense Fund.

"Congress passed the law, but it's a piece of paper until someone is making it work through enforcing and implementing it," said Jack Pope, the chemicals campaign director at the nonprofit advocate group. "It needs someone to dislodge it and putting it into action."

See More

Share your feedback to help improve our site experience!



Air Force Academy chief: Racists 'need to get out'



'Shower Man', Chicked Hillary: See Trump's nickname come to life



Place couples into men, lips into pumps lot



How a small town became an unlikely hero of 9/11



Trump gets millions from golf club members who get access

Each mass problematic. That said, a 4th current continues to load the U.S. Environmental Protection Agency (EPA) and Centers for Disease Control and Prevention (CDC) are reviewing the investment for blocks. That continues Mitchell Dickson, who is slated to run the Office of Chemical Safety and Pollution Prevention and has worked at the agency since 1998.

He adds that a helpful of suggesting and visiting to lower easily standards and guidelines on chemicals and toxins, Pratt said. Chemicals such as TCES — some of the same chemicals found at the Hoosic Heights dump site near Pinedale in Johnson County.

In an effort to keep Dawson rid of the position and dormant action on Trent's Law, GOP members at its Wednesday home meetings with Hawley took serious risk over the matter at its Wednesday home meetings with Hawley took serious risk.

"We need someone in that position we can trust and we want to put the blame on making sure sick kids are protected from harmful chemicals," Pratt said. "There is a reason why Missouri has the highest rate of childhood cancer in the country. We have 20,534 roommates know they are not meeting that challenge set a year ago."

Davidson and Rheinelt hope a mood on the gubernatorial's front step might yield better results.

'True Travesty'

Sr. Sub. Trevor Schaefer, the son's namesake, who will also be traveling to Capitol Hill this fall, is a relentless bunch.

Schaefer, 21, graduated from the school in 2009, a sign of it. The founder and president of Focus 4 Trial foundation said he wishes this type of effort and grassroots weren't necessary.

Overdosing, he, he's asking to see how many people are willing to bone together to help a friend in need, a friend who's in trouble.

"Blame and Alpha said everyone in Johnson County thing to get someone sure a strong example of what communities have to do to get groups and lawmakers to board for Missouri," Schaefer said. "Missouri is the only state in the country that doesn't have a law. And it's a shame that we have and there is true travesty."

Kansas City Star reporter Jason Hancock contributed to this report. Department of Health is anticipated for a return in mid-to-late March, to address the type of effort and grassroots concern of Focus 4 Trial foundation.

Rates of cancer in Johnson County children are rising, according to National Cancer Institute data. Between 1999 and 2015, the rate of childhood cancer in Johnson County was 21.1 cases of cancer in people younger than 20 between 1999 and 2015.

Still, not even a month after beginning the investigation, the state agency said it found "multiple cases of violation and violations."

Nevertheless, the agency said it has been "basic and not common" in the investigation. Specifically, the current means the guidelines used by investigators. One of the first agency officials met with Schaefer and other parents of children diagnosed with cancer was Pratt, who was elected to the Missouri House in 2016.

"We are monitoring the implementation of Trent's Law and, like the families who have attended, would welcome any additional resources it brings that help protect Missouri children," Pratt said.

Shortest well ever does, but could the Pinedale community could be identified as a cancer cluster if it were investigated again.

She said trying to the community makes consideration of the Webb Method how exactly the agency would determine whether a cancer cluster exists. Before a determination can be able for decades, seemingly it met assessments, one is part of the state's clean-up program.

"We made a good collection and was of what's going on with Gatsby's and what's not," Pratt said. "I'm more satisfied and classified as a doctor work for law, data they wouldn't be able to agree. We had should be completed in three months."

'Pillar of strength'

As difficult and disoccupying as this type very cocommercial, Schaefer said, his engaging cross-cross-country for daughter during those times.

But Ahn Mi-hyun's work is hard. Her room said.

"She could see the manufacturing side of strength, and courage to create a product and to share with the people. She's a very strong woman, and I'm very proud of her," Yoon Ji-hyun, 10, the sister, told reporters. Her strength and courage to help one still feels strong."

She plans to interview the strength of G-C. Sia Hwa.

"I love to be the best! Eileen who controlling. Get crowded this, something that she wrecked, can only run it briefly but many stories. Whatever it stated, "She's it's first of its town I have a very strong woman and I don't want to be a."

Discussion agenda.

She recalls that video they learned Sora had study transmitted, relatively in 2014, the two mighty public stars know know who kills now. What. And, published most recent, how many of and of the Sora and Sora. Then, Sora's Sora Sora Sora

Trump Nominee for EPA Chemical Safety Post Raises Ethics Concerns

By MARIAN CONWAY | September 26, 2017

17
SHARES



CC BY-SA 3.0, Link

September 20, 2017; Chicago Tribune

One of the latest nominees to the U.S. Environmental Protection Agency is Michael Dourson, a nomination that is already raising considerable hackles in the science and environmental communities. Dourson, a toxicologist who once worked as a manager of an EPA lab that calculated the danger of chemical exposure, has been named to head the EPA's Office of Chemical Safety and Pollution Prevention.

On the surface, Dourson would seem to be highly qualified. Dourson founded a nonprofit organization in 1995, Toxicology Excellence for Risk Assessment (TERA), which tests and reports on whether chemicals are toxic and at what rate. The organization has 20 employees and a $2.5 million budget. Dourson's salary is paid jointly by TERA and the University of Cincinnati. But the nonprofit relies heavily on corporate contracts to fund its operations.

Web2PDF
converted by Web2PDFConvert.com

Dourson's past clients have included Koch Industries, Chevron, and Dow Chemical, and his work has been underwritten by trade and lobbying groups that produce pesticides and cigarettes, among others. Ethics experts have expressed concerns both about the nonprofit and Dourson's writings. For example, Sheldon Krimsky, from Tufts University said that "appointing Dourson to oversee EPA's chemical safety programs is part of a broader effort to undermine federal regulations protecting public health."

> "It is not even subtle," said Krimsky, who reviewed Dourson's recent published work. "He has chosen to be the voice of the chemical industry. His role as a scientist is simply the role of an industry-hired lawyer—only to give the best case for their client."

For instance, Dourson and TERA produced three recent papers that said there were flaws in peer-reviewed papers that showed a link between the use of the pesticide chlorpyrifos and delays in fetal development. The chemical is produced by Dow AgroSciences, a past client. Dourson and his coauthors declared that money did not influence their findings, but thanked Dow in a 2005 paper for its support of the study. The American Chemistry Council has stated support for Dourson's nomination. The trade organization has paid Dourson for scientific reviews. Their spokesperson, Jon Corley, said, "His knowledge, experience and leadership will strengthen EPA's processes for evaluating and incorporating high quality science into regulatory decision making."

Dourson has also been an unpaid consultant with Toxicology Forum and the Toxicology Education Foundation, two 501(c)(3)s whose primary funders include the American Chemistry Council, oil companies, and the makers of food additives. If he is confirmed for the EPA, he has promised to end these affiliations.

One of Dourson's largest accounts was for DuPont. The company was blamed for polluting a West Virginia town with toxic perfluoroctanoic acid, or PFOA. Dourson's team determined in 2002 that PFOA levels of 150 ppb were safe, and the 188 private wells tested had a lower level. Dourson's findings were well above the 1 ppb that the internal findings at DuPont stated were safe. The EPA has since declared that only .05 percent of Dourson's acceptable level of 150ppb is actually safe.

One DuPont executive praised Dourson's "ability to assemble a 'package' and then sell this to the EPA, or whomever we desired," according to an email cited in a 2013 legal claim by people who blamed exposure to the chemical for cancer, birth defects, and other health problems.

It appears that the Trump administration has a practice of hiring people for agencies on the inside of the corresponding industry. It also appears they often have views that are incompatible with the mission of the agency where they will be working. We have looked at some of the nominees and their ties to for-profit business here and here. Dourson's ethics filing for transition to a government position will likely be a long one.—Marian Conway

17
SHARES

ABOUT MARIAN CONWAY

Web2PDF
converted by Web2PDFConvert.com



Marian Conway, the executive director of the NY Community Bank Foundation, has a Masters in Interdisciplinary Studies, Writing and a Ph.D. in Public Policy, Nonprofit Management. She has discovered that her job and education have made her a popular person with nonprofits and a prime candidate for their boards. Marian keeps things in perspective, not allowing all that to go to her head, but it is difficult to say no to a challenge, especially participating in change, in remaking a board. She is currently on eleven boards of various sizes and has learned to say no.

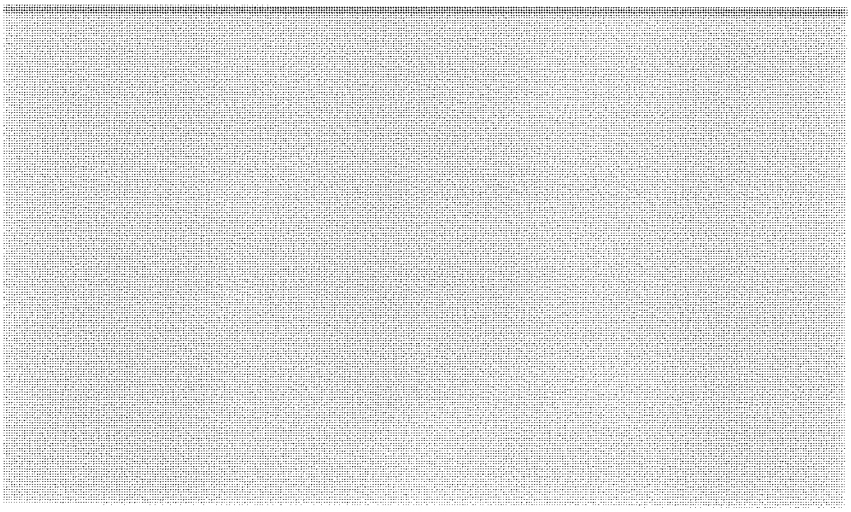
More by Marian

READ NEXT



Investigation Reveals Widespread Use of Chemical Restraints in PA Juvenile Facilities

A new investigative report reveals inappropriately high use of psychiatric drugs on young people in the Pennsylvania juvenile justice system as a form of restraint. These off-label uses can have serious consequences on physical and mental health.



What's Trending

Web2PDF
converted by Web2PDFConvert.com

The News Observer

GOCOASTGUARD.COM

OP-ED

Wilmington demands clean water, clean EPA

BY ANSIE MILLER

Don't drink the water. That's something you'd expect to hear when you travel to a developing country. But that's what people are saying in Wilmington, a historic beach, tourist and retiree destination and the eighth-largest city in this state. It also happens to be one of my favorite places to go when I need a reprieve from the heat and humidity of central North Carolina. With its charming historic riverfront, shops, delicious restaurants, parks, water sports and beautiful beaches, it's a great place to relax and unwind. The last thing one should have to worry about is the safety of the local drinking water.

Over the past couple of months, Wilmington residents have learned that DuPont and its spinoff company Chemours have been dumping unregulated chemicals into the Cape Fear River for decades and only recently stopped at the request of the governor. The result: Disturbing levels of chemicals like 1,4-dioxane, GenX and PFOA have been found in the drinking water of residents in Wilmington, Brunswick and the surrounding area.

{"type":"headsupcheck","url":"http://www.lightstal
king.com/restore-your-photos/"}

These types of of chemicals, called fluorinated compounds, have been linked to cancer, thyroid disease and obesity. GenX and other fluorinated compounds are used in the making of Teflon, Scotchgard and other stain-resistant and water-repellant products. They are designed so that they are water- and oil-repellant, which means that they are extremely difficult to treat in water-treatment plants before they hit our taps.

While GenX has received a lot of the attention, the chemical 1,4-dioxane – which is much more well-studied – has been found in some places to be in excess of 35 parts per billion, a level at which, when consumed regularly over the course of a lifetime, cancer risk becomes two orders of magnitude higher than that at generally acceptable levels. Many Wilmington residents have been drinking this water their whole lives. Now they must worry about the risks to their and their children's health.

Web2PDF
converted by Web2PDFConvert.com

Breaking News

Be the first to know when big news breaks

Enter Email Address

SIGN UP

Wilmington has asked the EPA to start looking into GenX and investigating the safety of its water. But with asbestos denier Scott Pruitt and chemical industry representative Nancy Beck overseeing EPA's program in charge of regulating these chemicals, I don't have much faith in their investigation. Now, the Trump Administration has nominated Michael Dourson to lead the entire toxics program at the EPA. Will Mr. Dourson provide hope for Wilmington?

A look at his background also leaves me skeptical. In 2002, DuPont hand-picked Dourson's firm Toxicology Excellence for Risk Assessment (TERA) to advise West Virginia's Department of Environmental Quality on setting health levels for PFOA, one of the same chemicals now found in Wilmington's water. His firm came up with a level that was thousands of times less protective than a later EPA assessment. 1,4-dioxane is currently under review by the very office that Mr. Dourson has been nominated to lead. Yet he also published research on that chemical paid for entirely by PPG, a company responsible for discharging this chemical and contaminating Ohio's waterways.

Saturday, I went to a Rally for Clean Water in Wilmington to talk with residents about their concerns. They want what we all want - to know that when they open up the tap, they can drink the water without worrying about toxic chemicals. And they deserve better: corporate polluters that are held accountable for egregious pollution and government officials who will protect their health and safety at the local and the national level.

ANSJE MILLER RESIDES IN HILLSBOROUGH AND IS THE DIRECTOR OF POLICY AND PARTNERSHIPS FOR THE CENTER FOR ENVIRONMENTAL HEALTH.



Web2PDF
converted by Web2PDFConvert.com

E&E: Group outlines bias concerns over chemicals office pick

https://www.eenews.net/greenwire/2017/07/25/stories/1060057872

July 25,2017

At least a quarter of the scientific papers by U.S. EPA's assistant administrator for toxic substances nominee were bankrolled exclusively by industry sources, according to a review by the Environmental Defense Fund.

The public health advocacy group, which opposes Michael Dourson's nomination to lead the Office of Chemical Safety and Pollution Prevention, examined the funding sources for several dozen papers he authored or co-authored between 2005 and this year that were listed in the National Institutes of Health's biomedical database.

Richard Denison, EDF's lead senior scientist, noted in a blog post yesterday that his estimate of Dourson's reliance on industry funding may be understated since about a quarter of the papers it reviewed didn't disclose who paid for them. And even studies that weren't solely financed by industry often included some money from chemical companies or involved "industry-affiliated participants," Denison wrote.

In total, Dourson or his former company, Toxicology Excellence for Risk Assessment, were paid for their work on about three dozen chemicals by more than three dozen companies or trade associations, EDF found.

Some of Dourson's notable industry-backed efforts include a study of petroleum coke for Koch Industries Inc., an examination of petroleum substances for the American Petroleum Institute, and two papers on chlorpyrifos for Dow AgroSciences LLC, which manufactures the pesticide.

EPA has repeatedly found that chlorpyrifos is linked to brain damage in children, but Administrator Scott Pruitt earlier this year decided to keep the compound on the market while the agency conducts additional studies of it (Greenwire, March 30).

Dourson has also done work for industry on two chemicals — trichloroethylene (TCE) and 1,4-Dioxane — that the chemical safety office he is poised to lead is currently reviewing. The Obama-era EPA also proposed banning the manufacture, import, processing and distribution of TCE, a known carcinogen, in degreasing and dry-cleaning operations — the compound's two primary uses in the United States (Greenwire, Dec. 7, 2016).

The assistant administrator nominee's October 2016 TCE study said it was made possible by "a gift from the American Chemistry Council" but added that "the research hypotheses addressed, findings, and conclusions expressed in this paper are solely those of the authors and not necessarily those of supporting groups."

Yet the study, published in the journal Regulatory Toxicology and Pharmacology, on whose editorial board Dourson sits, found that the safety range for TCE exposure was three to 30 times higher than the level recommended by EPA in 2014.

EDF raised concerns about what Dourson's past work for industry means for the future of the

Toxic Substances Control Act. With the support of industry, the law was reformed last year for the first time since it was enacted in 1976 by a bill named after the late Sen. Frank Lautenberg (D-N.J.).

"In finally embracing TSCA reform, the chemical industry said it needed a neutral referee, an impartial arbiter of the many disputes over the safety of chemicals," Denison said. "Now with Dourson's nomination, any remaining semblance of impartiality and balance is gone."

The EDF scientist added, "The chemical industry needs to be seriously asking itself: Is this any way to restore confidence in this country's chemical safety system?"

EPA didn't immediately respond to a request for comment on the blog post.

But the ACC defended Dourson's work and urged his confirmation."We believe his knowledge, experience and leadership will strengthen EPA's processes for evaluating and incorporating high quality science into regulatory decision making," ACC spokesman Jon Corley said in a statement. "The Senate should act on Dr. Dourson's nomination without delay as it comes during a crucial point in the implementation of the Lautenberg Chemical Safety Act."

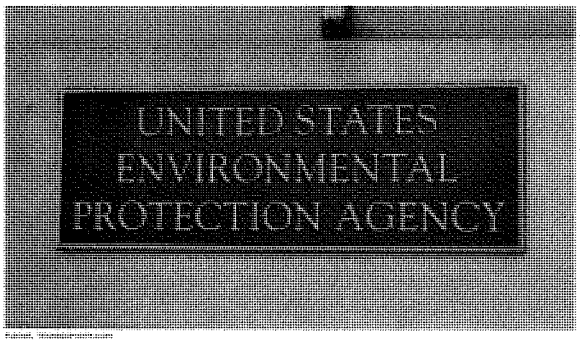
TheScientist
EXPLORING LIFE, INSPIRING INNOVATION
25-40% OFF
News Magazine Multimedia Subjects Surveys Careers Search



Trump Nominates Toxicologist for Key EPA Position

Michael Dourson, a former staffer at the Environmental Protection Agency, has controversial ties to industry.

By Diana Kwon | July 19, 2017



On Monday (July 17), the White House announced that President Donald Trump had nominated toxicologist Michael Dourson to head the Environmental Protection Agency (EPA) Office of Chemical Safety and Pollution Prevention.

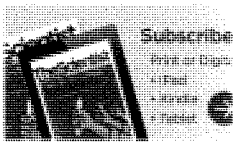
Dourson, who is currently a professor at the University of Cincinnati College of Medicine, worked at the EPA for 15 years, between 1980 and 1995. While the EPA release cited praise for the nominee from a number of professors and religious leaders, some experts and environmental advocates have expressed concern about Dourson's ties to the chemical industry.

"We are deeply concerned over the nomination of Michael Dourson to head the toxics office at EPA," Richard Denison, lead senior scientist at the Environmental Defense Fund, an environmental advocacy group, wrote in a recent blog post. "Unfortunately, this nomination fits the clear pattern of the Trump Administration in appointing individuals to positions for which they have significant conflicts of interest."

A key concern regards TERA (Toxicology Excellence for Risk Assessment), a consulting firm that was founded by Dourson in 1995. A 2014 investigation by *InsideClimate News* and the Center for Public Integrity found the firm had close ties to the chemical manufacturing and tobacco industries.

"Jesus hung out with prostitutes and tax collectors. He had dinner with them," Dourson told *InsideClimate News* in 2014 to defend his decision to work with the tobacco industry. "We're an independent group that does the best science for all these things. Why should we exclude anyone that needs help?"

Adam Finkel, a clinical professor of environmental health sciences at the University of Michigan, tells *Buzzfeed* that he ran into disagreements with Dourson when they worked together on critiquing a set



Popular Now



News Analysis
Publishers' Legal Actic Advances Against Sci-Hub
The pirate site plans to ignor the lawsuits from Elsevier a the American Chemical Soci



Daily News
The Caterpillar that Cr Wolf
In a case of acoustic decept caterpillars mimic bird alarm calls to defend themselves.



Notebook
How Microbes May Influence Our Behavio
Researchers are piecing together the links between t gut microbiome and mental health.



Daily News
Sexual Touch Promote Early Puberty
The brains and bodies of yo female rats can be accelera into puberty by the presenc an older male or by stimulat of the genitals.

Web2PDF
converted by Web2PDFConvert.com

of recommendation from the National Academy of Sciences on calculating chemical risk. He adds that the pair did not agree on best methods, and that Dourson tended to "think that the EPA overestimates risk."

Bob Sussman, a former EPA deputy administrator and senior policy counsel to the EPA administrator, tells *Bloomberg BNA* in an email, "We need someone at the helm who will provide leadership in addressing chemical risks, despite industry pressures to block action. Dourson's record raises questions whether he will provide that kind of leadership."

On the other hand, William Jordan, retired deputy director of the EPA's pesticide program, was more optimistic about the nominee. "Not only does he bring a lifetime of experience working on human health risk assessment issues, but he is familiar with EPA, serving in the Office of Research & Development, as well as a detail in EPA's Office of Pesticide Programs," he told *Bloomberg BNA* in an email.

Tags

politics, policy, EPA, Environmental Protection Agency and Donald Trump



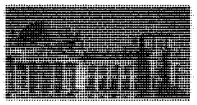
Add a Comment

You

Sign In with your LabX Media Group Passport to leave a comment

Not a member? Register Now!

Related Articles



Potential New German Coalition Government Likely to Clash on Energy

By Diana Kwon

After Sunday's federal election, Chancellor Angela Merkel is faced with political parties that disagree on key scientific and environmental issues.



Canada Names Chief Science Advisor

By Ashley P. Taylor

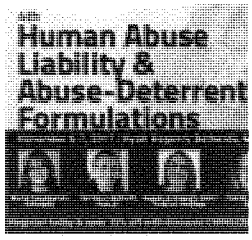
Scientists speculate about whether the appointment will mean more funding for research.



Opinion: Banning Shark Fin Sales in the U.S. Will Backfire

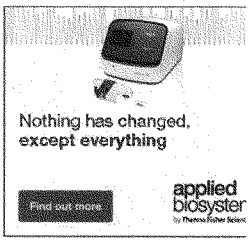
By Robert Hueter

A proposal to do so would cause waste, promote less sustainable fisheries, and penalize US fishers who follow best practices.

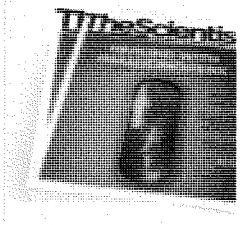


Stay Connected with The Scientist

- The Scientist
- The Scientist Careers
- Neuroscience News and Research
- Genetics in Life Science
- Biology Brief
- Biochemistry & Chemistry
- Bench to Bedside
- Cell Biology Research
- Microbiology and Immunology
- Cancer Research News
- Stem Cell and Regenerative Science



Current Issue

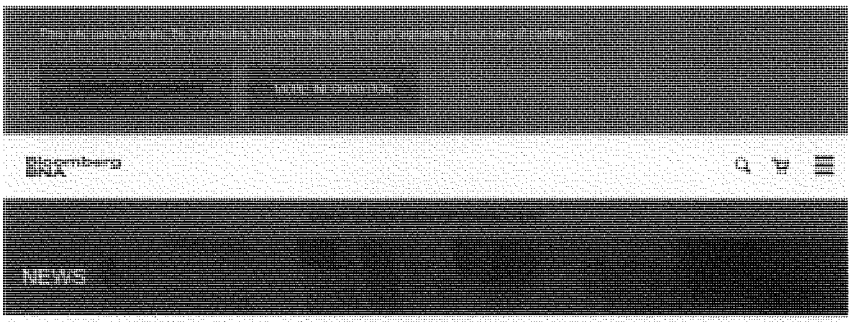


View the September 2017 contents.

Subscribe to RSS feed

- All
- The Nutshell
- News & Opinion

Web2PDF
converted by Web2PDFConvert.com



July 18, 2017

From Environment and Energy Report FREE TRIAL

Turn to the nation's most objective and informative daily environmental news resource to learn how the United States and key players around the world are responding to the environmental...

By Tiffany Stecker and Steve Gibb

President Donald Trump's choice to head the EPA's chemical safety and pesticides office is winning praise from the American Chemistry Council and other industry groups, but some ex-agency officials say Michael Dourson's ties to industry need to be scrutinized.

Trump late July 17 announced his intent to nominate Dourson, a professor of environmental health at the University of Cincinnati and founder of the Risk Science Center. Dourson spent 15 years at the Environmental Protection Agency's offices in Cincinnati, Washington, D.C., and Region 5 headquarters in Chicago under Presidents Ronald Reagan, George H. W. Bush, and Bill Clinton.

After leaving the agency in 1995, he founded Toxicology Excellence for Risk Assessment (TERA), a regulatory and chemical risk analysis firm that became the Risk Science Center when it joined with the University of Cincinnati in 2015.

"His knowledge, experience and leadership will strengthen EPA's processes for evaluating and incorporating high quality science into regulatory decision making," American Chemistry Council spokesman Jon Corley said. "The Senate should act on Dr. Dourson's nomination without delay as it comes during a crucial point in the implementation of the Lautenberg Chemical Safety Act."

And Jay Vroom, president of the pesticide trade association CropLife America, hailed the choice. "We're delighted with the science and policy experience Dr. Dourson has under the industrial chemical and pesticide laws," Vroom told Bloomberg BNA.

But Bob Sussman, a former EPA deputy administrator and senior policy counsel to the EPA administrator, said in an email that senators should look at Dourson's industry ties "to determine whether he has the impartiality and commitment to objective science necessary for sound public health decisions."

No information was immediately available on when the Senate might receive or begin considering Dourson's nomination.

Risk Assessment Background

Web2PDF
converted by Web2PDFConvert.com

Dourson was considered in 2014 to lead the EPA's Integrated Risk Information System, which identifies and characterizes chemicals' health hazards. The job went instead to Vincent Cogliano, then acting director of IRIS and currently an employee at the EPA.

Dourson has published widely in the fields of environmental risk assessment by co-authoring more than 150 peer-reviewed articles and has given more than 150 invited presentations, according to his biography on the University of Cincinnati's website.

Most recently, Dourson served as a member of the EPA Science Advisory Board, where he chaired an ammonia chemical review panel.

In 2014, the Center for Public Integrity and InsideClimate News published an investigation of TERA, suggesting it worked closely with the chemical and tobacco industries to fast-track chemical risk assessments. Dourson said in response that the criticism didn't bother him: "We get criticized by everyone. But that doesn't change the fact that TERA is neutral."

Dourson defended his decision to work with the tobacco industry. "Jesus hung out with prostitutes and tax collectors. He had dinner with them," he said, according to the investigation. "We're an independent group that does the best science for all these things. Why should we exclude anyone that needs help?"

Vroom said his organization has no doubts that Dourson could become acclimated to pesticide issues after a background in the industrial chemicals world.

"The same science and risk assessment principles apply to assessing pesticides," Vroom said. "Having a leader in place and the extra capacity that brings is what's important, and we commend the president and Administrator [Scott] Pruitt on this nomination."

Unease Among NGO Community

The Environmental Defense Fund is opposing the nomination, and farmworker groups are raising concerns about EPA decision-making and several worker protection rules that the toxics office oversees.

"Farmworkers face unique pesticide risks, and if confirmed, we hope the EPA's toxics office under Dourson won't continue to delay the farmworker protection standard and certification of pesticide applicators rule," Virginia Ruiz, director of environmental and occupational health at Farmworker Justice, told Bloomberg BNA. The latter rule creates more standardized training and certification requirements for applicators.

Officials at the Natural Resources Defense Council and Environmental Defense Fund said they plan to raise questions about what they called Dourson's failure to report his financial ties to the chemical industry.

"Unfortunately, this nomination fits the clear pattern of the Trump administration in appointing individuals to positions for which they have significant conflicts of interest," Richard Denison, senior scientist with the Environmental Defense Fund, said in a blog post.

Former EPA Officials

Former EPA policy official and scientist Tracey Woodruff—now with the University of California-San Francisco—shared Denison's concern. She worked at EPA from 1997 to 2007 and echoed Sussman's emphasis on the importance of EPA properly implementing the overhaul of the Toxic Substances Control Act (TSCA).

"Dourson's documented work with the industry could lead to a literal 'open for business' access to EPA decision making about toxic chemicals at a critical time of TSCA implementation," Woodruff said in an email.

Sussman, who is a consultant to the advocacy group Safer Chemicals-Healthy Families, said the new TSCA "is at a critical stage right now."

"We need someone at the helm who will provide leadership in addressing chemical risks, despite industry pressures to block action. Dourson's record raises questions whether he will provide that kind of leadership," Sussman said.

Web2PDF
converted by Web2PDFConvert.com

But William Jordan, who served at the EPA between 1975 and 2016 and retired as the deputy director of pesticide program, cited Dourson's experience in expressing his support.

"Not only does he bring a lifetime of experience working on human health risk assessment issues, but he is familiar with EPA, serving in the Office of Research & Development, as well as a detail in EPA's Office of Pesticide Programs," Jordan said in an email.

To contact the reporters on this story: Tiffany Stecker in Washington at tstecker@bna.com; Steve Gibb at sgibb@bna.com

To contact the editor responsible for this story: Rachael Daigle at rdaigle@bna.com

Copyright © 2017 The Bureau of National Affairs, Inc. All Rights Reserved.

Try Environment and Energy Report now

RELATED NEWS

Puerto Rico Eyed As Electricity Grid Innovation Testing Ground

Frack My Land or Lose the Rights, Ohio Woman Tells Driller

Chile's Plastics Industry Seeks to Avert Potential Bag Ban

Dubai Introduces Incentives to Spur Electric Vehicle Market

Cities Chafe at Clean Water Rules for L.A.'s Concrete River

U.S., Mexico on Verge of New Colorado River Water Pact

RELATED BLOGS

PODCAST: Finger Pointing on the Farm Amid Weed Killer Calamity

First Move: Refineries' Toxic Gas, Harvey Damage, EPA Economic Reviews

First Move: Harvey's Water Effects, Disaster Aid Surge, Pruitt Audited

Corporate America May be Best Hope to Re-Engage Trump on Climate

Week Ahead: 'Garbage Juice,' Snow Leopards, EPA Modeling Debated

Week Ahead: Chemical Society Event to Explore Industry's Impacts

Legal News

Tax & Accounting News

EHS News

HR & Payroll News

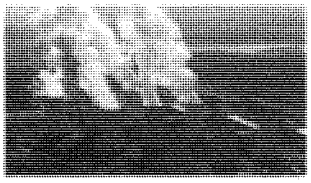
Web2PDF
converted by Web2PDFConvert.com

USA TODAY

SUBSCRIBE NOW
to get home delivery

Trump's controversial EPA nominee faces sharp questions over ties to chemical industry

Deirdre Shesgreen, USA TODAY Published 6:30 a.m. ET Sept. 13, 2017



Share your feedback to help improve our site experience!

The Trump administration ended the panel that explains the federal climate change report to the public. Video provided by Newsy Newslook



(Photo: Courtesy of the University of Cincinnati)

WASHINGTON — A University of Cincinnati professor nominated by President Trump for a top job at the Environmental Protection Agency is coming under intense scrutiny for his financial ties to the chemical industry.

Michael Dourson is a toxicologist who specializes in environmental risk assessment, now tapped to lead the EPA's Office of Chemical Safety and Pollution Prevention.

Much of Dourson's research has been funded by the very industries he would regulate if he wins confirmation. Among the interest groups financing his work: the American Petroleum Institute, the American Chemistry Council and the American Cleaning Institute.

Critics fear Dourson would use the EPA post to weaken safety standards for a raft of chemicals and pesticides, potentially setting dangerous levels for contaminants allowed in everything from cosmetics to paint thinner to drinking water.

"We think he would be an atrocious choice for this position," said Richard Denison, a senior scientist at the Environmental Defense Fund, a Washington-based advocacy group. "Having someone of his ilk, who is so tilted in one direction, would just be really a problem."

Dourson, who earned his Ph.D. from UC in 1980, referred questions about his work to the EPA. An EPA spokeswoman did not respond to emailed questions. But in announcing his nomination in July, the agency touted him as a renowned toxicology expert with unparalleled credentials and included endorsements from several other experts in his field.

"Dr. Michael Dourson has been a foundational thinker in the protection of human health from chemical exposure," Oliver Kroner, who works in the city of Cincinnati's Office of Environment and Sustainability, said in a statement included in the EPA's release. "He has been a tireless champion of science, and the role of science to help quantify risk and uncertainty."

Dourson has worked at the EPA before, serving in various positions from 1980 until 1994. He has been affiliated with the University of Cincinnati since 2015, and he's now a faculty member at the school's Risk Science Center, which says its mission is to work at the "intersection of science and health protection."

"Chemicals are an important part of our daily lives," the center's website states. "Some chemicals are essential to a healthy life, but exposure to chemicals may also present health risks. We study the way our bodies interact with the chemicals around us to determine the nature and extent of health risks."

Read more:

Stalled on health care, President Trump quietly scores wins on energy agenda

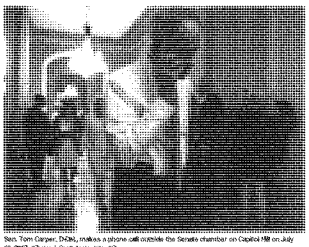
Does President Trump believe in climate change? White House, EPA won't say

Dourson, who also writes "science Bible books," could receive a confirmation hearing as soon as next week, and it's sure to be contentious.

In preparation for the grilling, Sen. Tom Carper, the top Democrat on the Environment and Public Works Committee, has asked Dourson for a raft of documents related to his research and the industries that have funded it.

In an Aug. 4 letter, the Delaware senator asked Dourson to detail any work he's done on behalf of chemical companies entangled in lawsuits, to specify any corporate work that might force him to recuse himself from EPA decisions, and to itemize the funding sources for his nonprofit research organization, among other queries.

WebZIP



Sen. Tom Carper, D-Del., makes a phone call outside the Senate chamber on Capitol Hill on July 13, 2017. (Photo: J. Scott Applewhite, AP)

Carper noted that Dourson's nomination comes at a pivotal moment — as the EPA implements a new chemical safety law, passed last year with bipartisan support. Under that law, the office Dourson is nominated to lead will evaluate the risks and set safety standards for a bevy of chemicals.

"It is imperative that we make sure EPA is up to the task of implementing those critical reforms in a credible and objective way, and giving all Americans the protection and peace of mind they deserve," Carper said in a statement to USA TODAY. "Based on his record, I'm not convinced Dr. Dourson is the right person for this important job."

Dourson's role as founder and president of a Cincinnati-based nonprofit — Toxicology Excellence for Risk Assessment — is perhaps the most controversial item on his résumé.

Dourson started TERA in 1995, and its mission, according to the group's website, is to "protect human health by conducting scientific research and development on risk issues in a transparent and collaborative fashion." The group says its research is objective and it operates independently of its funders.

"We operate at the highest level of ethical and scientific standards," the website states.

According to the most recent tax documents available, TERA's revenue in 2014 was about $2.48 million. By TERA's own accounting, 43% of its work that year was sponsored by industry groups seeking TERA's scientific assessments. The remainder was government or nonprofit-funded work.

TERA says it strives for a balance between for-profit and non-profit clients. Its website lists its industry and other sponsors but does not specify donation amounts. The percentage of its industry-funded work has ranged from 18% to 82%, according to its disclosures.

But others say TERA is anything but balanced or neutral.

A 2014 investigation by the Center for Public Integrity and InsideClimate News found that TERA's corporate ties were extensive.

"More than 50 percent of the peer-review panels TERA has organized since 1995 were for studies funded by industry groups," the investigation found. "TERA also runs a risk-assessment database that receives financial and in-kind support from many companies and government agencies. Some of those groups have also paid TERA to peer-review studies they hope will be included in the database."

Denison, the Environmental Defense Fund scientist, said he fears Dourson will give the chemical industry a free pass. He said Dourson has worked on behalf of companies that make or use three of the first 10 chemicals EPA is supposed to review under the 2016 law.

"In all three cases, he proposed (safety) standards that are *many* times less protective than the standards that other authoritative bodies have set for those same chemicals," Denison said.

If he's confirmed, Denison said, it will have a "very direct and very immediate" impact on public health.

f 9093 in 38 t
COMPACT TWEET LINKEDIN COMMENT EMAIL MORE

Web2PDF

The New York Times

SCIENCE

By SHEILA KAPLAN and ERIC LIPTON SEPT. 19, 2017



Michael L. Dourson, nominated by President Trump to oversee the Environmental Protection Agency's chemical safety programs, was on Capitol Hill last week. Mr. Dourson has spent years helping companies fight restrictions on the use of potentially toxic chemicals in consumer goods. Al Drago for The New York Times

WASHINGTON — The scientist nominated to head the federal government's chemical regulatory program has spent much of his career helping businesses fight restrictions on the use of potentially toxic compounds in consumer goods.

That record is expected to figure prominently in a Senate confirmation hearing for the scientist, Michael L. Dourson, who critics say is too closely tied to the chemical industry to be its chief regulator.

The source of the concern is a consulting group that Mr. Dourson founded in 1995, which has been paid by chemical companies for research and reports that frequently downplayed the health risks posed by their compounds.

Four chemicals that are nearly ubiquitous in everyday products — 1,4-

Web2PDF
converted by Web2PDFConvert.com

dioxane, 1-bromopropane, trichloroethylene and chlorpyrifos — are now under review by agency regulators to determine whether they pose a threat to public health. If confirmed, Mr. Dourson would oversee the review of some chemicals produced by companies that his firm used to represent.

Mr. Dourson, 65, worked for the Environmental Protection Agency from 1980 to 1994, according to his résumé, starting as a staff toxicologist, preparing health assessments of various substances. He worked his way up over time, becoming chief of the pesticides and toxics team in 1989, supervising scientists who support the E.P.A.'s regulatory work. Mr. Dourson ultimately oversaw a team of scientists conducting risk assessments for the agency's offices of water, solid wastes and air quality.

The following year he created a nonprofit consulting firm that became a line of first defense for companies facing health and safety challenges from the E.P.A.

Mr. Dourson has a popular sideline as a writer of books that combine Bible stories with his views on science. His series, "Evidence of Faith," is an examination of the intersection of evolution and hible history.

At a time when the E.P.A. is in the early stages of putting in place Congress's 2016 overhaul of the law governing toxic chemicals, Mr. Dourson's nomination to become the agency's assistant administrator for chemical safety has alarmed Democrats and some former E.P.A. officials.

"Dr. Dourson's consistent endorsement of chemical safety standards that not only match industry's views, but are also significantly less protective than E.P.A. and other regulators have recommended, raises serious doubts about his ability to lead those efforts," said Senator Tom Carper, Democrat of Delaware, the ranking minority member on the panel that will assess Dr. Dourson's qualifications. "This is the first time anyone with such clear and extensive ties to the chemical industry has been picked to regulate that industry."

Neither Mr. Dourson nor the E.P.A. would comment on the criticisms of his industry ties. A notice on the E.P.A.'s website praises Mr. Dourson's achievements in toxicology and the quality of his research. Trade groups for the $800 billion chemical industry are supportive of the nominee. CropLife America, which lobbies for purveyors of pesticides, fungicides and rodenticides, called Mr. Dourson "a perfect fit."

"We welcome Dr. Dourson's nomination," CropLife America notes on its website. "His extensive experience in risk assessment and science, both in government and private sector make him a valuable addition to the office."

The confirmation hearing for Mr. Dourson and others had been scheduled for Wednesday, but it has been postponed and a new date has not been set.

Senator John Barrasso, Republican of Wyoming and chairman of the Senate committee that will hold the hearing, defended Mr. Dourson's nomination.

"Dr. Dourson is an experienced toxicologist who deserves full and fair committee consideration, followed by a Senate vote," Mr. Barrasso said. "That should be the case for all of the nominees for leadership roles at the

Web2PDF
converted by Web2PDFConvert.com

E.P.A."

The nonprofit consulting firm that Mr. Dourson founded and ran, TERA, became part of the University of Cincinnati in July 2015. The department changed its name from the TERA Center to the Risk Science Center in January 2017. The center disclosed that it collected about 30 percent of its funding from for-profit sources in the 2015-16 fiscal year.

Mr. Dourson's ethics agreement says that he will not, once confirmed, participate for one year in any "particular matter involving specific parties" related to University of Cincinnati work he has done.

But Mr. Dourson's financial disclosure report — filed after he was nominated — shows no direct payments to him from any chemical company, meaning any company-funded research Mr. Dourson did in the last year would likely have been paid for through the University of Cincinnati or another organization.

As a result, it is unlikely ethics rules would bar him from overseeing issues related to chemicals manufactured by companies he has conducted research for. Grants given by companies to universities, but not to the scholars themselves, generally do not create conflicts that require individuals to recuse themselves from matters involving the companies, said Walter Shaub, the former head of the federal Office of Government Ethics.

Mr. Dourson's firm's clients have included the American Chemistry Council, the industry's top lobbying group. The firm also advised individual companies, makers of flame retardants, compounds that are called "chemicals of concern," and pesticides.

In some cases, his firm provided results that suggested the health risk of a certain chemical or product was less than the assessment by the E.P.A. and other researchers.

PPG Industries, for example, a paint and coatings manufacturer, uses a chemical called 1,4-dioxane, which the E.P.A. designated "a likely carcinogen," in its products. The substance is also created incidentally in some shampoos, cosmetics and personal care products through chemical reactions.

PPG hired Mr. Dourson's group, which proposed establishing a safe level for 1,4-dioxane that would allow 1,000 times more risk than the E.P.A's recommended level.

Other clients have included Albemarle, which makes flame retardants; Dow AgroSciences, which makes the pesticide chlorpyrifos; Waste Management; and Monsanto. He has also helped DuPont defend a chemical called PFOA, used to make nonstick substances, from states, including West Virginia, that sued the company to clean up contaminated water.

Each of the four chemicals has been associated with severe health issues, like cancer, birth defects and developmental problems in children. Mr. Dourson's studies frequently concluded that the risk associated with these substances is much lower or more dubious than what E.P.A. scientists and independent researchers have found.

Web2PDF
converted by Web2PDFConvert.com

The most striking discrepancy between findings by the agency and his firm is likely Mr. Dourson's research funded by Dow AgroSciences on the pesticide chlorpyrifos, in which the authors recommended a safe level that was actually 33 times higher than the agency's standard, according to an analysis by Richard Denison, lead senior scientist at the Environmental Defense Fund.

The agency subsequently lowered its standard even more, to a level nearly 6,000 times less than Mr. Dourson's, according to Mr. Denison's analysis. E.P.A. scientists then recommended that the product be banned for commercial use as a pesticide.

But E.P.A. Administrator Scott Pruitt overruled a staff recommendation for a ban, after objections were raised by Dow and other industry players.

More recently, Mr. Dourson published a report titled "A case study of potential human health impacts from petroleum coke transfer facilities," that was funded by Koch Industries, which has a subsidiary that handles petroleum coke and coal. The report concluded that human exposures, if any, "are well below levels that could be anticipated to produce adverse health effects in the general population."

Adam Finkel, executive director of the Penn Program on Regulation at the University of Pennsylvania Law School, who worked as a partner on a project with Mr. Dourson, said he observed a disturbing pattern.

"Most of what he has done over time is to rush headlong to exonerate chemicals," Mr. Finkel said, adding that he stopped working with Mr. Dourson based on these concerns.

"Pretty much every piece of work he's ever done, it just so happens that when they are finished with it, the risk is smaller than when they started, the doubt is larger, the concern is less."

But Oliver Kroner, now a Cincinnati city environmental official, praised Mr. Dourson, with whom he worked at TERA for nearly 10 years.

"I think Mike is widely misunderstood," Mr. Kroner said. "Here in chemical regulation, we're faced with a decision of whether we accept all the health science available to us, or if we exclude some science depending on the source."

"Mike has worked hard to help strengthen the regulatory environment by improving the science coming out of industry and bringing a collaborative peer review approach to help assess the quality of industry-derived science," Mr. Kroner said.

Three other E.P.A. nominees will be vetted at the confirmation hearing, one of whom also has spent much of his career defending businesses against the E.P.A.: William L. Wehrum, named to head the agency's Office of Air and Radiation.

Mr. Wehrum, who was acting assistant administrator for air and radiation from 2005 to 2007, is now a partner in Hunton & Williams, which has a large energy and environmental law practice.

Web2PDF
converted by Web2PDFConvert.com

In the past few years, Mr. Wehrum has represented the Rubber Manufacturers Association, the American Petroleum Institute, the American Forest & Paper Association, and electric utilities, among others, against the E.P.A., legal records show. Mr. Wehrum did not return messages seeking comment.

Liz Bowman, an E.P.A. spokeswoman, pointed to Mr. Wehrum's decades of working for the government and private sector as evidence of his qualifications for the new job.

"Mr. Wehrum's career includes over 31 years working in the environmental field through engineering, legal practice, and administrative duties," said Ms. Bowman, who used to work for the American Chemistry Council, in a statement. "This addresses that criticism directly."

Like the Science Times page on Facebook. | Sign up for the Science Times newsletter.

A version of this article appears in print on September 20, 2017, on Page A16 of the New York edition with the headline: Chemical Industry Ally Vies for Top E.P.A. Post. Order Reprints | Today's Paper | Subscribe

The New York Times

NEWS

OPINION

ARTS

LIVING

LISTINGS & MORE

SUBSCRIBE

© 2017 The New York Times Company Privacy Terms of Service

Site Map Help Site Feedback

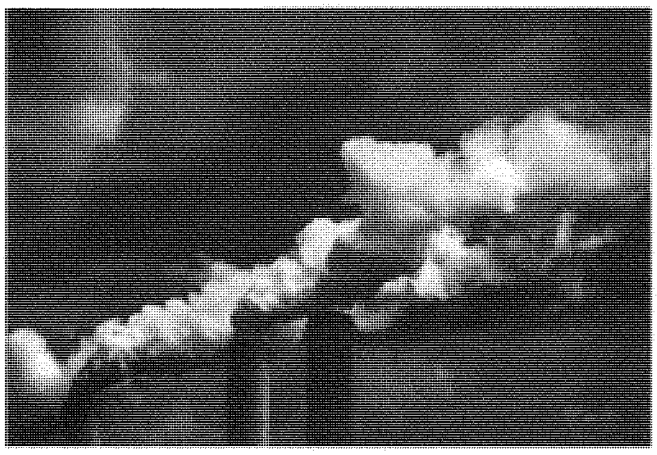
Web2PDF
converted by Web2PDFConvert.com

HUFFPOST

Mary Anne Hitt, Contributor
Director of the Sierra Club Beyond Coal Campaign

Meet The Four Horsemen Of The EPA-pocalypse

09/19/2017 01:34 pm ET | **Updated** Sep 19, 2017



Every week, another decision that endangers our families seems to come out of Scott Pruitt's and Donald Trump's Environmental Protection Agency (EPA). The latest facepalm/outrage comes in the form of confirmation hearings that start this week for four completely unacceptable nominees to critical leadership positions at EPA.

This Wednesday, September 20, the Senate Committee on the Environment and Public Works will decide whether to confirm **Bill Wehrum** to lead the EPA's Office of Air and Radiation, **David Ross** as chief of the EPA's Office of Water, and **Michael Dourson** to head up the agency's chemical safety programs. Later this month, they will hold a hearing on the nomination of **Andrew Wheeler** as EPA's Deputy Administrator, the agency's second-in-command.

We can thank EPA administrator Scott Pruitt for these four horsemen of the EPA-pocalypse — four people who will gladly choose polluters over public health and clean air and water standards every time.

Andrew Wheeler, who Pruitt has tapped for the number two spot at EPA, was described by the Washington Post as a "longtime coal lobbyist" and has worked on behalf of a company which reportedly has numerous environmental and worker safety violations. Wheeler has spent his career challenging vital life-saving environmental protections that keep our air and water clean so that we can keep our families safe (I wrote this post about him earlier this summer). He also used to be an aide for outspoken climate-denying and corporate-polluter-loving senator, James Inhofe.

Bill Wehrum, Pruitt's pick to head up the office in charge of enforcing the Clean Air Act and keeping your air safe to breathe, is a lobbyist who represents a host of coal, oil, gas, and chemical companies, and was a former George W. Bush-

Web2PDF
converted by Web2PDFConvert.com

era EPA official. If you recognize his name, it's because he was also nominated to this position in 2006 — his nomination was withdrawn when he failed to earn support of the 60 Senators needed for confirmation.

And while he's nominated to lead the EPA's air and radiation office, ironically enough, he's said that the Clean Air Act shouldn't apply to the carbon pollution that contributes to climate change and superstorms like Hurricane Harvey. As my friend John Walke at NRDC put it, Wehrum "is an industry lawyer who was largely responsible for the Bush EPA's record of violating the Clean Air Act more often, and allowing more illegal emissions of harmful air pollution, than any EPA administration before or since."

David Ross, nominated for for the top spot at the Office of Water, has sued the EPA many times related to its clean water safeguards in his work representing fossil fuel states like Wyoming, including challenging the Clean Water Rule and the Chesapeake Bay cleanup program (he lost the latter lawsuit, which the court called "long on swagger, but short on specificity"). According to E&E News, he "has represented states and industry in lawsuits against the agency — some of which were filed by then-Oklahoma Attorney General and now EPA Administrator Scott Pruitt."

Finally, **Michael Dourson** is on deck to head up the EPA division that oversees the chemical industry, called the Office of Chemical Safety and Pollution Prevention. According to the Environmental Defense Fund, "Dourson has extensive, longstanding ties to the chemical industry (as well as earlier ties to the tobacco industry). He also has a history of failing to appropriately address his conflicts of interest." The first example they cite hits close to home for me as a West Virginian — they report he was the sole spokesperson for an expert panel studying the 2014 Elk River chemical spill but failed to disclose, until cornered by a reporter, that he had previously "done paid work for both of the companies that produced the chemicals involved in the spill."

In addition, Dourson has spent much of his professional career writing studies that undermine existing science and concerns about toxic chemicals, and call for weaker regulations on chemicals like pesticides. As our friends at the United Farm Workers explain, Dourson was paid by Dow Agrosciences to downplay concerns about a toxic pesticide and cast doubt on a Columbia University study linking exposure to it by pregnant women to irreversible neurodevelopmental problems in children — in other words, to hide the fact that the pesticide is dangerous to kids. As you may have heard, in a highly controversial move the EPA recently reversed restrictions on the use of this pesticide, called chlorpyrifos, shortly after meeting with officials from Dow.

Senators shouldn't get fooled — Scott Pruitt has seized the EPA and is trying to install polluter lobbyists in key positions. **We can't let dirty fuel lobbyists win — we need the Senate to draw the line and reject these nominations.**

M O R E :

U.S. News | Public Health | Sustainability | Coal | Environmental Protection Agency

You May Like

Sponsored Links by Taboola

Web2PDF
converted by Web2PDFConvert.com

USA TODAY

SUBSCRIBE NOW
to get home delivery

EPA nominee Michael Dourson endorsed weak standard for chemical linked to tumors in industry-funded research

Deirdre Shesgreen, USA TODAY Published 5:40 p.m. ET Sept. 18, 2017 | Updated 8:58 p.m. ET Sept. 18, 2017

326 SHARES 2 COMMENTS



(Photo: Courtesy of the University of Cincinnati)

WASHINGTON — If University of Cincinnati toxicologist Michael Dourson wins confirmation as a top environmental regulator, one of the first chemicals he will assess is called 1,4 dioxane — a likely carcinogen linked to liver tumors and found in drinking water across the country.

Dourson, nominated to lead the Environmental Protection Agency's chemical and pesticide safety office, has twice accepted money from one of the companies that uses the industrial solvent: PPG Industries, a global company that manufactures paints and coatings in Circleville, Ohio.

The PPG money went to a Cincinnati-based nonprofit that Dourson runs, called the Toxicology Excellence for Risk Assessment (TERA). Dourson then produced two research papers endorsing levels of the chemical 1,000 times less protective than the EPA's suggested standard. One of Dourson's co-authors on the papers is a PPG employee.

Environmentalists say Dourson's work on 1,4-dioxane illustrates a broader pattern, in which the professor takes chemical-industry money through TERA and then twists the research to reach industry-friendly conclusions.

"If Mike Dourson is confirmed, the environmental health of every child in the country will be tossed aside," Ken Cook, president of the Environmental Working Group, a research and policy organization that pushes for tougher environmental protections. Dourson "will almost certainly continue his work from inside EPA to greenwash chemicals and pesticides to protect the profits of the companies that make them."

Dourson's defenders say he's a top-notch expert with decades of work studying chemicals — including a previous stint at the EPA — and that TERA produces objective research for a gamut of clients.

"Toxicology Excellence for Risk Assessment is an organization uniquely positioned to provide an unbiased, objective review as the only non-profit toxicology organization that conducts chemical risk assessments for state and federal agencies as well as industry," said Mark Silvey, director of corporate communications for PPG.

Dourson did not respond to emailed questions about his work on 1,4-dioxane. An EPA spokeswoman also did not respond to a request for comment.

Read more:

Trump's controversial EPA nominee faces sharp questions over ties to chemical industry

Delaware Sen. Tom Carper emerges as unlikely environmental warrior

Does Trump believe in climate change? White House, EPA won't say

Dourson's work on 1,4-dioxane, which has also been linked to kidney and other kinds of tumors in animal studies, will almost certainly come up at his confirmation hearing before the Senate Environment and Public Works Committee, which could happen as early as next week.

It's no wonder, since the chemical is widely used in the U.S. and has been found in drinking water and household products across the country. It's also in some cosmetics and other household products.

According to an Environmental Working Group analysis, water tests from local utilities across the country show that more than 7 million Americans, living in 27 states, are served by water systems with levels of 1,4 dioxane that could at least marginally increase their cancer risk.

Right now, there is no federal limit on how much 1,4-dioxane is allowed in drinking water. The EPA recommends no more than .350 parts per billion, and states have deemed widely varying levels as safe for local drinking water.

The office that Dourson has been nominated to lead will have the power to mandate a federal standard for 1,4-dioxane, along with a bevy of other chemicals, under a bipartisan chemical safety law passed by Congress last year.

In his 2014 study sponsored by PPG, Dourson concluded that if 1,4 dioxane causes liver tumors or other mutations, "it is only at high ... doses."

That paper, and a second PPG-funded one published earlier this year, recommended allowing 350 parts per billion of the industrial solvent in drinking water — 1,000 times higher than the level the EPA has suggested. That's is also exponentially higher than the levels most states have endorsed.

The state of Michigan reviewed Dourson's work and rejected it.

"The currently available scientific information regarding the carcinogenicity of 1,4-dioxane does not support TERA's hypothesis," the Michigan review concluded,

Share your feedback to help improve our site experience!

Web2PDF
converted by Web2PDFConvert.com

determining instead that the EPA's much stronger recommendation was sound. "The most compelling argument for retaining the U.S. EPA default assumption ... is the presence of multiple tumor types in rodent models, all of which are relevant to humans."

Environmentalists say Dourson's work on 1,4-dioxane is just one of many examples in which the nominee produces "junk science" at the bidding of industry groups that fund TERA.

"His whole step-by-step enterprise has been set up to bend the science in support of the interests of his corporate clients," wrote Richard Denison, a senior scientist at the Environmental Defense Fund, a Washington-based advocacy group, in a recent analysis.

"He uses a process that virtually assures those companies are going to get what they paid for," Denison said in a conference call on Tuesday with reporters. The companies then use his data "to argue against a tougher regulation that a federal or state agency has put in place."

Silvey, the PPG spokesman, declined to say how much his company paid TERA for the two research papers. He also did not answer questions about how PPG used the papers that Dourson wrote on 1,4-dioxane.

But he defended the company and Dourson.

"TERA and Mike Dourson ... were selected by PPG because of their independence and extensive experience in conducting objective risk assessments," Silvey said. "PPG's request to TERA and Dr. Dourson was to provide a comprehensive review that was objective and based on sound science."

Web2PDF
converted by Web2PDFConvert.com

By MICHAEL BIESECKER and JEFF HORWITZ
Sep. 20, 2017

https://www

WASHINGTON (AP) — President Donald Trump's nominee to oversee chemical safety at the Environmental Protection Agency has for years accepted payments for criticizing studies that raised concerns about the safety of his clients' products, according to a review of financial records and his published work by The Associated Press.

Michael L. Dourson's nomination as head of EPA's Office of Chemical Safety and Pollution Prevention was to be considered by a Senate committee Wednesday, but was postponed when the Senate adjourned early for the week. If confirmed, ethics experts said, Dourson's past writings and the money paid to him and a nonprofit he founded could represent potential conflicts of interest.

Planning to create a content strategy for the internet of things?
See the e-book

Past corporate clients of Dourson and of a research group he ran include Dow Chemical Co., Koch Industries Inc. and Chevron Corp. His research has also been underwritten by industry trade and lobbying groups representing the makers of plastics, pesticides, processed foods and cigarettes.

A toxicologist, Dourson worked at the EPA for more than a decade, leaving in 1994 as the manager at a lab that assessed the health risks of exposure to chemicals. The following year, he founded Toxicology Excellence for Risk Assessment, a private toxicity evaluation nonprofit organization that tests chemicals and produces reports on which chemicals are hazardous in what quantities.

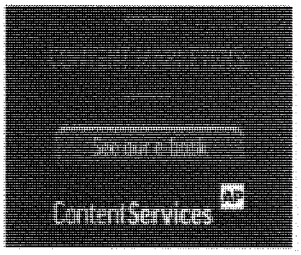
Dourson's views toward industry are consistent with others Trump has selected as top federal regulators. Among them is EPA Administrator Scott Pruitt, who in March overruled the findings of his agency's own scientists to reverse an effort to ban chlorpyrifos, one of the nation's most widely used pesticides.

Dourson and his organization previously worked under contract for Dow AgroSciences, the Dow subsidiary that makes chlorpyrifos. In three papers, Dourson and his colleagues pointed to what they said were flaws in peer-reviewed studies that linked delays in fetal development with even low levels of exposure to the pesticide, commonly sprayed on citrus fruits and apples.

In a 2005 paper on the topic, Dourson and his co-authors thanked Dow for its support over a number of years to study chlorpyrifos' toxicology and assess its risk and said that money in no way influenced their findings favoring the company's position.

Web2PDF
converted by Web2PDFConvert.com

Dourson did not immediately respond Tuesday to emails or phone messages seeking comment.



Sheldon Krimsky, a Tufts University professor who studies ethics in science and medicine, said appointing Dourson to oversee EPA's chemical safety programs is part of a broader effort to undermine federal regulations protecting public health.

"It is not even subtle," said Krimsky, who reviewed Dourson's recent published work. "He has chosen to be the voice of the chemical industry. His role as a scientist is simply the role of an industry-hired lawyer — only to give the best case for their client."

In addition to its corporate clients, Douson's organization gets money from the U.S. and Canadian governments. In some instances, companies pay the group to evaluate a chemical and it organizes a scientific panel to validate the findings.

According to the nonprofit's most recent publicly available IRS filing, Dourson was paid $131,000 for his work there in 2015. He separately earns $103,000 a year from the University of Cincinnati, where he holds a research position.

Dourson's pro-industry leanings were also evident in a now defunct website called "Kids + Chemical Safety," which his group ran. The site, which described itself as a source of information about the safe use of chemicals around children, mirrored talking points by chemical companies and trade groups that financed Dourson's work.

One 2016 article defended glycophospate, the active ingredient in Monsanto's RoundUp weedkiller, saying it was too early to start pointing fingers. One post assured parents that exposure to fire retardant chemicals in children's pajamas was too low to be a health risk. Dourson was paid $10,000 by the North American Flame Retardant Alliance, according to a financial disclosure form he filed with the Office Government Ethics. That group is a subsidiary of the American Chemistry Council, an industry trade group that has paid Dourson to conduct scientific reviews.

Dourson's willingness to align his scientific opinions with those of his corporate patrons has earned him support from influential industry groups now supporting his nomination.

The American Chemistry Council said he would make an excellent addition at EPA.

"His knowledge, experience and leadership will strengthen EPA's processes for evaluating and incorporating high quality science into regulatory decision making," said Jon Corley, the group's spokesman.

Dourson has also served without pay for two groups, the Toxicology Forum and the Toxicology Education Foundation, whose primary funders include the American Chemistry Council, oil companies and the makers of food additives. He has resigned or promised to resign from these posts if confirmed for the EPA job.

On the side, Dourson has also written three books seeking to reconcile his work as a scientist and a devoted Christian. His "Evidence of Faith" series seeks to align scientific knowledge with biblical accounts, such as how the Big Bang Theory could mesh with the Book of Genesis, whether the Shroud of Turin is real and whether evidence of the Nativity story can be found in the stars.

Court records show Dourson and his work have often been called on when his corporate clients are seeking to fend off lawsuits.

DuPont was accused of polluting a West Virginia town with Perfluorooctanoic acid, or PFOA, a chemical that the company's internal tests had long ago concluded were toxic. Corporate officials discussed hiring Dourson as part of a strategy to defend themselves.

One DuPont executive praised Dourson's "ability to assemble a 'package' and then sell this to the EPA, or whomever we desired," according to an email cited in a 2013 legal claim by people who blamed exposure to the chemical for cancer, birth defects and other health problems.

Web2PDF
converted by Web2PDFConvert.com

Dourson led a team that found in 2002 that PFOA levels up to 150 parts per billion were safe, a level higher than was found in testing of 188 private wells and springs.

That was also well above the 1 part per billion Dupont's own scientists had concluded could be considered safe years before. The EPA now says that only 70 parts per trillion of PFOA are acceptable — or only 0.05 percent of what Dourson's team said was safe.

DuPont and a former subsidiary, Chemours Co., later paid $761 million to settle 3,550 lawsuits stemming from its use of the chemical.

Follow Associated Press reporters Michael Biesecker at http://twitter.com/mbieseck and Jeff Horwitz at http://twitter.com/jeffhorwitz

---

Submit a confidential tip to The Associated Press at https://www.ap.org/tips

More From AP by Taboola

- **'Dukes of Hazzard' star charged with assaulting girl, 16**
- **Chief resigns after labeling Steelers' Tomlin with slur**
- **US-based actor Jan Triska dies after fall from Prague bridge**
- **Kevin Hart apologizes to wife, kids for 'mistakes'**

Ad Content Sponsored Links by Taboola

These 99 Retirement Tips May Surprise You
Fisher Investments

Web2PDF
converted by Web2PDFConvert.com

WATCH LIVE: TRUMP MAKES REMARKS ON TAX REFORM GET ALERTS

NBC NEWS SECTIONS

POLITICS > CONGRESS

WHITE HOUSE JUSTICE DEPARTMENT NATIONAL SECURITY FIRST READ

POLITICS SEP 19 2017, 7:13 PM ET

Democrats Target Trump EPA Pick With Chemical Industry Ties

by SUZY KHIMM

SHARE

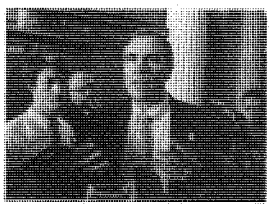
advertisement

WASHINGTON — President Donald Trump's pick to be the nation's top chemical regulator is expected to face tough questions from Senate Democrats for spending decades working on behalf of corporations trying to stave off tougher chemical regulations.

Michael Dourson, who's been nominated by the White House to lead the Environmental Protection Agency's chemical safety program, was slated to appear at a Senate confirmation hearing on Wednesday, but it was postponed on Tuesday. A new hearing date has not been announced.

Senate Democrats have already expressed serious concerns about Dourson's long career of conducting industry-funded research, which major manufacturers and lobbying groups have used to downplay the effects of potentially toxic substances.

"Dourson's work presents a disturbing track record of consistently claiming that these chemicals are much safer than independent scientists have determined," said Sen. Jeff Merkley, D-Ore., who's on the Senate committee that's considering Dourson's nomination.



Sen. Jeff Merkley, D-Ore. speaks to reporters just outside the Senate chamber on Capitol Hill on April 5, 2017 in Washington. J. Scott Applewhite / AP

The nomination comes at a pivotal moment for chemical oversight: Last year, Congress passed a major overhaul of the Toxic Substances Control Act for the first time in 40 years. The new law is intended to fix serious shortcomings in the federal government's ability to regulate hazardous substances in everything from drinking water to household cleaning products. But the EPA is still in the earliest stages of implementing the new law, and, if confirmed, Dourson would be leading that effort.

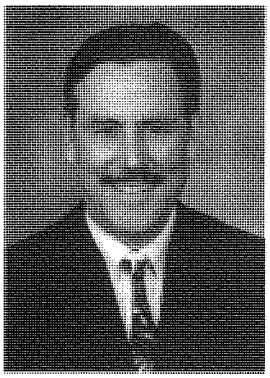
"It is imperative that we make sure EPA is up to the task of implementing those critical reforms in a credible and objective way, and giving all Americans the protection and peace of mind they deserve," said Sen Tom Carper, D-Del., the highest-ranking Democrat on the Senate committee for Environment and Public

Web2PDF
converted by Web2PDFConvert.com

Works.

"Based on his record, I'm not convinced Dr. Dourson is the right person for this important job," he added.

At the heart of the controversy is Dourson's work for Toxicology Excellence for Risk Assessment (TERA), a non-profit he founded in 1995 to provide chemical risk assessments and other research on behalf of clients. Industry groups and private corporations sponsored one-third of the group's work in 2015. TERA has now folded into the University of Cincinnati, where Dourson currently works as a toxicologist.



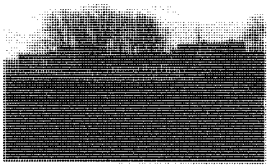
Michael Dourson © University of Cincinnati

Asked about the criticism of Dourson's record, the Trump administration said that he was "receiving high accolades from experts across the country," according to Liz Bowman, an EPA spokesperson. She cited his leadership positions at the American Board of Toxicology, scientific journals, and the EPA, where Dourson worked from 1980 to 1994. Dourson did not respond to a request for comment.

But critics argue that Dourson has consistently recommended standards for chemical exposure that are far weaker than what federal agencies have recommended, and that are highly favorable to the corporate interests that have funded his research. Dourson was paid by PPG, a major paint manufacturer, to examine the health efforts of 1,4-Dioxane, an industrial solvent that the EPA describes as "a likely human carcinogen."

Dourson concluded that the safe level for exposure was 1,000 times higher than the EPA's recommendation, advocates from the Environmental Working Group pointed out in a recent report. 1,4-Dioxane is among the first 10 chemicals that the EPA have made a priority for risk assessments, as required under the 2016 chemical safety law.

Dourson has also published industry-funded research on two other chemicals that are on the fast track for the EPA review: Trichloroethylene, an industrial solvent linked to kidney and liver cancer; and 1-Bromopropane, a dry cleaning chemical that has been linked to reproductive and neurological problems.



DuPont headquarters in Wilmington, Delaware. © Jennifer Corbett / AP file

In addition to his research, Dourson has also served as an expert witness for companies being sued for toxic exposure and contamination. He was hired, for example, as a consultant for DuPont when the company was facing extensive litigation around PFOA, a chemical used to make Teflon that's been linked to cancer. Residents of West Virginia, where DuPont had

Web2PDF
converted by Web2PDFConvert.com

made Teflon for decades, sued the company, which settled in early 2017.

"How does he put aside a 20-year career of being paid by the industry to do science in a way that favors their desired outcomes?" asked Richard Denison of the Environmental Defense Fund. "He creates an aura of legitimacy around a process that's fundamentally conflicted."

At his confirmation hearing, Senate Democrats are likely to push Dourson to explain if and when he would recuse himself from policymaking decisions at the EPA because of his work on behalf of industry.

Sen. John Barrasso, R-Wyo., the chairman of the Senate committee on Environment and Public Works, defended Dourson as "an experienced toxicologist who deserves full and fair committee consideration, followed by a Senate vote."

Barrasso also criticized Democrats for holding up consideration of other EPA nominees, stressing the importance of filling the agency's top positions. "Democrats would rather play politics with nominations, than see polluters held accountable," he said.

CORRECTION (Sept. 19, 2017, 6:33 p.m. ET): An earlier version of this article misidentified the employer of Richard Denison. He works for the Environmental Defense Fund, not the Environmental Working Group.

SUZY KHIMM

TOPIC CONGRESS

FIRST PUBLISHED SEP 19 2017, 5:41 PM ET

NEXT STORY After Health Care Debacle, Trump Eyes Democrats for Tax Deal

More to Explore

Sponsored Links by Taboola

An 18-year-old Saudi female is using her passion to change lives.
ArabiaNow

Web2PDF
converted by Web2PDFConvert.com

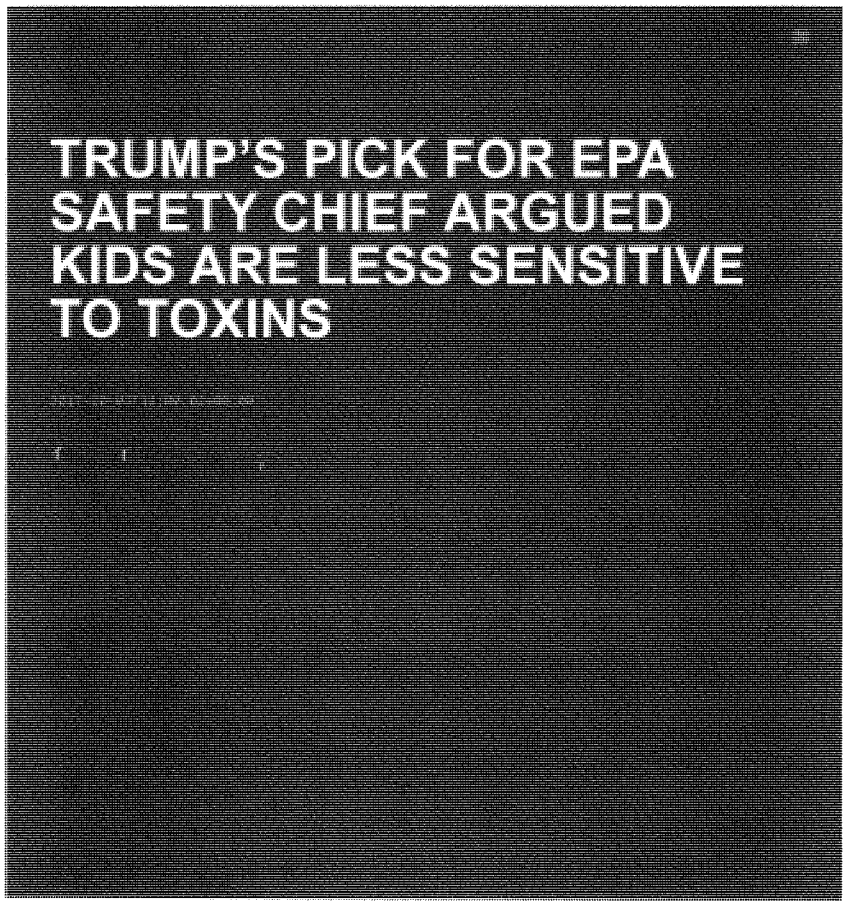


Photo: Wolfgang Kaehler/UPPA/Zuma Press

MICHAEL DOURSON, THE toxicologist who will be the subject of a confirmation hearing on Wednesday for what many consider the second most

powerful post at the Environmental Protection Agency, has been hired by industry to consult on at least 30 of the chemicals he may be responsible for reviewing if he assumes office.

Dourson's consulting company, Toxicology Excellence for Risk Assessment, or TERA, was paid by Dow Chemical, CropLife America, the American Chemistry Council, the American Petroleum Institute, Koch Industries, and other companies and industry groups to study dozens of chemicals. The evaluations TERA produced consistently failed to recognize threats that were clear to scientists and regulators not on the companies' payrolls.

If confirmed as director of the EPA's Office of Chemical Safety and Pollution Prevention, Dourson will be in a position to set safety levels for many of the same chemicals his company was paid to defend, including nine pesticides scheduled for scrutiny and 20 industrial compounds that may be evaluated under the recently updated chemical safety law.

Dourson would also be in a position to make decisions affecting chlorpyrifos, another pesticide he's been paid to research, which can cause memory, intelligence, attention, and motor problems in children. Based on numerous studies that found that very low doses of the pesticide can harm children's brains, the EPA proposed banning chlorpyrifos in 2016. In research paid for by Dow, the manufacturer of chlorpyrifos, Dourson came up with a safety threshold that was some 5,000 times less protective than what the EPA recommended for children between the ages of one and two.

After reversing the proposed ban, EPA Administrator Scott Pruitt recently delayed the evaluation of both chlorpyrifos and other organophosphates, the chemical class to which it belongs, which had been scheduled to begin in 2017. Dourson would have input on the timing of those evaluations, as well as the research considered in them. About two dozen organophosphate pesticides are commercially available, all of which are neurotoxins.

Environmental scientists have long recognized that children are especially

vulnerable to chemicals, including organophosphates, throughout their development. But in a 2002 paper paid for by the American Chemistry Council and the pesticide industry group CropLife America, Dourson suggested that after six months, most children are no more sensitive to chemical toxicity than adults and that in some cases, they are even less sensitive. This idea places him well outside the scientific mainstream and suggests how he might approach not just these pesticides but all chemicals affecting children.



Michael Dourson, nominated by President Donald Trump to oversee the Environmental Protection Agency's chemical safety programs, on Capitol Hill in Washington, Sept. 14, 2017. Photo: Al Drago/The New York Times/Redux

In addition to overseeing pesticides if confirmed, Dourson would be responsible for the implementation of the new Toxic Substances Control Act, which entails

setting safety levels for some of the most dangerous chemicals in use. As the 2016 law required, the EPA has already chosen the first 10 substances to be evaluated. Of those 10, Dourson has been paid to work on three — Trichloroethylene, 1-Bromopropane, and 1,4-Dioxane — and in each case, found them to be safer than independent scientists did.

Often the standards TERA recommended weren't just off, they were wildly off. In the research commissioned by manufacturers of 1-Bromopropane, which the EPA is considering adding to its list of hazardous air pollutants, TERA put forward a safety level that was 67 times higher than one recommended by the National Institute for Occupational Safety and Health. For 1,4-Dioxane, a solvent that harms the liver, kidneys, and nervous system, TERA calculated a safety level that was 1,166 time less protective than that of the EPA.

For PFOA, a chemical used to make nonstick products that has been found in the drinking water of 6.5 million Americans, Dourson helped West Virginia set a state safety standard in 2002 that was 150 times higher than an internal level DuPont itself had set years earlier and 7,500 time higher than the lowest standard set by a state.

TERA consulted on another 17 worrisome chemicals — including lead, arsenic, and the carcinogens chromium and benzene — that the EPA has identified as needing further assessment as part of the Toxic Substances Control Act Work Plan.

In 2015, Dourson and TERA joined the University of Cincinnati and rebranded as the Risk Science Center. Since then, Dourson has co-authored at least one scientific paper with staff of the American Chemistry Council, Dow Chemical, and Exxon.

Dourson and the EPA declined repeated requests to answer questions for this article.

After Dourson's nomination was announced in July, the agency issued a press

release that cited "widespread praise" for the toxicologist from his colleagues. "Dr. Dourson has a can do and winning temperament that inspires confidence," said Gio Batta Gori, who, like Dourson, has consulted for tobacco companies.

Chemical safety advocates say the overlap between Dourson's work and the chemicals under EPA scrutiny isn't surprising. "These companies aren't hiring Dourson if their product is hunky-dory," said Jack Pratt, chemicals campaign director for the Environmental Defense Fund. "He comes in when they've got a fire. Over and over, he's the guy that chemical companies hire when some regulator looks at their products and might potentially set a regulation."

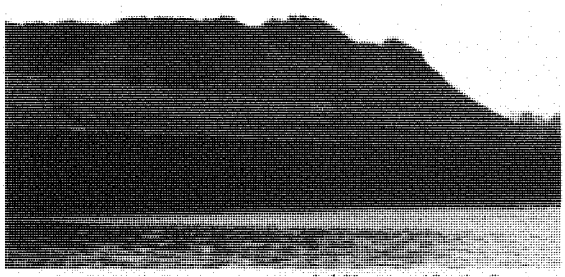
This coziness with industry has led environmental groups to wage a vocal campaign against Dourson, one of four nominees to high-level EPA positions being considered by the Senate's Environment and Public Works committee this week.

"It's simply absurd that industry's go-to science-for-hire guy would now be charged with reviewing the safety of many of the same chemicals he's previously greenwashed," said Scott Faber, senior vice president of the Environmental Working Group, which has dubbed Dourson Mr. Pay to Spray. "It's like putting Philip Morris in charge of the American Lung Association."

Patti Goldman, an attorney at Earthjustice, also strongly opposes his confirmation. But she has already begun focusing on how to limit the harm Dourson could cause if confirmed. "As someone who's been a scientist for hire, Dourson should recuse himself from decisions affecting chemicals he's worked on," said Goldman. "It's impossible for Dourson to be free of bias. What's he going to do, cite his own studies?"

Top photo: A biplane crop dusts a wheat field with pesticide, in Palouse, Idaho, on July 28, 2016.

We depend on the support of readers like you to help keep our nonprofit newsroom strong and independent. **Join Us**



Josh Hopkins / Creative Commons

Piles of petroleum coke along the Calumet River in Chicago in 2013.

EPA toxics nominee provided Koch-funded study in Chicago petcoke battle

WRITTEN BY

Kari Lydersen
September 7, 2017

Advocates concerned about pollution from petroleum coke are worried an Ohio professor's study downplaying the risks

LATEST NEWS



Minnesota project explores solar's role in development along transit line

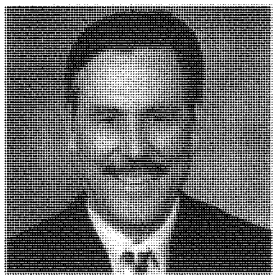


Iowa utility 'repowering' to increase production, efficiency of wind turbines



will gain new prominence now that he has been named to a key EPA post.

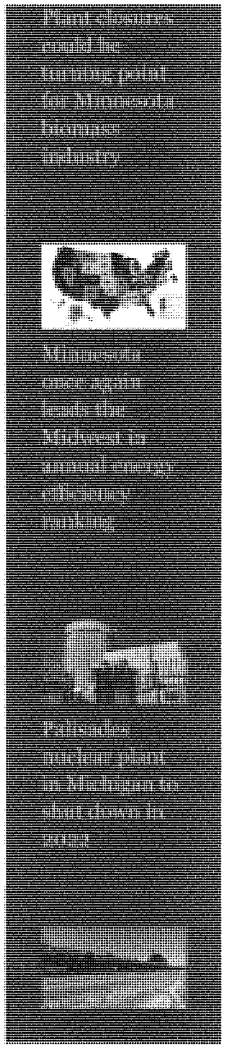
In July President Trump announced his intent to nominate University of Cincinnati environmental health professor Michael Dourson to head the division of the Environmental Protection Agency responsible for chemical safety and enforcing the Toxic Substances Control Act.



Michael Dourson

Environmental and consumer watchdogs quickly raised concerns about Dourson's history working for industry, authoring studies commissioned by DuPont, Dow and other chemical companies and the tobacco industry.

Dourson was also hired by Koch Industries to study the health impacts of petroleum coke (petcoke) in Chicago, with his research starting soon after residents began raising concerns about the piles of



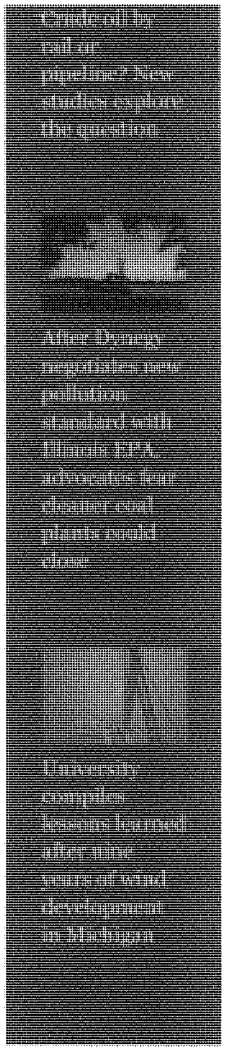
petcoke quickly growing at Koch subsidiary KCBX Terminals on the city's Southeast Side.

The study, funded by Koch Industries and carried out by Dourson and two other scientists paid by Koch, found no risk of adverse health impacts from exposure to petcoke in the air or on surfaces in neighborhoods around KCBX's two petcoke transfer and storage facilities.

One of those has since been closed, and the other one was forced by a city ordinance, following intense community pressure, to stop storing petcoke in the open. But residents are still concerned about petcoke escaping into the air and the Calumet River during the transfer process between barges and trains.

And as they also fight other environmental battles, including around manganese contamination from a facility next to KCBX, Dourson's role in the petcoke battle underscores the odds residents are up against when fighting big business, especially with such an industry-friendly administration in the White House.

"I'm not surprised that this person is being promoted. We've seen it happen on the national scale, we also see it on the local level," said Olga Bautista, a leader of



the Southeast Side Coalition to Ban Petcoke.

"When you fall in line with these industries and people of power, you get rewarded and put in positions that have a lot of influence. And the people who are actually suffering from the pollution have very little recourse. They're calling the shots and deciding what is deemed dangerous and what is not deemed dangerous. When we try to speak for ourselves and defend ourselves, they say we are not experts."

KCBX spokesman Jake Reint provided a statement about Dourson's work for the company, saying: "Dr. Dourson was one of several experts KCBX retained to make sure our bulk material terminals in Chicago were operating in compliance with all rules and regulations, and with respect for the environment and our neighbors. This work included analysis of several years of air monitoring data and tests on more than 100 soil and surface samples collected from the neighborhoods near the KCBX terminals."

Science in the service of industry

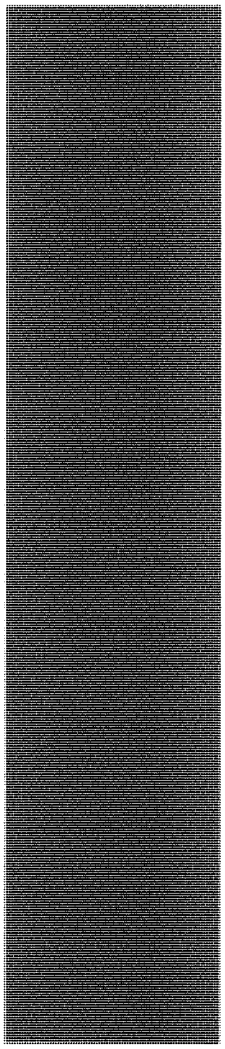
The Environmental Defense Fund and Greenpeace USA are among the groups

raising alarms about Dourson's ties to industry and urging Congress not to confirm his nomination when hearings are convened.

Richard Denison, lead senior scientist for EDF, wrote in a blog post about Dourson's "extensive, longstanding financial ties to the chemical industry – an industry that, if he is confirmed, he will be in charge of regulating. And not only does Dourson have these financial ties to the industry, he has made a career of helping industry play down concerns about chemicals."

Denison said that a review of Dourson's published papers between 2005 and 2017 showed half of those where funding sources were revealed were fully funded by industry, and most were at least partially funded by industry. These studies covered controversial pesticides and other chemicals that are currently undergoing EPA review and which Dourson if confirmed would be in charge of regulating.

After Trump's announcement, The Intercept published a chronicle of how Dourson's work for DuPont helped the company avoid providing clean water to West Virginia residents after the company's chemicals used in making Teflon polluted local groundwater. DuPont later was found liable and ordered



to pay $1.6 million to a woman who developed kidney cancer linked to the contaminated water.

Petcoke study

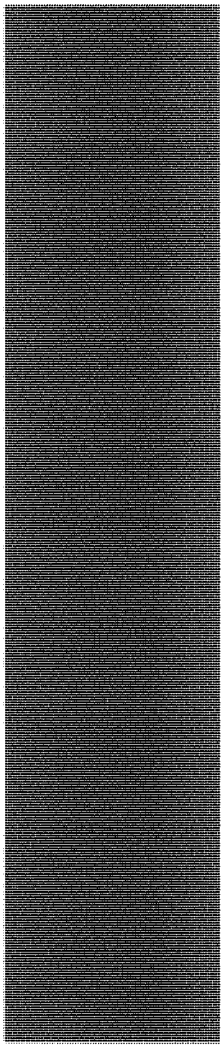
Environmental groups say such a record casts doubt on all of Dourson's work, including the petcoke study in Chicago.

"I certainly wouldn't trust any study he did on its face," said Charlie Cray, a research specialist for Greenpeace USA. "It doesn't mean all the work he's done is suspect or biased, but when it's underwritten by a company like Koch Industries I would be skeptical from the start."

Dourson and his colleagues sought to monitor petcoke in the air around the facilities and accumulated in soil and on surfaces.

Their paper notes that the only significant study to previously examine health impacts of petcoke exposure in humans involved Canadian petroleum workers and found an increased risk of lung cancer. But once smoking and asbestos exposure were accounted for among those workers, Dourson wrote, petcoke was not found to be a risk factor.

Since human studies are lacking, Dourson



used studies in rats to determine what levels of petcoke exposure could be considered harmful. Those studies showed no significant impacts from the chemicals in petcoke, including when petcoke was applied to rats' skin. Exposure to petcoke dust at certain levels was found to cause accumulation of petcoke in the lungs and lung inflammation in rats.

In November 2013 and April 2014, Dourson's team gathered petcoke dust accumulated on surfaces in bus stops, parks and rights-of-way near the Chicago petcoke facilities. The study determined that chemical indicators of petcoke contamination in the soil and on surfaces were no different than baseline accumulation elsewhere in the city.

Inhalation of particulate matter from petcoke has been the main health concern in the area. Particulate matter is known to cause cardiac, respiratory and other health problems regardless of the chemical makeup of the material.

Dourson's study found that based on KCBX's on-site air monitors, the level of PM10 (particulate less than 10 microns in size) dispersed was not likely to cause health impacts. The study concluded that "estimated human exposures, if any, are well below levels that could be anticipated

to produce adverse health effects in the general population."

James Brusslan, an attorney who represented residents in a class action lawsuit that ultimately resulted in a $1.4 million settlement, disputed those results. He cited research commissioned by the city of Chicago and residents' own documentation of petcoke on their property.

"CDM, an environmental expert retained by the city of Chicago, issued several reports which flatly disagreed with the conclusions by Dourson's colleagues and others hired by KCBX that KCBX's operations were having little impact on the neighborhood," Brusslan said. "CDM determined that KCBX's periphery fence line monitoring was inconclusive, that its bulk sample testing had no persuasive value and that any air modeling performed in the area was unpredictable. As residents could see with their own eyes, dust from KCBX's facility inundated the neighborhood for years."

CDM's criticisms of Dourson's study include a finding that petcoke dust could migrate off the site into residential areas without being logged by the company's on-site air monitors, since it might settle on the ground and later be lifted into the air. CDM argued that Dourson's study did

not involve monitors between the company fence-line and the nearest residences, and found that PM10 impacts on nearby neighborhoods could be "substantially greater" than Dourson allowed.

Implications

By the time Dourson's study was officially published in May 2016, KCBX had already been ordered to remove its open piles of petcoke and the class action lawsuit was being settled. Brusslan said that Dourson's co-author Lyle Chinkin was involved in the lawsuit proceedings. The study notes that Chinkin, along with Dourson and co-author David MacIntosh, were "retained experts for litigation purposes" for Koch, and "Koch Industries was involved in the problem formulation phase of this research."

Dipro Bhowmik, a researcher for Greenpeace, analyzed Dourson's research record and related policy developments in different areas. He theorized that since Koch Industries was forced to stop storing petcoke in Chicago, and had previously been forced to stop storage in Detroit, the company may hope to use Dourson's findings to combat opposition in other cities or states where it seeks to store petcoke.

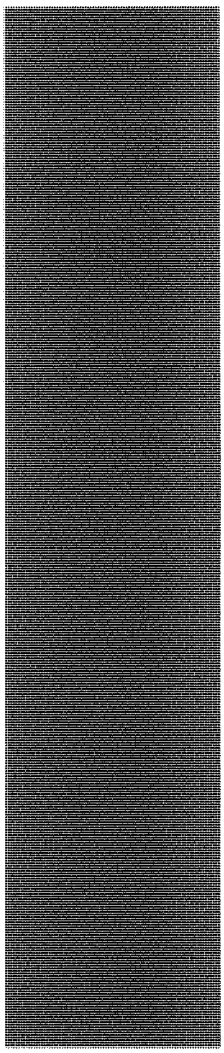
"It builds that cache of research that absolves petcoke of health impacts, so in the next community that's impacted, the industry is protected," Bhowmik said.

Public health and environmental watchdog groups have long complained that studies funded by industry are entered into the public and legal record as independent research.

KCBX portrayed Dourson's research this way, including in a statement the company made at the time of the class action lawsuit, saying that: "Independent laboratories also have conducted tests on more than 100 soil and surface samples from the neighborhoods near the terminal and found no evidence of coal or petcoke dust."

Bautista noted that community residents have partnered with universities and non-profit organizations to do their own data collection and studies, including using balloons for aerial mapping and systematic air testing.

"We've been using DIY methods for collecting data since the onset of this problem, which was absolutely crucial in how far we've gotten," said Bautista. "We can be experts in these fields because we're the ones who are impacted the most, and we have the most to gain from having

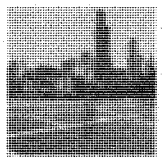


this information available."

FILED UNDER:

NEWS | CHICAGO | EPA | POLLUTION

READ NEXT



Chicago town hall urges communities to take advantage of solar incentives

Almost a year after Illinois enacted a sweeping energy bill, Chicago-area developers, advocates, and government agencies are hustling to prepare local communities to take full advantage of state incentives coming in the next few years.

Senator CARPER. Some of you have been in this room before, some of you several times. I joined this Committee almost 17 years ago, and I have sat through a lot of hearings. Senator Inhofe has sat through more. Our Chairman has sat through a bunch of them, too.

This has been an extraordinary hearing. Extraordinary hearing. And these decisions that we are going to make, that you would make, if confirmed, are really life and death decisions. No question. And you have witnessed, in some cases, an outpouring of emotion, almost fear about what your service, not all of you, but some of you, what your service might lead to.

And I just want to say, Dr. Dourson, I try to treat other people the way I want to be treated. I met with you, and I appreciate the time you spent with me, and I care about surrounding myself with people who have good mind, also a good heart, and there is no question you have a good mind. You are well educated. You are a scientist. You are smart.

I think what we are hearing from the Senators on our side, there is a question about your heart. And I don't mind people saying to me that they think I am dumb. I don't like it, but what really hurts me is when they question my heart. And there are really serious questions about your heart.

A woman named Maya Angelou, now deceased, a great poetess. She used to say these words. She used to say, people won't remember what you said. People may not remember what you do or did. They will always remember how you made them feel. They will always remember how you made them feel.

And honestly, some of the people in this audience here that have lived through exposure of materials that we are talking about, they are afraid. They are afraid. And they represent a lot of other people as well. And I am afraid what you said here today does not diminish those concerns or those fears. I just have to say that to you.

Thanks very much.

Mr. DOURSON. Thank you, Senator.

Senator BARRASSO. Thank you, Senator Carper.

Thanks to all of the members.

I am going to submit for the record a final letter from Sean Alteri, who is the Director of Kentucky Division of Air Quality, stating that "Considering his education," regarding Mr. Wehrum, "his education and experience as a chemical engineer and environmental attorney, Mr. Wehrum will be well positioned to provide clear, concise director to address the many diverse, complex air quality issues." He goes on to say, "As a study of the Clean Air Act, Mr. Wehrum's knowledge and experience will greatly benefit EPA, State, and local air pollution control agencies."

Without objection, that will be submitted.

[The referenced information follows:]

MATTHEW G. BEVIN
Governor

CHARLES G. SNAVELY
Secretary

ENERGY AND ENVIRONMENT CABINET
DEPARTMENT FOR ENVIRONMENTAL PROTECTION

AARON B. KEATLEY
Commissioner

300 SOWER BOULEVARD
FRANKFORT, KENTUCKY 40601

September 18, 2017

The Honorable John Barrasso
Chairman, Senate Committee on Environment & Public Works
410 Dirksen Senate Office Building
Washington, DC 20510-6175

Dear Senator Barrasso,

Through this letter, I am formally offering support for the nomination of Mr. William L. Wehrum as the Assistant Adminstrator of EPA's Office of Air and Radiation. Considering his education and experience as a chemical engineer and an environmental attorney, Mr. Wehrum will be well-positioned to provide clear, concise direction to address the many diverse, complex air quality issues. As a student of the Clean Air Act, Mr. Wehrum's knowledge and experience will greatly benefit EPA, state, and local air pollution control agencies.

The Kentucky Division for Air Quality supports Mr. Wehrum's nomination to serve as the Assistant Administrator of EPA's Office of Air and Radiation.We look forward to working with Mr. Wehrum and EPA's senior leadership to continue the great improvement of air quality in Kentucky and throughout our nation.

Sincerely,

Sean Alteri

Sean Alteri, Director
Division for Air Quality

Senator BARRASSO. Finally, with regard to the Nuclear Regulatory Commission and the issues of NEPA and licensing, I find the position that the nominee today has taken deeply troubling and outside the mainstream. I think it is just tailor made to those looking to delay the NRC's licensing process indefinitely and to stop nuclear energy production from going forward in the United States, and I believe we need all the sources of energy.

Finally, Mr. Ranking Member, if no one else has questions today, members are going to be able to submit written follow up questions for the record. We will do it by the close of business on Friday. The nominees will then respond to those questions by the close of business Thursday, October 12th.

So, I want to thank each of the nominees, commend you, and congratulate you on the nominations, and the hearing is adjourned.

[Whereupon, at 12:58 a.m. the Committee was adjourned.]

[Additional material submitted for the record follows:]

Audubon FLORIDA

4500 Biscayne Blvd.
Suite 350
Miami, FL 33137
Tel: 305-371-6399
www.fl.audubon.org

September 19, 2017

The Honorable John Barrasso
Chairman, Environment and Public Works Committee
United States Senate

The Honorable Thomas Carper
Ranking Member, Environment and Public Works Committee
United States Senate

RE: Appointment of Matthew Leopold as General Counsel, Environmental Protection Agency

Dear Chairman Barrasso and Senator Carper,

Please accept my comments as you consider the qualifications of Matthew Leopold for appointment as General Counsel, Environmental Protection Agency. I direct Florida's largest and most respected conservation organization and have worked with and observed Mr. Leopold over several years. He has a good legal mind, strong leadership skills, and knows how to work with different interests to bring resolution to complicated issues.

During Mr. Leopold's tenure at the Florida Department of Environmental Protection, I worked closely with the department on resolution of Everglades water quality issues necessary to settle federal litigation. Being directly involved, I saw that the state was successful in negotiating with USEPA a plan that allowed agreement on and eventual legislative approval of a program called "Restoration Strategies" to create remedies to meet Everglades water quality criterion.

It was also during that work that Mr. Leopold approached me to encourage Audubon's involvement in the State of Florida's efforts to litigate a resolution to the ongoing conflict between Florida and Georgia on interstate water use. I thought then, and continue to think, that the case and the State's involvement reflected strategic insight and ambition to deal with an extraordinary set of legal issues.

I further gained respect for Mr. Leopold because he recognized that environment stakeholders had interests in common with the State and could be enlisted to help further Florida's case. Later, when Mr. Leopold was representing Florida in the case as a private attorney, he again encouraged our involvement, and Audubon became the lead on an amicus curiae brief that added considerable evidence to the State's case.

When I heard that Mr. Leopold was being considered for the position of General Counsel at USEPA, I was glad to offer my enthusiastic support. The agency and nation are facing serious challenges as rules and programs evolve to meet changing circumstances and views on the role of government regulation. We need good lawyers at USEPA who understand the importance of bringing people together to solve problems. I urge approval of his appointment.

Sincerely,

Eric Draper
Executive Director

We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

EPA United States Environmental Protection Agency

News Releases from Headquarters › Office of the Administrator (AO)

Widespread Praise for Matt Leopold

Leopold Nominated as EPA General Counsel

09/02/2017

Contact Information:
(press@epa.gov)

WASHINGTON - Yesterday, President Donald J. Trump announced his intent to nominate Matt Leopold to serve as general counsel for the U.S. Environmental Protection Agency. Mr. Leopold previously served as general counsel for Florida Department of Environmental Protection from March 2013 to February 2015 and as an attorney for the United States Department of Justice Environment and Natural Resources Division from January 2007 to February 2013. He is currently of counsel for Carlton Fields Jorden Burt, P.A. focusing on environment, energy, water law, and litigation.

His nomination is receiving high accolades from environmental leaders across the country:

Marco Rubio, United States senator: "Matt Leopold's experience and knowledge will serve EPA well, and I'm glad the president nominated a Floridian who understands the importance of our state's vast ecosystems to our economy and residents' quality of life."

Pam Bondi, attorney general of Florida: "Matt Leopold was a great asset to the Florida Department of Environmental Protection and I look forward to him working together with my friend Scott Pruitt."

Adam Putnam, Florida commissioner of agriculture: "I'm thrilled to see another Floridian joining President Trump's Administration. After eight years of increased regulations and fees under President Obama, with little to nothing to show for it, I'm grateful for folks like Matt Leopold, who bring a wealth of expertise and experience to Washington, as well as a common sense approach to protecting our environment, while enabling our economy to grow and thrive."

John Cruden, president-elect of the American College of Environmental Lawyers and Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice (12/2014-1/2017): "Matt Leopold was a valued colleague of mine at the Department of Justice. He is committed to the rule of law and can be counted on to give sound and candid advice to EPA decision makers."

Eric Draper, executive director, Florida Audubon: "He has a good legal mind, strong leadership skills and knows how to work with different interests to bring resolution to complicated issues. During Mr. Leopold's tenure at the Florida Department of Environmental Protection, I worked closely with the department on resolution of Everglades water quality issues necessary to settle federal litigation. Being directly involved, I saw that the state was successful in negotiating with USEPA a plan that allowed agreement on, and eventual legislative approval of, a plan called 'Restoration Strategies' to create remedies to meet Everglades water quality criterion."

Eric Eikenberg, chief executive officer, The Everglades Foundation: "Few attorneys in America are as familiar with the legal issues – and importance – of Everglades restoration as is Matt Leopold, and I heartily applaud his nomination to be the next general counsel of EPA. Our paths have crossed often in the 12 years since I first met Matt. I respect him as an attorney and a person of integrity. He understands the importance of America's Everglades and the critical need for restoration. Matt will serve Florida and our nation well, and I look forward to working with him and EPA to ensure America's Everglades are protected and restored."

Ethan Shenkman, EPA deputy general counsel (05/2014-01/2016) and DOJ deputy assistant attorney general, Environment and Natural Resources Division (03/2010-05/2014): "During the Obama Administration, I served in the DOJ environmental division and then at EPA. During that time, I had the opportunity to work closely with Matt Leopold on a number of environmental issues, where we crafted creative and responsible legal solutions to protect the environment, especially relating to the State of Florida where Matt served as general counsel of the Florida Department of Environmental Protection. In addition to his legal acumen and broad knowledge of environmental law, I believe Matt's previous experience as a well-respected career attorney at ENRD will serve him well should he be confirmed, and will enable him to foster a productive working relationship with the talented and dedicated career staff in EPA's legal shop."

Herschel Vinyard, co-chair, Gulf Coast Ecosystem Restoration Council; secretary, Florida Department of Environmental Protection (01/2011-12/2014): "The first thing that the nation will learn about Matt Leopold is his unassailable integrity. The second thing the nation will learn about Matt Leopold is his unwavering commitment to following the law. I have seen firsthand how he brings those two key traits to the table, applies common sense and arrives at the ideal solution to complex problems. Kudos to the Trump Administration and Administrator Pruitt for making this selection."

LAST UPDATED ON SEPTEMBER 2, 2017

We've made some changes to EPA.gov. If the information you are looking for is not here, you may be able to find it on the EPA Web Archive or the January 19, 2017 Web Snapshot.

News Releases from Headquarters › Office of the Administrator (AO)

Widespread Praise From Environmental Officials for David Ross

Ross Nominated to Head EPA Office of Water

09/02/2017

Contact Information:
(press@epa.gov)

WASHINGTON - President Donald J. Trump announced yesterday his intent to nominate David Ross to serve as assistant administrator for the U.S. Environmental Protection Agency's Office of Water. Mr. Ross currently serves as Wisconsin assistant attorney general and director of the Environmental Protection Unit for the Wisconsin Department of Justice. As Wisconsin assistant attorney general, he is responsible for managing the environmental litigation unit which prosecutes violations of state environmental and natural resources laws and defends administrative decisions and rules issued by the Wisconsin Department of Natural Resources. Mr. Ross previously served in the Wyoming Attorney General's Office from 2014-2016 as senior assistant attorney general and as a member of the Water and Natural Resources Division.

His nomination is receiving high accolades from environmental leaders across the country:

David Freudenthal, former governor of Wyoming: "Dave Ross is first and foremost an excellent, pragmatic lawyer. His private practice experience in DC combined with his service in two state environmental protection agencies make him uniquely qualified to implement America's nuanced structure of federal and state environmental protection."

Misael Cabrera, director, Arizona Department of Environmental Quality: "Mr. Ross has exceptional credentials and experience for the role of Water Director. In addition, his views on cooperative federalism are exactly what is needed at US EPA."

Carol Comer, director of the Missouri Department of Natural Resources: "The Missouri Department of Natural Resources would welcome the opportunity to work with Dave on our critical water issues. He has valuable experience with complex, multi-state policy decisions, and he understands the infrastructure challenges and needs of states like Missouri that have a significant number of small communities."

David Glatt, chief, North Dakota Department of Health, Environmental Health Section: "Mr. Ross exhibits an excellent understanding of western water issues and challenges faced by rural states and tribal nations. His knowledge and work experience coupled with his willingness to pursue a renewed approach to cooperative federalism make him an excellent candidate for the position."

Elliott Laws, Crowell and Moring LLP, former assistant administrator of EPA's Office of Solid Waste (Clinton): "I know David Ross to be smart, innovative and practical in all of his professional dealings. I fully expect him to bring those qualities with him to the Office of Water."

Todd Parfitt, director, Wyoming Department of Environmental Quality: "Mr. Ross possesses the necessary tools to effectively and appropriately oversee EPA's Water program in a fair, balanced and practical way. He has demonstrated his ability to objectively analyze and consider inputs from all points of view and formulate a fair and reasoned approach resulting in clear and concise decisions."

Steve Quarles, attorney at Nossaman LLP, former deputy under secretary of the U.S. Department of the Interior (Carter): "I have worked with Dave for many years as law firm partners. Dave's greatest skill may be leading people with diverse views and interests to common ground. People with such diverse views and interests naturally gravitate to Dave and look to him for leadership. This happens because Dave is highly intelligent, both in mastering issues and devising innovative solutions, and is an excellent listener, encouraging all to participate. He also has exhibited masterful administrative skills – from leading informal cohorts of private attorneys through complex decision making to managing high performing public offices."

Gary Rikard, director, Mississippi Department of Environmental Quality: "I believe Dave Ross would be an excellent addition to EPA's Office of Water. His experience and real world view in working for two different states would enhance this administration's goal of improving cooperative federalism and building relationships between EPA and the states in administering environmental regulations and policy. That perspective, along with his environmental experience and legal background, will be an asset for the Agency."

Matthias Sayer, deputy cabinet secretary, New Mexico Energy Minerals and Natural Resource Department: "We out west are beyond satisfied with the appointment of Mr. Ross as the assistant administrator for Water. Mr. Ross has a full understanding of those statutes aimed at protecting our water, coupled with a full understanding of how those statutes can and do impact state and local communities. Furthermore, through his boots on the ground experience, Mr. Ross has gained an appreciation for the important role states play, both in the east and dryer west, in protecting our water, and he understands that it is by working in cooperation with the states that the greatest degree of success in this important program will be achieved."