

Message

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**From:** Jackson, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38BC8E18791A47D88A279DB2FEC8BD60-JACKSON, RY]  
**Sent:** 8/24/2018 6:46:06 PM  
**To:** Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]  
**CC:** Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]  
**Subject:** Re: Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

# Deliberative Process / Ex. 5

Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

On Aug 24, 2018, at 2:41 PM, Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)> wrote:

# Deliberative Process / Ex. 5

Sent from my iPhone

On Aug 24, 2018, at 2:13 PM, Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)> wrote:

# Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

On Aug 24, 2018, at 1:36 PM, Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)> wrote:

Ryan –

## Deliberative Process / Ex. 5

Molly

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**From:** Grantham, Nancy  
**Sent:** Friday, August 24, 2018 1:33 PM  
**To:** Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>  
**Cc:** Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)>  
**Subject:** RE: Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

## Deliberative Process / Ex. 5

**Nancy Grantham**  
**Office of Public Affairs**  
**US Environmental Protection Agency**

Personal Matters / Ex. 6 (desk)  
Personal Matters / Ex. 6 (mobile)

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**From:** Jackson, Ryan  
**Sent:** Friday, August 24, 2018 12:53 PM  
**To:** Konkus, John <konkus.john@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>  
**Subject:** Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

Did we even get asked to comment on this?

<https://www.nytimes.com/2018/08/24/business/epa-pesticides-studies-epidemiology.html?action=click&module=Top%20Stories&pgtype=Homepage>

## **Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science'**

Backed by agrochemical companies, the current administration and Congress are moving to curb the role of human health studies in regulation.

Aug. 24, 2018



A strawberry field in California's Salinas Valley, where a yearslong study, funded in part by the Environmental Protection Agency, has linked pesticides to ailments in children of farm workers. Carlos Chavarria for The New York Times

SALINAS, Calif. — José Camacho once worked the fields here in the Salinas Valley, known as “the Salad Bowl of the World” for its abundance of lettuce and vegetables. His wife still does.

But back in 2000, Mr. Camacho, who is 63, got an unusual phone call. He was asked if he wanted to work for a new project studying the effects of pesticides on the children of farm workers.

“This seemed really crazy,” he recalled saying at the time, since he barely spoke English. “A research study?”

The project, run by scientists from the University of California, Berkeley, and funded in part by the Environmental Protection Agency, is still going all these years later. Known as Chamacos, Spanish for “children,” it has linked pesticides sprayed on fruit and vegetable crops with respiratory

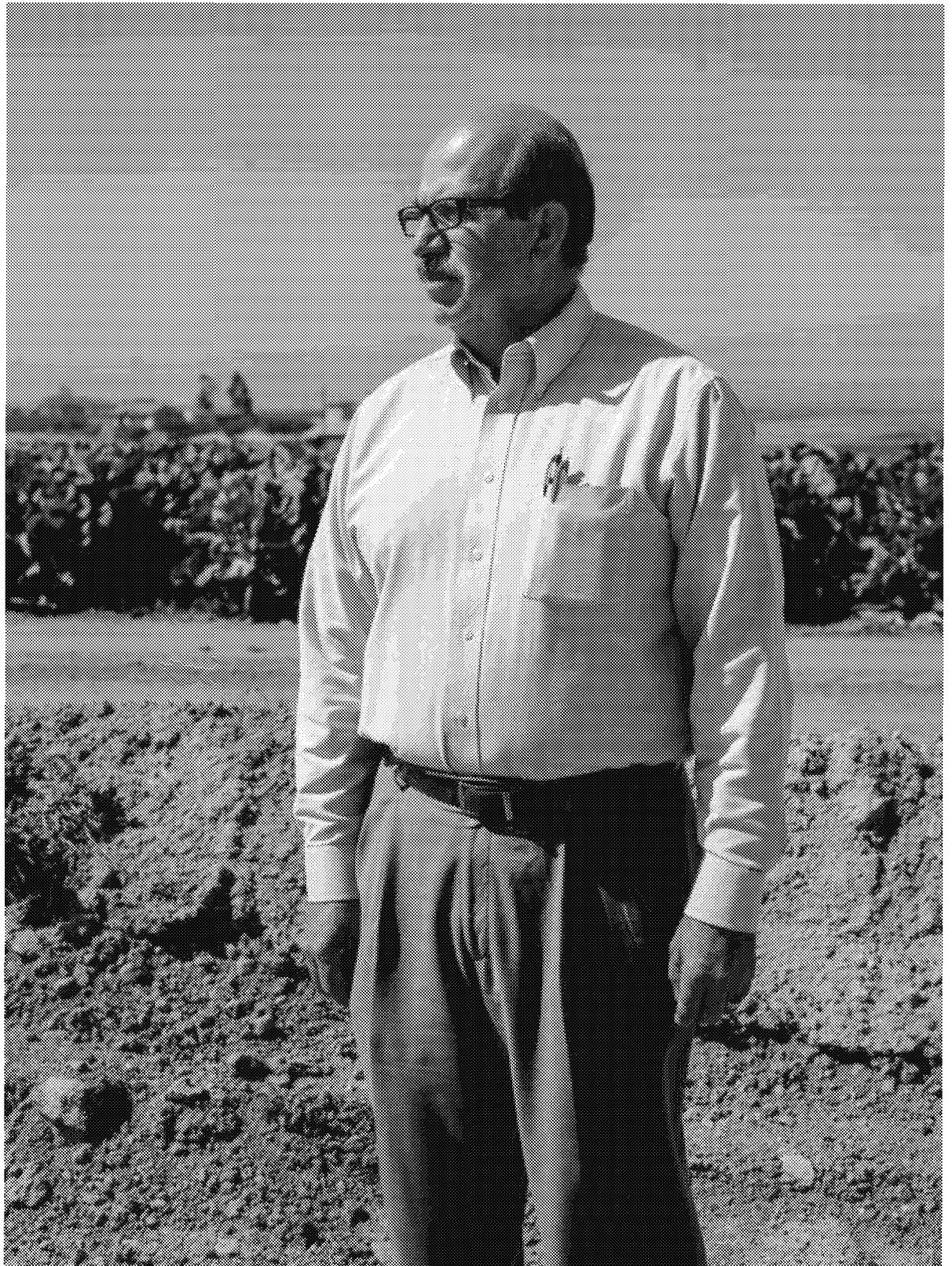
complications, developmental disorders and lower I.Q.s among children of farm workers. State and federal regulators have cited its findings to help justify proposed restrictions on everything from insecticides to flame-retardant chemicals.

But the Trump administration wants to restrict how human studies like Chamacos are used in rule-making. A government proposal this year, called Strengthening Transparency in Regulatory Science, could stop them from being used to justify regulating pesticides, lead and pollutants like soot, and undermine foundational research behind national air-quality rules. The E.P.A., which has funded these kinds of studies, is now labeling many of them “secret science.”

Studying disease trends in specific groups of people — a branch of medicine known as epidemiology — started to gain currency at the E.P.A. in recent years. These studies can be difficult because they require adjusting for all the various substances people are exposed to beyond pesticides. But researchers had amassed years of data from a wave of compelling chemical studies begun in the 1990s, giving regulators a new body of research to incorporate into their decision-making.

Under the Obama administration, the E.P.A., which had long favored tests on rats and other laboratory animals in its pesticide regulation, began considering epidemiological studies more seriously. The agency leaned on this type of research in proposing to ban an insecticide called chlorpyrifos in late 2016, and has been repeatedly prodded to take action on the chemical by federal courts.

But weeks after Donald J. Trump was elected president, CropLife America, the main agrochemical trade group, petitioned the E.P.A. to “halt regulatory decisions that are highly influenced and/or determined by the results of epidemiological studies” unless universities were forced to share more of their data.



José Camacho was asked in 2000 to participate in the study, which tracks families as they go about their normal lives. Such research was embraced by the E.P.A. during the Obama administration. Carlos Chavarría for The New York Times

Industry leaders aggressively challenged such studies in high-level meetings and emails with E.P.A. leaders, according to thousands of pages of documents obtained through Freedom of Information Act requests. One trade group invited a top E.P.A. official to meet with its Washington lobbyist last year, complaining that “carefully controlled” animal studies were giving way to “conclusions reflected in epidemiological papers.”

Gary W. Van Sickle, executive director of the California Specialty Crops Council, wrote to the agency last September that “there have been serious flaws with E.P.A.’s conclusion to use these data.”

The council, representing growers of crops as diverse as carrots, garlic, pears and peppers, cited “inappropriate use of the epidemiology.”

The E.P.A., whose new leadership is seeded with industry veterans, has responded. In a mid-July assessment of atrazine, a widely used weed killer long banned in Europe, the agency reviewed and dismissed 12 recent epidemiological studies linking the herbicide to such ailments as childhood leukemia and Parkinson’s disease. It echoed the conclusions of research funded by Syngenta, atrazine’s manufacturer, finding the chemical unlikely to cause cancer.

Before scandals forced Scott Pruitt out last month as head of the E.P.A., he proposed the transparency regulation. It would ban many epidemiological studies, and other outside research, unless more data behind the studies was made public. In doing so, he revived a strategy advanced for years by congressional Republicans and corporate interests like tobacco companies.

“The era of secret science at E.P.A. is coming to an end,” Mr. Pruitt proclaimed at the time. The agency’s new acting administrator, Andrew R. Wheeler, says he’s moving forward with the proposal, as the agency re-evaluates a class of widely used insecticides, called organophosphates, that have been the subject of numerous epidemiological studies like Chamacos.

Nancy B. Beck, a chemical industry veteran who is the E.P.A.'s deputy assistant administrator, said there was no attempt to thwart epidemiology, adding that the agency was committed to "the best available science in the most transparent manner."

But academics and state health officials say universities are being pressured to release data that would ultimately divulge the identities of study participants, a strategy once used by tobacco companies seeking to undermine research on the dangers of smoking. While participant data is shared with regulators in drug trials, academics fear that the E.P.A.'s proposal would additionally require divulging confidential personal information, potentially violating privacy regulations for federally funded research.



Ana Lilia Sanchez, a farm worker and the mother of a participant in the Salinas Valley study, said her family took precautions to avoid pesticide contamination. Carlos Chavarría for The New York Times

"It is a naked attempt to use a false claim that something nefarious is going on with these studies in an effort to allow industry to challenge conclusions that are not in their favor,"

said James Kelly, a manager of environmental surveillance at the Minnesota Department of Health.

## **A Wave of Studies, an Uneasy Industry**

An advertisement in a Nebraska student newspaper was looking for people who wanted to “earn extra money.” Thirty-six college student volunteers and others from the community who responded were paid \$460 to drink gelatin capsules filled with the pesticide chlorpyrifos, at up to 300 times levels the E.P.A. considered safe, without a full discussion of the risks.

Sponsored by Dow Chemical, this study, conducted in 1998, was one of the last of its kind. That year, the E.P.A. banned the use of studies exposing people to pesticides, and it continues to severely restrict them.

Epidemiology, which has been used to examine everything from the effects of climate change to childhood obesity, offered a way to continue studying disease trends, amid new legal requirements to examine how pesticides particularly affect infants and children. And it could do so by tracking people during their normal lives instead of treating them as if they were lab rats. Chamacos and other studies began almost immediately, although it took decades to collect sufficient data and study how participants changed over time.

One study by Columbia University researchers linked an insecticide to developmental delays in toddlers. Another, by scientists at the University of California, Los Angeles, connected pesticides to Parkinson’s disease. Academics at the University of Rochester found that pesticides lower sperm counts in men, while researchers from the Harvard School of Public Health found lower fertility in women.

By 2015, there was a growing body of research, often funded in part by the E.P.A. The agency decided that year to consult epidemiology more seriously in its evaluation of glyphosate, the world’s most popular weed killer and the active ingredient in Monsanto’s Roundup.

“This is a watershed event in our Program, and one which I feel particularly proud to be a part (go epi!),” Carol Christensen, then an E.P.A. epidemiologist, wrote in a 2015 email to a colleague — using “epi” as shorthand for epidemiology. “In the 35 year history of our program, this will be the FIRST time epi studies are actively considered in the decision making.”

Yet even then, there was friction over what to make of studies aiming to determine whether glyphosate causes cancer.

One E.P.A. division, the Office of Research and Development, closely examined epidemiological research and came to believe either that glyphosate was likely to cause cancer or that there was at least some evidence suggesting a problem. But another division, the Office of Pesticide Programs, was dismissive of epidemiological studies and determined that glyphosate was not a carcinogen, a view that prevailed at the E.P.A., according to interviews, emails and an internal memo obtained by The New York Times. Those involved in the agency’s debates on epidemiology spoke on the condition of anonymity because the discussions weren’t public.

Monsanto said in a statement that “we cannot speak to the internal E.P.A. discussions” but emphasized the agency’s ultimate finding that glyphosate was not likely to cause cancer.

The cancer question received renewed attention this month when a California jury awarded \$289 million to a groundskeeper who alleged that the chemical had sickened him. In his closing argument, the plaintiff’s attorney, R. Brent Wisner, called epidemiology one of “the three pillars of cancer science” that the case relied on.

At the E.P.A., the debate swung in favor of epidemiology. While such studies are often complex and can be of varying quality, the agency was reluctant in the past to give them as much weight as lab experiments on animals. But by the Obama administration’s final months, the agency moved for

the first time to ban a pesticide largely because of epidemiological research.

The pesticide, chlorpyrifos, was the same one ingested years earlier by unwitting Nebraskans. It is applied to crops like apples, oranges and strawberries to combat insects like spider mites and sap-sucking bugs.

In California alone, chlorpyrifos was sprayed on 640,000 acres in 2016, according to state data. And research from Salinas, and the Chamacos study, became a central element in the E.P.A.'s recommendation.

“There is a breadth of information available on the potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos,” the agency concluded in 2016, also citing epidemiological research from Columbia University and the Icahn School of Medicine at Mount Sinai.

The pesticide industry's reaction was loud and intense.

Monsanto, in emails with the E.P.A., was dismissive of critical epidemiological research related to Roundup, writing that “such studies are well known to be prone to a number of biases.”



A Trump administration proposal would prevent the E.P.A. from using many epidemiological studies, like the one in Salinas, unless more data behind them was made public. Carlos Chavarría for The New York Times

Dow Chemical said in reports submitted to the E.P.A. that “the evidence from these studies is insufficient” and called chlorpyrifos a “proven first-line of defense” against new pest outbreaks.

A month after taking over the E.P.A., Mr. Pruitt acted. He disregarded agency scientists and rejected the proposed chlorpyrifos ban, later calling for “a new day, a new future, for a common-sense approach to environmental protection.”

## **View From the Field**

Ana Lilia Sanchez, 50, has worked in the fields in Salinas more than half her life, and one of her daughters has been a Chamacos study participant.

Ms. Sanchez has learned to watch for drifting droplets or the whirl of a helicopter spraying overhead.

“Sometimes when we feel it, or we hear it, we start talking about it,” she said recently, sitting with her 5-month-old granddaughter at her home on a Salinas cul-de-sac. “Why wouldn’t they tell us, you know, to get out of here, to not come today?” she asked. “Women, they cover themselves, but men are working in short sleeves, so they are more exposed.”

Insecticides like chlorpyrifos are organophosphates, from the same chemical family as nerve agents like sarin and Novichok, the Russian-developed compound linked to recent attacks in Britain. While the safety of insecticides is extensively tested, long-term health impacts, or even how far pesticides drift, are the subject of continuing disagreement.

Ms. Sanchez showers after work, before touching her granddaughter.

“I also put my clothes aside,” she said. “We separate the clothes we use when we’re working, both my husband and I, and wash them separately so they’re not contaminated.”

While some human studies examine potential harm from pesticide residue found on fruits and vegetables, the Chamacos project is more personal, following hundreds of children in the heart of where American food is grown. California has the nation’s largest agricultural industry and uses more than 200 million pounds of pesticides annually.



Brenda Eskenazi, the director of the Salinas Valley project, said that “well-controlled epidemiologic studies” were

essential for understanding “how things affect human health.” Carlos Chavarría for The New York Times

For locals, pesticides are part of life. “It’s a big difference from when I was working,” Mr. Camacho said, while standing in a strawberry field framed on three sides by distant hills. Men and women were bent over nearby, pulling weeds. “My supervisor would say: ‘That’s not dangerous. Just keep working.’ There was no information.”

Chamacos is built on an unsettling premise: What happens to children of pregnant mothers certain to have pesticides in their bloodstreams? The E.P.A. and other government agencies have spent millions of dollars funding Chamacos.

Half the Chamacos children have been tracked since before birth. Researchers have collected 350,000 samples of blood, urine, breast milk and even household dust and spent nearly two decades studying maturing children. They perform neurodevelopmental and physical assessments and study factors like diet and school performance. After nearly two decades, the study’s data appears in more than 160 academic papers.

During a visit to the Chamacos office in Salinas, Brenda Eskenazi, the director of the project and a professor of epidemiology at Berkeley, was testing out brain monitoring equipment, wearing what looked like a black swim cap strewn with knobs and wiring. She has long been fascinated with cognitive development, going back to when she saw a Woodstock reveler — one having a bad acid trip — dive into pavement.

“Why did he do that?” Ms. Eskenazi remembers wondering at the time. “What was he thinking? What’s going on in that brain?”

“Any science is imperfect,” she said, but stressed that “well-controlled epidemiologic studies” were essential for understanding “how things affect human health.” She added,

“Otherwise you’re just making huge assumptions that a rodent is the same as a human.”

## A Bitter Debate

The day after Mr. Pruitt made his March 2017 decision to reject a ban on chlorpyrifos, he hosted top executives from one of the nation’s largest farming and pesticide trade organizations for a closed-door conversation.

Near the top of the meeting agenda was “Epidemiology Study Policy” in the aftermath of the “chlorpyrifos matter,” according to internal records.



McKinnon Elementary School in Salinas. The pesticide industry contends that epidemiological studies are prone to biases and not as reliable as testing on lab animals. Carlos Chavarría for The New York Times

“There are no guideposts, if you will, for what is a legitimate, useful epidemiology study and what is not,” Jay Vroom, CropLife America’s president, said in an interview, explaining what he had told agency officials at this and other meetings.

In a subsequent letter to the E.P.A., a CropLife America lobbyist said the agency was relying on a “shortsighted approach,” and the group submitted formal proposals to curb the embrace of epidemiology the E.P.A. undertook under the Obama administration.

Mr. Pruitt responded with his proposal, made this past spring, to ban epidemiological and other studies that did not make study details public, including at least some information on study participants.

Academics have resisted previous requests to review their data, notably at Columbia University. In a 2016 letter to the agency, a university official wrote that it could not provide “extensive individual level data to E.P.A. in a way that ensures the confidentiality” of “our research subjects.”

David Michaels, an epidemiologist at George Washington University’s School of Public Health and head of the Occupational Safety and Health Administration during the Obama administration, said Mr. Pruitt’s plan was not about transparency but about discrediting studies that made pesticides look bad.

“The underlying justification for this ‘transparency’ proposal is a caricature of how science really works,” Mr. Michaels said at a recent hearing. “The cynical approach proposed by E.P.A. can be best described as ‘weaponized transparency.’”

It is no coincidence, he said, that the term “secret science” was also used in the 1970s when the tobacco industry was trying to forestall critical research about smoking.

Researchers have had wins. This month, a federal appeals court ordered the E.P.A. to ban chlorpyrifos, citing findings from human studies. The Trump administration is mulling whether to appeal.

But epidemiologists are unsettled. In mid-July, after nearly two decades of work on Chamacos, the E.P.A. emailed Ms. Eskenazi requesting “the original data” from her research,

citing “uncertainty around neurodevelopmental effects associated” with pesticides she has studied. The agency made a similar request to Columbia.

Ms. Eskenazi, worried about her study participants’ privacy, alerted university lawyers. She is now concerned that the E.P.A. may try to undermine her study’s repeated findings that some pesticides may be harming children.

“I knew this was going to come sooner or later,” she said. “And here it is.”

Danny Hakim reported from Salinas, and Eric Lipton from Washington.

## **The All-New DealBook**

**Our columnist Andrew Ross Sorkin and his Times colleagues help you make sense of major business and policy headlines — and the power-brokers who shape them.**

**More in Business Day**



Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

Message

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**From:** Bowman, Liz [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3D4D94D3E4B4B1F80904056703EBC80-BOWMAN, ELI]  
**Sent:** 4/24/2018 6:03:22 PM  
**To:** Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]  
**CC:** Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Letendre, Daisy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b691cccca6264ae09df7054c7f1019cb-Letendre, D]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]  
**Subject:** RE: For Review: Science Transparency News Release  
**Attachments:** 2018-04-24 DRAFT News Release re Science Transparency.docx

Attached, and below, please find the updated release – we plan to send this out shortly

## **EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent that underlying scientific information is publicly available in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s [Science for Policy Project](#) and the Administrative Conference of the United States’ [Science in the Administrative Process Project](#).

The proposed rule builds upon President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
- **Executive Order 13783**, also issued in March 2017, provides that “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** “The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process.”

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** “I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** “EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** “IDEM supports transparency in rulemaking. Good, sound science leads to better regulations.”

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 – 1996):** “In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and

models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

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**From:** Palich, Christian  
**Sent:** Tuesday, April 24, 2018 12:47 PM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Ringel, Aaron <ringel.aaron@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
**Subject:** RE: For Review: Science Transparency News Release

Below is from Senator Rounds.

**“Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”**

Christian R. Palich  
*Deputy Associate Administrator*  
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**From:** Bowman, Liz  
**Sent:** Tuesday, April 24, 2018 11:17 AM  
**To:** Ringel, Aaron <ringel.aaron@epa.gov>; Palich, Christian <palich.christian@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
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**Deliberative Process / Ex. 5**

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**From:** Ringel, Aaron  
**Sent:** Monday, April 23, 2018 5:46 PM  
**To:** Palich, Christian <palich.christian@epa.gov>

Cc: Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>

Subject: Re: For Review: Science Transparency News Release

## Deliberative Process / Ex. 5

Sent from my iPhone

On Apr 23, 2018, at 5:38 PM, Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)> wrote:

## Deliberative Process / Ex. 5

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: [Personal Matters / Ex. 6](#)

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

<Document1.docx>

## EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent that underlying scientific information is publicly available in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s *Science for Policy Project* and the Administrative Conference of the United States’ *Science in the Administrative Process Project*.

The proposed rule builds upon President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
- **Executive Order 13783**, also issued in March 2017, provides that “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more

accountable to the American people and help everyone understand the impact of EPA's decisions. Today's directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected."

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** "The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process."

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** "I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy."

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** "EPA's proposed rule, Strengthening Transparency in Regulatory Science, is badly needed "Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based."

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** "IDEM supports transparency in rulemaking. Good, sound science leads to better regulations."

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA's Clean Air Scientific Advisory Committee (1992 – 1996):** "In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations."

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Message

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**From:** Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]  
**Sent:** 4/24/2018 4:32:17 PM  
**To:** Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]  
**Subject:** Fwd: For Review: Science Transparency News Release

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Nancy B. Beck, Ph.D. DABT  
Deputy Assistant Administrator, OCSPP  
P: 202-564-1273  
M: [Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov) / Ex. 6

Begin forwarded message:

**From:** "Konkus, John" <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>  
**Date:** April 24, 2018 at 12:27:34 PM EDT  
**To:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>, "Yamada, Richard (Yujiro)" <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** "Bowman, Liz" <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>, "Bolen, Brittany" <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>, "Baptist, Erik" <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>, "Beck, Nancy" <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>, "Gordon, Stephen" <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>, "Letendre, Daisy" <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>, "Beach, Christopher" <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>, "Ringel, Aaron" <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>, "Palich, Christian" <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>, "Jackson, Ryan" <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>, "Ferguson, Lincoln" <[ferguson.lincoln@epa.gov](mailto:ferguson.lincoln@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

For awareness, social media will start posting at the top of the hour as follows:

EPA Twitter and FB, post at 1pm: At 2pm today, please tune-in for a special event streaming live from EPA HQ: [www.epa.gov/live](http://www.epa.gov/live)

EPA Twitter and FB, post at 1:30pm: Please tune-in for a special event with Administrator Pruitt streaming live from EPA HQ at 2pm today: [www.epa.gov/live](http://www.epa.gov/live)

EPA Twitter and FB, post at 2pm: Tune-in NOW as Administrator Pruitt signs a proposed rule to strengthen science used in EPA regulations, via live stream: [www.epa.gov/live](http://www.epa.gov/live)

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**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 10:12 AM  
**To:** Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

A few minor edits below – Deletions ~~struck through~~ and additions in yellow. Thanks!

---

**From:** Woods, Clint

**Sent:** Monday, April 23, 2018 6:14 PM

**To:** Yamada, Richard (Yujiro) <yamada.richard@epa.gov>

**Cc:** Bowman, Liz <Bowman.Liz@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Ringel, Aaron <ringel.aaron@epa.gov>; Palich, Christian <palich.christian@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>

**Subject:** Re: For Review: Science Transparency News Release

Thanks so much **Deliberative Process / Ex. 5** Two other quick thoughts:

## Deliberative Process / Ex. 5

On Apr 23, 2018, at 5:53 PM, Yamada, Richard (Yujiro) <yamada.richard@epa.gov> wrote:

(This Email contains predecisional and deliberative matters)

## Deliberative Process / Ex. 5

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <Bowman.Liz@epa.gov> wrote:

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

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<Document1.docx>

Message

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**From:** Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]  
**Sent:** 2/21/2018 10:05:37 PM  
**To:** Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]  
**Subject:** draft memo  
**Attachments:** data\_access\_memo V4 (002) cw 2-20.2.docx

(This email contains pre-decisional and deliberative material)

Hi Jennifer, Jerry and John:

Please see attached draft of a potential policy memo on data transparency:

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

I appreciate your thoughts and comments. If you could provide by tomorrow afternoon, that would be ideal. (OGC will be looking at this shortly afterwards, so I wanted our team to weigh in)

**Deliberative Process / Ex. 5**

*- Thank you.*

Thanks much,

Richard

Richard Yamada  
Deputy Assistant Administrator  
Office of Research and Development  
U.S. Environmental Protection Agency

Phone: **Personal Matters / Ex. 6**  
yamada.richard@epa.gov

Message

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**From:** Blancato, Jerry [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=232DE363DADB4CD9961900E10F56FDDF-BLANCATO, JERRY]  
**Sent:** 1/26/2018 6:01:24 PM  
**To:** Linkins, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7a94aa2975d4933981a8a9bf12aaa40-Linkins, Samantha]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]  
**Subject:** RE: today's call

Me too.

Jerry  
919-541-2854

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 1:01 PM  
**To:** Teichman, Kevin <Teichman.Kevin@epa.gov>  
**Cc:** Blancato, Jerry <Blancato.Jerry@epa.gov>  
**Subject:** Re: today's call

Will do.

Sent from my iPhone

On Jan 26, 2018, at 12:59 PM, Teichman, Kevin <[Teichman.Kevin@epa.gov](mailto:Teichman.Kevin@epa.gov)> wrote:

I would still like to meet at 1:00. Sam, please initiate the call.

We'll decide then who, in addition to Tom, should participate in the meeting.

Thanks.

Kevin Teichman  
Senior Science Advisor  
Office of Research and Development (8101R)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Phone: (301) 975-6421  
Fax: (301) 975-4409

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 12:57:15 PM  
**To:** Blancato, Jerry  
**Cc:** Teichman, Kevin  
**Subject:** Re: today's call

Yup. (Unless you'd like to be a fly on the wall.)

Sent from my iPhone

On Jan 26, 2018, at 12:47 PM, Blancato, Jerry <[Blancato.Jerry@epa.gov](mailto:Blancato.Jerry@epa.gov)> wrote:

Does this mean Kevin and I can stand down?

Jerry  
919-541-2854

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 12:45 PM  
**To:** Blancato, Jerry <[Blancato.Jerry@epa.gov](mailto:Blancato.Jerry@epa.gov)>  
**Subject:** Fwd: today's call

FYI

Sent from my iPhone

Begin forwarded message:

**From:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Date:** January 26, 2018 at 12:27:34 PM EST  
**To:** "Linkins, Samantha" <[Linkins.Samantha@epa.gov](mailto:Linkins.Samantha@epa.gov)>, "Teichman, Kevin" <[Teichman.Kevin@epa.gov](mailto:Teichman.Kevin@epa.gov)>  
**Subject:** Fwd: today's call

Sent from my iPhone

Begin forwarded message:

**From:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Date:** January 26, 2018 at 8:33:06 AM EST  
**To:** "Yamada, Richard (Yujiro)" <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** today's call

I plan to call in today for the internal pre-brief. If asked  
– I think the bullets I would make are ..

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Thomas Sinks, Ph.D.  
Director, Office of the Science Advisor  
Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Room 41251 RRB, MC 8105 R  
Washington DC, 20460  
office: (202) 564-3099 mobile: Personal Matters / Ex. 6  
email: [sinks.tom@epa.gov](mailto:sinks.tom@epa.gov)

Message

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**From:** Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]  
**Sent:** 2/22/2018 10:09:08 PM  
**To:** Feeley, Drew (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=abae82aa36da4d3383eae19a8efa683c-Feeley, Rob]  
**Subject:** here's latest draft  
**Attachments:** data\_access\_memo V6.docx

This should have most of your comments, etc answered – I left a few unanswered, as you can see,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

You can leave the comments in for now.

Could you give a look, and then we can send to Schwab?

Richard Yamada  
Deputy Assistant Administrator  
Office of Research and Development  
U.S. Environmental Protection Agency

Phone: Personal Matters / Ex. 6  
yamada.richard@epa.gov

Message

**From:** Christian, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64A0F5E0E9D94271B23CAD28DB653851-LIZOTTE, ME]  
**Sent:** 5/31/2018 3:09:51 PM  
**To:** Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]  
**CC:** McPherson, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraf3de097]; Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]  
**Subject:** RE: Items for your review

Hi Chris,

Thank you for the quick reviews.

# Deliberative Process / Ex. 5

Best,  
Megan

Megan Christian, MPH  
Office of Research and Development  
U.S. Environmental Protection Agency  
[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)  
202-564-6184

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**From:** Robbins, Chris  
**Sent:** Thursday, May 31, 2018 9:44 AM  
**To:** Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>  
**Cc:** McPherson, Mark <[McPherson.Mark@epa.gov](mailto:McPherson.Mark@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** RE: Items for your review

Hi Megan,

I've reviewed all of these documents **Deliberative Process / Ex. 5** thx

Christopher S. Robbins  
Deputy Assistant Administrator for Management (Acting)  
Office of Research and Development  
**Personal Matters / Ex. 6**

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**From:** Christian, Megan  
**Sent:** Wednesday, May 30, 2018 4:54 PM  
**To:** Robbins, Chris <[Robbins.Chris@epa.gov](mailto:Robbins.Chris@epa.gov)>  
**Cc:** McPherson, Mark <[McPherson.Mark@epa.gov](mailto:McPherson.Mark@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>;

Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>

**Subject:** Items for your review

Good afternoon Chris,

Since we have a variety of items circulating around the IO for review, I wanted to consolidate all items in your wheelhouse into one email:

# Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

Megan Christian, MPH  
Office of Research and Development  
U.S. Environmental Protection Agency  
[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)  
202-564-6184

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Message

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**From:** Jackson, Ryan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=38BC8E18791A47D88A279DB2FEC8BD60-JACKSON, RY]  
**Sent:** 8/24/2018 6:46:06 PM  
**To:** Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]  
**CC:** Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60d0c681a16441a0b4fa16aa2dd4b9c5-Block, Moll]; Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Bertrand, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f044d768e05842e1b75321ff6010e1b8-Bertrand, Charlotte]  
**Subject:** Re: Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

# Deliberative Process / Ex. 5

Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

On Aug 24, 2018, at 2:41 PM, Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)> wrote:

# Deliberative Process / Ex. 5

Sent from my iPhone

On Aug 24, 2018, at 2:13 PM, Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)> wrote:

# Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

On Aug 24, 2018, at 1:36 PM, Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)> wrote:

Ryan –

## Deliberative Process / Ex. 5

Molly

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**From:** Grantham, Nancy  
**Sent:** Friday, August 24, 2018 1:33 PM  
**To:** Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>  
**Cc:** Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)>  
**Subject:** RE: Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

## Deliberative Process / Ex. 5

**Nancy Grantham**  
**Office of Public Affairs**  
**US Environmental Protection Agency**

Personal Matters / Ex. 6 (desk)  
Personal Matters / Ex. 6 (mobile)

---

**From:** Jackson, Ryan  
**Sent:** Friday, August 24, 2018 12:53 PM  
**To:** Konkus, John <konkus.john@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>  
**Subject:** Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science' - The New York Times

Did we even get asked to comment on this?

<https://www.nytimes.com/2018/08/24/business/epa-pesticides-studies-epidemiology.html?action=click&module=Top%20Stories&pgtype=Homepage>

## **Pesticide Studies Won E.P.A.'s Trust, Until Trump's Team Scorned 'Secret Science'**

Backed by agrochemical companies, the current administration and Congress are moving to curb the role of human health studies in regulation.

Aug. 24, 2018



A strawberry field in California's Salinas Valley, where a yearslong study, funded in part by the Environmental Protection Agency, has linked pesticides to ailments in children of farm workers. Carlos Chavarria for The New York Times

SALINAS, Calif. — José Camacho once worked the fields here in the Salinas Valley, known as “the Salad Bowl of the World” for its abundance of lettuce and vegetables. His wife still does.

But back in 2000, Mr. Camacho, who is 63, got an unusual phone call. He was asked if he wanted to work for a new project studying the effects of pesticides on the children of farm workers.

“This seemed really crazy,” he recalled saying at the time, since he barely spoke English. “A research study?”

The project, run by scientists from the University of California, Berkeley, and funded in part by the Environmental Protection Agency, is still going all these years later. Known as Chamacos, Spanish for “children,” it has linked pesticides sprayed on fruit and vegetable crops with respiratory

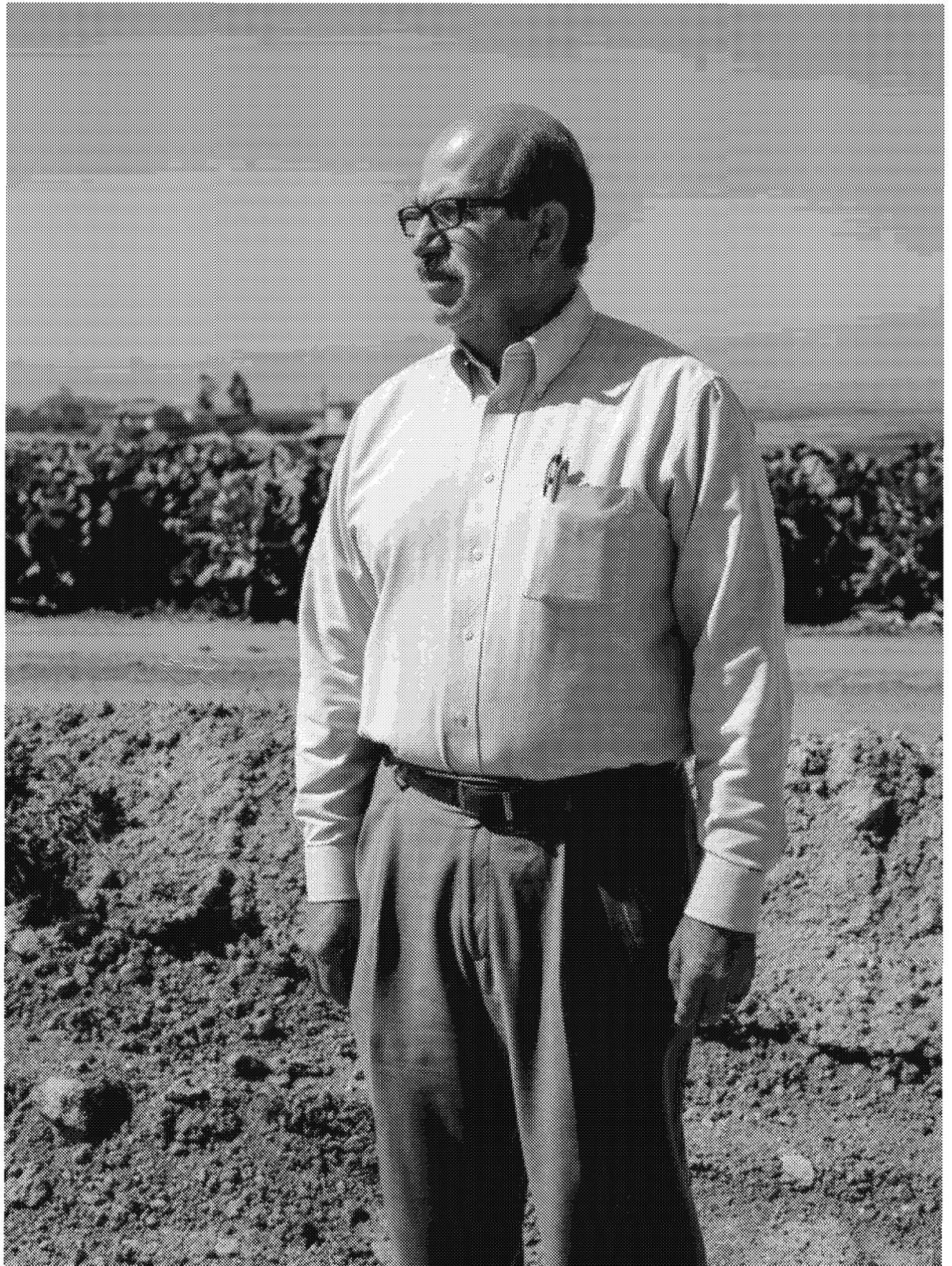
complications, developmental disorders and lower I.Q.s among children of farm workers. State and federal regulators have cited its findings to help justify proposed restrictions on everything from insecticides to flame-retardant chemicals.

But the Trump administration wants to restrict how human studies like Chamacos are used in rule-making. A government proposal this year, called Strengthening Transparency in Regulatory Science, could stop them from being used to justify regulating pesticides, lead and pollutants like soot, and undermine foundational research behind national air-quality rules. The E.P.A., which has funded these kinds of studies, is now labeling many of them “secret science.”

Studying disease trends in specific groups of people — a branch of medicine known as epidemiology — started to gain currency at the E.P.A. in recent years. These studies can be difficult because they require adjusting for all the various substances people are exposed to beyond pesticides. But researchers had amassed years of data from a wave of compelling chemical studies begun in the 1990s, giving regulators a new body of research to incorporate into their decision-making.

Under the Obama administration, the E.P.A., which had long favored tests on rats and other laboratory animals in its pesticide regulation, began considering epidemiological studies more seriously. The agency leaned on this type of research in proposing to ban an insecticide called chlorpyrifos in late 2016, and has been repeatedly prodded to take action on the chemical by federal courts.

But weeks after Donald J. Trump was elected president, CropLife America, the main agrochemical trade group, petitioned the E.P.A. to “halt regulatory decisions that are highly influenced and/or determined by the results of epidemiological studies” unless universities were forced to share more of their data.



José Camacho was asked in 2000 to participate in the study, which tracks families as they go about their normal lives. Such research was embraced by the E.P.A. during the Obama administration. Carlos Chavarría for The New York Times

Industry leaders aggressively challenged such studies in high-level meetings and emails with E.P.A. leaders, according to thousands of pages of documents obtained through Freedom of Information Act requests. One trade group invited a top E.P.A. official to meet with its Washington lobbyist last year, complaining that “carefully controlled” animal studies were giving way to “conclusions reflected in epidemiological papers.”

Gary W. Van Sickle, executive director of the California Specialty Crops Council, wrote to the agency last September that “there have been serious flaws with E.P.A.’s conclusion to use these data.”

The council, representing growers of crops as diverse as carrots, garlic, pears and peppers, cited “inappropriate use of the epidemiology.”

The E.P.A., whose new leadership is seeded with industry veterans, has responded. In a mid-July assessment of atrazine, a widely used weed killer long banned in Europe, the agency reviewed and dismissed 12 recent epidemiological studies linking the herbicide to such ailments as childhood leukemia and Parkinson’s disease. It echoed the conclusions of research funded by Syngenta, atrazine’s manufacturer, finding the chemical unlikely to cause cancer.

Before scandals forced Scott Pruitt out last month as head of the E.P.A., he proposed the transparency regulation. It would ban many epidemiological studies, and other outside research, unless more data behind the studies was made public. In doing so, he revived a strategy advanced for years by congressional Republicans and corporate interests like tobacco companies.

“The era of secret science at E.P.A. is coming to an end,” Mr. Pruitt proclaimed at the time. The agency’s new acting administrator, Andrew R. Wheeler, says he’s moving forward with the proposal, as the agency re-evaluates a class of widely used insecticides, called organophosphates, that have been the subject of numerous epidemiological studies like Chamacos.

Nancy B. Beck, a chemical industry veteran who is the E.P.A.'s deputy assistant administrator, said there was no attempt to thwart epidemiology, adding that the agency was committed to "the best available science in the most transparent manner."

But academics and state health officials say universities are being pressured to release data that would ultimately divulge the identities of study participants, a strategy once used by tobacco companies seeking to undermine research on the dangers of smoking. While participant data is shared with regulators in drug trials, academics fear that the E.P.A.'s proposal would additionally require divulging confidential personal information, potentially violating privacy regulations for federally funded research.



Ana Lilia Sanchez, a farm worker and the mother of a participant in the Salinas Valley study, said her family took precautions to avoid pesticide contamination. Carlos Chavarría for The New York Times

"It is a naked attempt to use a false claim that something nefarious is going on with these studies in an effort to allow industry to challenge conclusions that are not in their favor,"

said James Kelly, a manager of environmental surveillance at the Minnesota Department of Health.

## **A Wave of Studies, an Uneasy Industry**

An advertisement in a Nebraska student newspaper was looking for people who wanted to “earn extra money.” Thirty-six college student volunteers and others from the community who responded were paid \$460 to drink gelatin capsules filled with the pesticide chlorpyrifos, at up to 300 times levels the E.P.A. considered safe, without a full discussion of the risks.

Sponsored by Dow Chemical, this study, conducted in 1998, was one of the last of its kind. That year, the E.P.A. banned the use of studies exposing people to pesticides, and it continues to severely restrict them.

Epidemiology, which has been used to examine everything from the effects of climate change to childhood obesity, offered a way to continue studying disease trends, amid new legal requirements to examine how pesticides particularly affect infants and children. And it could do so by tracking people during their normal lives instead of treating them as if they were lab rats. Chamacos and other studies began almost immediately, although it took decades to collect sufficient data and study how participants changed over time.

One study by Columbia University researchers linked an insecticide to developmental delays in toddlers. Another, by scientists at the University of California, Los Angeles, connected pesticides to Parkinson’s disease. Academics at the University of Rochester found that pesticides lower sperm counts in men, while researchers from the Harvard School of Public Health found lower fertility in women.

By 2015, there was a growing body of research, often funded in part by the E.P.A. The agency decided that year to consult epidemiology more seriously in its evaluation of glyphosate, the world’s most popular weed killer and the active ingredient in Monsanto’s Roundup.

“This is a watershed event in our Program, and one which I feel particularly proud to be a part (go epi!),” Carol Christensen, then an E.P.A. epidemiologist, wrote in a 2015 email to a colleague — using “epi” as shorthand for epidemiology. “In the 35 year history of our program, this will be the FIRST time epi studies are actively considered in the decision making.”

Yet even then, there was friction over what to make of studies aiming to determine whether glyphosate causes cancer.

One E.P.A. division, the Office of Research and Development, closely examined epidemiological research and came to believe either that glyphosate was likely to cause cancer or that there was at least some evidence suggesting a problem. But another division, the Office of Pesticide Programs, was dismissive of epidemiological studies and determined that glyphosate was not a carcinogen, a view that prevailed at the E.P.A., according to interviews, emails and an internal memo obtained by The New York Times. Those involved in the agency’s debates on epidemiology spoke on the condition of anonymity because the discussions weren’t public.

Monsanto said in a statement that “we cannot speak to the internal E.P.A. discussions” but emphasized the agency’s ultimate finding that glyphosate was not likely to cause cancer.

The cancer question received renewed attention this month when a California jury awarded \$289 million to a groundskeeper who alleged that the chemical had sickened him. In his closing argument, the plaintiff’s attorney, R. Brent Wisner, called epidemiology one of “the three pillars of cancer science” that the case relied on.

At the E.P.A., the debate swung in favor of epidemiology. While such studies are often complex and can be of varying quality, the agency was reluctant in the past to give them as much weight as lab experiments on animals. But by the Obama administration’s final months, the agency moved for

the first time to ban a pesticide largely because of epidemiological research.

The pesticide, chlorpyrifos, was the same one ingested years earlier by unwitting Nebraskans. It is applied to crops like apples, oranges and strawberries to combat insects like spider mites and sap-sucking bugs.

In California alone, chlorpyrifos was sprayed on 640,000 acres in 2016, according to state data. And research from Salinas, and the Chamacos study, became a central element in the E.P.A.'s recommendation.

“There is a breadth of information available on the potential adverse neurodevelopmental effects in infants and children as a result of prenatal exposure to chlorpyrifos,” the agency concluded in 2016, also citing epidemiological research from Columbia University and the Icahn School of Medicine at Mount Sinai.

The pesticide industry's reaction was loud and intense.

Monsanto, in emails with the E.P.A., was dismissive of critical epidemiological research related to Roundup, writing that “such studies are well known to be prone to a number of biases.”



A Trump administration proposal would prevent the E.P.A. from using many epidemiological studies, like the one in Salinas, unless more data behind them was made public. Carlos Chavarría for The New York Times

Dow Chemical said in reports submitted to the E.P.A. that “the evidence from these studies is insufficient” and called chlorpyrifos a “proven first-line of defense” against new pest outbreaks.

A month after taking over the E.P.A., Mr. Pruitt acted. He disregarded agency scientists and rejected the proposed chlorpyrifos ban, later calling for “a new day, a new future, for a common-sense approach to environmental protection.”

## **View From the Field**

Ana Lilia Sanchez, 50, has worked in the fields in Salinas more than half her life, and one of her daughters has been a Chamacos study participant.

Ms. Sanchez has learned to watch for drifting droplets or the whirl of a helicopter spraying overhead.

“Sometimes when we feel it, or we hear it, we start talking about it,” she said recently, sitting with her 5-month-old granddaughter at her home on a Salinas cul-de-sac. “Why wouldn’t they tell us, you know, to get out of here, to not come today?” she asked. “Women, they cover themselves, but men are working in short sleeves, so they are more exposed.”

Insecticides like chlorpyrifos are organophosphates, from the same chemical family as nerve agents like sarin and Novichok, the Russian-developed compound linked to recent attacks in Britain. While the safety of insecticides is extensively tested, long-term health impacts, or even how far pesticides drift, are the subject of continuing disagreement.

Ms. Sanchez showers after work, before touching her granddaughter.

“I also put my clothes aside,” she said. “We separate the clothes we use when we’re working, both my husband and I, and wash them separately so they’re not contaminated.”

While some human studies examine potential harm from pesticide residue found on fruits and vegetables, the Chamacos project is more personal, following hundreds of children in the heart of where American food is grown. California has the nation’s largest agricultural industry and uses more than 200 million pounds of pesticides annually.



Brenda Eskenazi, the director of the Salinas Valley project, said that “well-controlled epidemiologic studies” were

essential for understanding “how things affect human health.” Carlos Chavarría for The New York Times

For locals, pesticides are part of life. “It’s a big difference from when I was working,” Mr. Camacho said, while standing in a strawberry field framed on three sides by distant hills. Men and women were bent over nearby, pulling weeds. “My supervisor would say: ‘That’s not dangerous. Just keep working.’ There was no information.”

Chamacos is built on an unsettling premise: What happens to children of pregnant mothers certain to have pesticides in their bloodstreams? The E.P.A. and other government agencies have spent millions of dollars funding Chamacos.

Half the Chamacos children have been tracked since before birth. Researchers have collected 350,000 samples of blood, urine, breast milk and even household dust and spent nearly two decades studying maturing children. They perform neurodevelopmental and physical assessments and study factors like diet and school performance. After nearly two decades, the study’s data appears in more than 160 academic papers.

During a visit to the Chamacos office in Salinas, Brenda Eskenazi, the director of the project and a professor of epidemiology at Berkeley, was testing out brain monitoring equipment, wearing what looked like a black swim cap strewn with knobs and wiring. She has long been fascinated with cognitive development, going back to when she saw a Woodstock reveler — one having a bad acid trip — dive into pavement.

“Why did he do that?” Ms. Eskenazi remembers wondering at the time. “What was he thinking? What’s going on in that brain?”

“Any science is imperfect,” she said, but stressed that “well-controlled epidemiologic studies” were essential for understanding “how things affect human health.” She added,

“Otherwise you’re just making huge assumptions that a rodent is the same as a human.”

## **A Bitter Debate**

The day after Mr. Pruitt made his March 2017 decision to reject a ban on chlorpyrifos, he hosted top executives from one of the nation’s largest farming and pesticide trade organizations for a closed-door conversation.

Near the top of the meeting agenda was “Epidemiology Study Policy” in the aftermath of the “chlorpyrifos matter,” according to internal records.



McKinnon Elementary School in Salinas. The pesticide industry contends that epidemiological studies are prone to biases and not as reliable as testing on lab animals. Carlos Chavarría for The New York Times

“There are no guideposts, if you will, for what is a legitimate, useful epidemiology study and what is not,” Jay Vroom, CropLife America’s president, said in an interview, explaining what he had told agency officials at this and other meetings.

In a subsequent letter to the E.P.A., a CropLife America lobbyist said the agency was relying on a “shortsighted approach,” and the group submitted formal proposals to curb the embrace of epidemiology the E.P.A. undertook under the Obama administration.

Mr. Pruitt responded with his proposal, made this past spring, to ban epidemiological and other studies that did not make study details public, including at least some information on study participants.

Academics have resisted previous requests to review their data, notably at Columbia University. In a 2016 letter to the agency, a university official wrote that it could not provide “extensive individual level data to E.P.A. in a way that ensures the confidentiality” of “our research subjects.”

David Michaels, an epidemiologist at George Washington University’s School of Public Health and head of the Occupational Safety and Health Administration during the Obama administration, said Mr. Pruitt’s plan was not about transparency but about discrediting studies that made pesticides look bad.

“The underlying justification for this ‘transparency’ proposal is a caricature of how science really works,” Mr. Michaels said at a recent hearing. “The cynical approach proposed by E.P.A. can be best described as ‘weaponized transparency.’”

It is no coincidence, he said, that the term “secret science” was also used in the 1970s when the tobacco industry was trying to forestall critical research about smoking.

Researchers have had wins. This month, a federal appeals court ordered the E.P.A. to ban chlorpyrifos, citing findings from human studies. The Trump administration is mulling whether to appeal.

But epidemiologists are unsettled. In mid-July, after nearly two decades of work on Chamacos, the E.P.A. emailed Ms. Eskenazi requesting “the original data” from her research,

citing “uncertainty around neurodevelopmental effects associated” with pesticides she has studied. The agency made a similar request to Columbia.

Ms. Eskenazi, worried about her study participants’ privacy, alerted university lawyers. She is now concerned that the E.P.A. may try to undermine her study’s repeated findings that some pesticides may be harming children.

“I knew this was going to come sooner or later,” she said. “And here it is.”

Danny Hakim reported from Salinas, and Eric Lipton from Washington.

## **The All-New DealBook**

**Our columnist Andrew Ross Sorkin and his Times colleagues help you make sense of major business and policy headlines — and the power-brokers who shape them.**

**More in Business Day**



Ryan Jackson  
Chief of Staff  
U.S. EPA

Personal Matters / Ex. 6

Message

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**From:** Bowman, Liz [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3D4D94D3E4B4B1F80904056703EBC80-BOWMAN, ELI]  
**Sent:** 4/24/2018 6:03:22 PM  
**To:** Palich, Christian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=330ad62e158d43af93fcbbece930d21a-Palich, Chr]; Ringel, Aaron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1654bdc951284a6d899a418a89fb0abf-Ringel, Aar]  
**CC:** Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]; Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Baptist, Erik [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10fc1b085ee14c6cb61db378356a1eb9-Baptist, Er]; Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]; Gordon, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c8fb4d82bff4eec98f5c5d00a47f554-Gordon, Ste]; Letendre, Daisy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b691cccca6264ae09df7054c7f1019cb-Letendre, D]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Beach, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b124299bb6f46a39aa5d84519f25d5d-Beach, Chri]; Jackson, Ryan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38bc8e18791a47d88a279db2fec8bd60-Jackson, Ry]  
**Subject:** RE: For Review: Science Transparency News Release  
**Attachments:** 2018-04-24 DRAFT News Release re Science Transparency.docx

Attached, and below, please find the updated release – we plan to send this out shortly

## **EPA ADMINISTRATOR PRUITT PROPOSES RULE TO STRENGTHEN SCIENCE USED IN EPA REGULATIONS**

WASHINGTON – Today, U.S. Environmental Protection Agency (EPA) Administrator Scott Pruitt signed a proposed rule to strengthen the science used in regulations issued by EPA. The rule will ensure that the regulatory science underlying Agency actions is fully transparent that underlying scientific information is publicly available in a manner sufficient for independent validation.

“The era of secret science at EPA is coming to an end,” said EPA Administrator Scott Pruitt. “The ability to test, authenticate, and reproduce scientific findings is vital for the integrity of rulemaking process. Americans deserve to assess the legitimacy of the science underpinning EPA decisions that may impact their lives.”

This proposed rule is in line with the scientific community’s moves toward increased data sharing to address the “replication crisis”—a growing recognition that a significant proportion of published research may not be reproducible. The proposal is consistent with data access requirements for major scientific journals like *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* as well as recommendations from the Bipartisan Policy Center’s [Science for Policy Project](#) and the Administrative Conference of the United States’ [Science in the Administrative Process Project](#).

The proposed rule builds upon President Trump’s executive orders on regulatory reform and energy independence:

- **Executive Order 13777**, issued in March 2017, provides that regulatory reform efforts shall attempt to identify “those regulations that rely in whole or in part on data, information, or methods that are not publicly available or that are insufficiently transparent to meet the standard of reproducibility.”
- **Executive Order 13783**, also issued in March 2017, provides that “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more accountable to the American people and help everyone understand the impact of EPA’s decisions. Today’s directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected.”

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** “The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process.”

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** “I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy.”

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** “EPA’s proposed rule, Strengthening Transparency in Regulatory Science, is badly needed “Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based.”

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** “IDEM supports transparency in rulemaking. Good, sound science leads to better regulations.”

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA’s Clean Air Scientific Advisory Committee (1992 – 1996):** “In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and

models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations.”

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**From:** Palich, Christian  
**Sent:** Tuesday, April 24, 2018 12:47 PM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>; Ringel, Aaron <ringel.aaron@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
**Subject:** RE: For Review: Science Transparency News Release

Below is from Senator Rounds.

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Christian R. Palich  
*Deputy Associate Administrator*  
*Office of Congressional & Intergovernmental Affairs*  
*U.S Environmental Protection Agency*  
*O: 202.564.4944*  
C: Personal Matters / Ex. 6  
E: [Palich.Christian@epa.gov](mailto:Palich.Christian@epa.gov)

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**From:** Bowman, Liz  
**Sent:** Tuesday, April 24, 2018 11:17 AM  
**To:** Ringel, Aaron <ringel.aaron@epa.gov>; Palich, Christian <palich.christian@epa.gov>  
**Cc:** Woods, Clint <woods.clint@epa.gov>; Bolen, Brittany <bolen.brittany@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Baptist, Erik <Baptist.Erik@epa.gov>; Beck, Nancy <Beck.Nancy@epa.gov>; Gordon, Stephen <gordon.stephen@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Konkus, John <konkus.john@epa.gov>; Beach, Christopher <beach.christopher@epa.gov>; Jackson, Ryan <jackson.ryan@epa.gov>  
**Subject:** RE: For Review: Science Transparency News Release

**Deliberative Process / Ex. 5**

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**From:** Ringel, Aaron  
**Sent:** Monday, April 23, 2018 5:46 PM  
**To:** Palich, Christian <palich.christian@epa.gov>

Cc: Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Woods, Clint <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>

Subject: Re: For Review: Science Transparency News Release

## Deliberative Process / Ex. 5

Sent from my iPhone

On Apr 23, 2018, at 5:38 PM, Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)> wrote:

## Deliberative Process / Ex. 5

Christian R. Palich  
Deputy Associate Administrator  
Office of Congressional Affairs  
C: [Personal Matters / Ex. 6](#)

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

<Document1.docx>

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- **Executive Order 13783**, also issued in March 2017, provides that “It is the policy of the United States that necessary and appropriate environmental regulations comply with the law, are of greater benefit than cost, when permissible, achieve environmental improvements for the American people, and are developed through transparent processes that employ the best available peer-reviewed science and economics.”

**Chairman Lamar Smith (R-TX):** “Administrator Pruitt’s announcement ensures that data will be secret no more. For too long, the EPA has issued rules and regulations based on data that has been withheld from the American people. It’s likely that in the past, the data did not justify all regulations. Today, Administrator Pruitt rightfully is changing business as usual and putting a stop to hidden agendas.”

**Senator Mike Rounds (R-SD):** “Sound, reliable science is vital to helping us make important policy decisions that impact the health of American families and their livelihoods. Inserting new levels of transparency in the EPA rulemaking process will help make the agency more

accountable to the American people and help everyone understand the impact of EPA's decisions. Today's directive is a significant step toward making sure these decisions are not made behind closed doors with information accessible only to those writing the regulations, but rather in the full view of those who will be affected."

**Dr. Edward J. Calabrese, Professor, Environmental Health Sciences, University of Massachusetts:** "The proposal represents a major scientific step forward by recognizing the widespread occurrence of non-linear dose responses in toxicology and epidemiology for chemicals and radiation and the need to incorporate such data in the risk assessment process."

**Dr. Louis Anthony (Tony) Cox, President, Cox Associates; Member, National Academy of Engineering; and Editor-in-Chief of the journal *Risk Analysis*:** "I believe that transparency and independent reproducibility of analyses and conclusions are bedrock principles of sound science. Some commentators have expressed concerns that making the data behind policy conclusions and recommendations accessible and transparent might threaten the privacy of individuals. But this concern can be fully met by applying current privacy-protection techniques for data analysis. These techniques have been developed and used successfully for years at the Census Bureau and elsewhere. Thus, we can have the scientific benefits of accessible data while protecting individual privacy."

**Dr. Jason Scott Johnston, Director, Olin Law and Economics Program, University of Virginia School of Law:** "EPA's proposed rule, Strengthening Transparency in Regulatory Science, is badly needed "Best practice among peer-edited scientific journals is to require that data and statistical routines used in published papers be posted online and/or made publicly available. To apply the same standards to research that EPA says justify regulations affecting billions of dollars in economic activity and millions of human lives is essential for those regulations to truly be scientifically based."

**Bruno Pigott, Commissioner of the Indiana Department of Environmental Management (IDEM):** "IDEM supports transparency in rulemaking. Good, sound science leads to better regulations."

**Dr. George Wolff, Principal Scientist, Air Improvement Resource, Inc., and former Chairman of EPA's Clean Air Scientific Advisory Committee (1992 – 1996):** "In the development of regulations based on environmental studies, numerous subjective assumptions and choices must be made regarding the selection of data and models that have a profound impact on the strength of any statistical associations and even whether the associations are positive or negative. The appropriateness of the assumptions and choices are not adequately evaluated in the standard peer review process. That is why it is essential that the data and models be placed in the public domain for a more rigorous evaluation by qualified experts. The proposed regulation, Strengthening Transparency in Regulatory Science, will provide an opportunity for such evaluations."

###

## **MEMORANDUM**

**TO:** Members of the Chartered SAB and SAB Liaisons

**FROM:** Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science */signed/*

**DATE:** May 12, 2018

**SUBJECT:** Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)

The Chartered Science Advisory Board convened Work Groups to discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Spring and Fall 2017 semi-annual regulatory agenda at its May 31, 2018 meeting. To support this discussion a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB.

The Environmental Protection Agency announced the proposed rulemaking entitled Strengthening Transparency in Regulatory Science RIN (2080-AA14) on April 25, 2018 at a press event and published a *Federal Register* notice on April 30, 2018 with a 30-day public comments period. The Work Group notes that this planned action was not identified as a major action in either of the Spring 2017 nor Fall 2017 semi-annual Regulatory Agendas.

This memorandum summarizes the charge to the Work Group, their discussion regarding the planned action and issues and questions for the SAB to discuss at its May 31, 2018 meeting.

### **Background**

The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's current process is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda. These descriptions provide available information regarding the science informing agency actions. This process for engaging the SAB supplements the EPA's process for program and regional offices to request science advice from the SAB.

The SAB Work Group then follows a process adopted by the Chartered SAB in 2013<sup>1</sup> to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. This semi-annual regulatory agenda is available at <https://www.reginfo.gov/public/do/eAgendaMain>. The current SAB

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<sup>1</sup> Available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/\\$File/SABProtocol2017.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/$File/SABProtocol2017.pdf)

Work Group was formed in December 2017 to review the Fall 2017 semi-annual Regulatory Agenda and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions.

The Work Group met by teleconference on May 3, 2018 to discuss its recommendations on considered actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)<sup>2</sup> as part of the discussions. Members were made aware of the proposed rule via the *Federal Register* and news articles. The EPA did not provide a description of the planned action. SAB members on the Work Group teleconference include Drs. Alison Cullen (Work Group chair), Robert Blanz, Otto Doering, H. Christopher Frey, John Graham, Michael Honeycutt (SAB chair) Merl Lindstrom, Jay Turner, and Messers. Richard Poirot and Robert Merritt.

**Work Group Discussions Regarding Strengthening Transparency in Regulatory Science RIN (2080-AA14)**

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN	Planned Action Title	Workgroup Recommendation
<u>2080-AA14</u>	Proposed Rule: Strengthening Transparency in Regulatory Science RIN	Merits review by the SAB.

<sup>1</sup>There is no additional information available on the planned action provided in the Unified Regulatory Agenda on the OMB website <http://www.reginfo.gov/>. The OMB review was completed on April 23, 2018. The hyperlink is to the FR notice for the proposed rule.

**Recommendation:** This action merits further review by the SAB. The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board.

**Rationale:** In reviewing the Federal Register, Work Group members noted that EPA published a proposed rule that would limit the use of science based on human subject data and would impose requirements for the analysis of dose-response relationships widely used in risk assessments across a wide range of agency programs.

The Work Group recognizes that the long-term trend in most scientific fields is for authors to supply public access to data and analytic methods after scientific findings are published. Such transparency may help to detect and discourage scientific fraud, facilitate various forms of robustness analysis, and allow supplementary lines of knowledge to be developed from the same data. Some fields of science are moving faster than others in the direction of transparency.

<sup>2</sup> Available at: <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate. In addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for shouldering this burden. Thus, the development of guidelines and rules in this arena requires careful collaboration between the government and the scientific community.

Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community. Nor does the preamble to the rule describe precisely how the proposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines.

The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. The Work Group also found that the rule is highly controversial (indeed a similar legislative effort in the House has been stalled in Congress for several years) and could have long-term implications. Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate. On the other hand, the rule might stimulate researchers to make stronger efforts toward transparency so that their work may be considered in regulatory deliberations. It might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish. It might also be easier if the rule took into account reasonable areas for accommodation or exception in situations for which it is not possible to release a dataset publicly either entirely, or without revision, for legitimate reasons pertaining to the use, for example, of human subject data.

Among the key science issues that the rule touches upon are the following:

- Restrictions on the use of epidemiologic studies that are based on confidential human subject data. Although the epidemiologic community recognizes the need to make data public to the extent possible, in some cases it is not possible to make public full datasets. These include, but are not limited to, cases in which studies are subject to prior Institutional Review Board (IRB) conditions or in which prospective cohort studies include extensive personal data from which it would be possible to identify individual persons.

- The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis<sup>3</sup>. HEI did uncover some sensitivities in the original ACS cohort findings associated with multiple pollutants and with interactions of pollution with socio-economic status (SES) variables such as educational attainment. Furthermore, over time, additional studies have confirmed the basic findings. Thus, in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. And we note that some of the recent confirmation studies have used publicly available data.
- The proposed rule oversimplifies the argument that “concerns about access to confidential or private information can, in many case, be addressed through the application of solutions commonly in use across some parts of the Federal government.” For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential<sup>4</sup>.
- The requirement of the consideration of multiple dose-response models should explicitly state that this consideration is based on information relevant to the selection of the most scientifically-appropriate model(s) such as biological plausibility, mode of action, or mechanism of action. Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data. Concepts such as “replication” and “validation”, although they are surely crucial in sound science, are not clearly defined in the rule.
- The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels, including the EPA Science Advisory Board, the EPA Clean Air Scientific Advisory Committee, and the EPA FIFRA Scientific Advisory Panel (FIFRA is the Federal Insecticide, Fungicide, and Rodenticide Act). For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.

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<sup>3</sup> Health Effects Institute, 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michal Abrahamowicz, and Warren H. White.  
<https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air>

<sup>4</sup> Ibid.

## **Work Group Recommendations Regarding Improvements to the Process for Identifying EPA Planned Actions for SAB Consideration**

The Work Group notes that the Proposed Rule on Strengthening Transparency in Regulatory Science was not included in previous semi-annual regulatory agendas, is not available on the OMB website [www.reginfo.gov](http://www.reginfo.gov) and that the EPA did not provide a description of the action. The Work Group continues to urge the EPA to improve the process for future review of the semi-annual regulatory agenda and strongly recommends that EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the scientific basis for actions and more description of the scientific and technological bases for actions. EPA should provide such information in the initial descriptions provided to the work group.

Effective SAB evaluation of planned actions requires the agency to characterize the following.

- All relevant key information associated with the planned action.
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the agency is relying on existing science, provide a short description.
- The nature of the planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments are/were integrated into the planned action, and information about the qualifications of the reviewer(s).

This SAB made several of these recommendations in previous reviews<sup>5</sup>. We request that the chartered SAB highlight to the Administrator the need for the Agency to provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

References: Proposed Rule: Strengthening Transparency in Regulatory Science (RIN 2080-AA14) FR Vol 83, Num. 83, pages 18768-18774. Available at: <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

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<sup>5</sup> SAB Discussions about EPA Planned Actions in the Fall 2012 Unified (Regulatory) Agenda and their Supporting Science (see page 5 of the Work Group memorandum)

SAB Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science (Letter to the Administrator and Work Group memorandum [see page 5])

SAB Discussions about EPA Planned Actions in the Spring 2017 Unified Agenda and their Supporting Science (see page 7)

Message

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**From:** Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]  
**Sent:** 4/24/2018 4:32:17 PM  
**To:** Bolen, Derrick [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ffc58b0468c4deca51a8bad735b7d95-Bolen, Derr]  
**Subject:** Fwd: For Review: Science Transparency News Release

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Nancy B. Beck, Ph.D. DABT  
Deputy Assistant Administrator, OCSPP  
P: 202-564-1273  
M: Personal Matters / Ex. 6  
[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)

Begin forwarded message:

**From:** "Konkus, John" <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>  
**Date:** April 24, 2018 at 12:27:34 PM EDT  
**To:** "Woods, Clint" <[woods.clint@epa.gov](mailto:woods.clint@epa.gov)>, "Yamada, Richard (Yujiro)" <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** "Bowman, Liz" <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>, "Bolen, Brittany" <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>, "Baptist, Erik" <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>, "Beck, Nancy" <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>, "Gordon, Stephen" <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>, "Letendre, Daisy" <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>, "Beach, Christopher" <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>, "Ringel, Aaron" <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>, "Palich, Christian" <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>, "Jackson, Ryan" <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>, "Ferguson, Lincoln" <[ferguson.lincoln@epa.gov](mailto:ferguson.lincoln@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

For awareness, social media will start posting at the top of the hour as follows:

EPA Twitter and FB, post at 1pm: At 2pm today, please tune-in for a special event streaming live from EPA HQ: [www.epa.gov/live](http://www.epa.gov/live)

EPA Twitter and FB, post at 1:30pm: Please tune-in for a special event with Administrator Pruitt streaming live from EPA HQ at 2pm today: [www.epa.gov/live](http://www.epa.gov/live)

EPA Twitter and FB, post at 2pm: Tune-in NOW as Administrator Pruitt signs a proposed rule to strengthen science used in EPA regulations, via live stream: [www.epa.gov/live](http://www.epa.gov/live)

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**From:** Woods, Clint  
**Sent:** Tuesday, April 24, 2018 10:12 AM  
**To:** Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>  
**Subject:** RE: For Review: Science Transparency News Release

A few minor edits below – Deletions ~~struck through~~ and additions in yellow. Thanks!

---

**From:** Woods, Clint

**Sent:** Monday, April 23, 2018 6:14 PM

**To:** Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

**Cc:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Bolen, Brittany <[bolen.brittany@epa.gov](mailto:bolen.brittany@epa.gov)>; Baptist, Erik <[Baptist.Erik@epa.gov](mailto:Baptist.Erik@epa.gov)>; Beck, Nancy <[Beck.Nancy@epa.gov](mailto:Beck.Nancy@epa.gov)>; Gordon, Stephen <[gordon.stephen@epa.gov](mailto:gordon.stephen@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Beach, Christopher <[beach.christopher@epa.gov](mailto:beach.christopher@epa.gov)>; Ringel, Aaron <[ringel.aaron@epa.gov](mailto:ringel.aaron@epa.gov)>; Palich, Christian <[palich.christian@epa.gov](mailto:palich.christian@epa.gov)>; Jackson, Ryan <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>

**Subject:** Re: For Review: Science Transparency News Release

Thanks so much **Deliberative Process / Ex. 5** Two other quick thoughts:

## Deliberative Process / Ex. 5

On Apr 23, 2018, at 5:53 PM, Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)> wrote:

(This Email contains predecisional and deliberative matters)

## Deliberative Process / Ex. 5

Sent from my iPhone

On Apr 23, 2018, at 5:37 PM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

## Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

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<Document1.docx>

Message

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**From:** Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]  
**Sent:** 2/21/2018 10:05:37 PM  
**To:** Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Blancato, Jerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232de363dadb4cd9961900e10f56fddf-Blancato, Jerry]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]  
**Subject:** draft memo  
**Attachments:** data\_access\_memo V4 (002) cw 2-20.2.docx

(This email contains pre-decisional and deliberative material)

Hi Jennifer, Jerry and John:

Please see attached draft of a potential policy memo on data transparency: **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

I appreciate your thoughts and comments. If you could provide by tomorrow afternoon, that would be ideal. (OGC will be looking at this shortly afterwards, so I wanted our team to weigh in)

**Deliberative Process / Ex. 5**

*- Thank you.*

Thanks much,

Richard

Richard Yamada  
Deputy Assistant Administrator  
Office of Research and Development  
U.S. Environmental Protection Agency

Phone: **Personal Matters / Ex. 6**  
yamada.richard@epa.gov

Message

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**From:** Blancato, Jerry [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=232DE363DADB4CD9961900E10F56FDDF-BLANCATO, JERRY]  
**Sent:** 1/26/2018 6:01:24 PM  
**To:** Linkins, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7a94aa2975d4933981a8a9bf12aaa40-Linkins, Samantha]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]  
**Subject:** RE: today's call

Me too.

Jerry  
919-541-2854

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 1:01 PM  
**To:** Teichman, Kevin <Teichman.Kevin@epa.gov>  
**Cc:** Blancato, Jerry <Blancato.Jerry@epa.gov>  
**Subject:** Re: today's call

Will do.

Sent from my iPhone

On Jan 26, 2018, at 12:59 PM, Teichman, Kevin <[Teichman.Kevin@epa.gov](mailto:Teichman.Kevin@epa.gov)> wrote:

I would still like to meet at 1:00. Sam, please initiate the call.

We'll decide then who, in addition to Tom, should participate in the meeting.

Thanks.

Kevin Teichman  
Senior Science Advisor  
Office of Research and Development (8101R)  
U.S. Environmental Protection Agency  
1200 Pennsylvania Ave., NW  
Washington, DC 20460

Phone: (301) 975-6421  
Fax: (301) 975-4409

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 12:57:15 PM  
**To:** Blancato, Jerry  
**Cc:** Teichman, Kevin  
**Subject:** Re: today's call

Yup. (Unless you'd like to be a fly on the wall.)

Sent from my iPhone

On Jan 26, 2018, at 12:47 PM, Blancato, Jerry <[Blancato.Jerry@epa.gov](mailto:Blancato.Jerry@epa.gov)> wrote:

Does this mean Kevin and I can stand down?

Jerry  
919-541-2854

---

**From:** Linkins, Samantha  
**Sent:** Friday, January 26, 2018 12:45 PM  
**To:** Blancato, Jerry <[Blancato.Jerry@epa.gov](mailto:Blancato.Jerry@epa.gov)>  
**Subject:** Fwd: today's call

FYI

Sent from my iPhone

Begin forwarded message:

**From:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Date:** January 26, 2018 at 12:27:34 PM EST  
**To:** "Linkins, Samantha" <[Linkins.Samantha@epa.gov](mailto:Linkins.Samantha@epa.gov)>, "Teichman, Kevin" <[Teichman.Kevin@epa.gov](mailto:Teichman.Kevin@epa.gov)>  
**Subject:** Fwd: today's call

Sent from my iPhone

Begin forwarded message:

**From:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Date:** January 26, 2018 at 8:33:06 AM EST  
**To:** "Yamada, Richard (Yujiro)" <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>  
**Cc:** "Sinks, Tom" <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** today's call

I plan to call in today for the internal pre-brief. If asked  
– I think the bullets I would make are ..

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Thomas Sinks, Ph.D.  
Director, Office of the Science Advisor  
Environmental Protection Agency  
1200 Pennsylvania Ave NW  
Room 41251 RRB, MC 8105 R  
Washington DC, 20460  
office: (202) 564-3099 mobile: Personal Matters / Ex. 6  
email: [sinks.tom@epa.gov](mailto:sinks.tom@epa.gov)

Message

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**From:** Yamada, Richard (Yujiro) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4C34A1E0345E4D26B361B5031430639D-YAMADA, YUJ]  
**Sent:** 2/22/2018 10:09:08 PM  
**To:** Feeley, Drew (Robert) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=abae82aa36da4d3383eae19a8efa683c-Feeley, Rob]  
**Subject:** here's latest draft  
**Attachments:** data\_access\_memo V6.docx

This should have most of your comments, etc answered – I left a few unanswered, as you can see,

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

You can leave the comments in for now.

Could you give a look, and then we can send to Schwab?

Richard Yamada  
Deputy Assistant Administrator  
Office of Research and Development  
U.S. Environmental Protection Agency

Phone: Personal Matters / Ex. 6  
yamada.richard@epa.gov

Message

**From:** D'Amico, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78A91F83C4414910BE286EFE02004DBC-D'AMICO, LOUIS J.]  
**Sent:** 8/8/2018 10:50:38 PM  
**To:** Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]  
**CC:** Kuhn, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be20941b4c1144b8b3635e4df015924a-Kuhn, Kevin]; Christian, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a0f5e0e9d94271b23cad28db653851-Lizotte, Me]  
**Subject:** Small Group Transparency Rule Report  
**Attachments:** DRAFT Potential Implication 08072018 No Markup\_Lou.docx

Hi Jennifer,

Apologies for only getting this to you tonight. Attached is an electronic copy (to go along the printed version I just handed you) of the small group's evaluation of the impact of the transparency rule, in advance of your 11:00 meeting tomorrow morning with Kevin T. **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

I think Kevin T is going to be looking for input on at least two questions tomorrow w/r next steps in the document:



As background

**Personal Matters / Ex. 6**

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

hope this context helps! Have a good evening!

-Lou

Louis D'Amico, Ph.D.  
Senior Science Advisor  
Office of Research and Development  
U.S. Environmental Protection Agency  
Mail Code 8101R | 1200 Pennsylvania Ave, NW | Washington, DC 20460

Office: 202-564-4605 | Mobile: **Personal Matters / Ex. 6** | email: [damico.louis@epa.gov](mailto:damico.louis@epa.gov)

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

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Full Article:

Now Congress Should Act To Lock In Place Data Transparency

Steve Milloy

March 26, 2018

The Environmental Protection Agency will no longer rely on “secret” scientific data to justify regulations, Administrator Scott Pruitt announced last week. EPA regulators and agency-funded

researchers have become accustomed to producing unaccountable, dodgy science to advance a political agenda.

The saga began in the early 1990s, when the EPA sought to regulate fine particulate matter known as PM<sub>2.5</sub>—dust and soot smaller than 2.5 microns in diameter. PM<sub>2.5</sub> was not known to cause death, but by 1994 EPA-supported scientists had developed two lines of research purporting to show that it did. When the studies were run past the EPA’s Clean Air Science Advisory Committee, it balked. It believed the studies relied on dubious statistical analysis and asked for the underlying data. The EPA ignored the request.

As the EPA prepared to issue its proposal for PM<sub>2.5</sub> regulation in 1996, Congress stepped in. Rep. Thomas Bliley, chairman of the House Commerce Committee, sent a sharply written letter to Administrator Carol Browner asking for the data underlying studies. Ms. Browner delegated the response to a subordinate, who told Mr. Bliley the EPA saw “no useful purpose” in obtaining the data. Congress responded by inserting a provision in a 1998 bill requiring that data used to support federal regulation must be made available to the public via the Freedom of Information Act. But it was hastily written, and a federal appellate court held the law unenforceable in 2003.

The controversy went dormant until 2011, when a newly Republican Congress took exception to the Obama EPA’s anticoal rules, which relied on the same PM<sub>2.5</sub> studies. Again the EPA was defiant. Administrator Gina McCarthy refused requests for the data sets and defied a congressional subpoena.

Bills to resolve the problem died in the Senate. Democrats argued that requiring data for study replication is a threat to intellectual property and an invasion of medical privacy. In fact, the legislation would protect property by requiring a confidentiality agreement, and no personal medical data or information would have been released.

This sort of data is already routinely made public for research use. In 2012 I was desperate for a way around the Obama EPA’s secrecy on the PM<sub>2.5</sub> issue, I found out in 2012 that I could get California death-certificate data in electronic form. The state’s Health Department calls this sort of data “Death Public Use Files.” They are scrubbed of all personal identifying and private medical information. Some of my colleagues used this data to prepare a 2017 study, which found PM<sub>2.5</sub> was not associated with death.

The best part is that if you don’t believe the result, you can get the same data for yourself from California and run your own analysis. Then we’ll compare, contrast and debate. That’s how science is supposed to work.

It would be better if Congress would pass a law requiring data transparency. A future administrator may backslide on the steps Mr. Pruitt is taking. In the meantime, we have science in the sunshine.



Message

**From:** Christian, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=64A0F5E0E9D94271B23CAD28DB653851-LIZOTTE, ME]  
**Sent:** 5/31/2018 3:09:51 PM  
**To:** Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]  
**CC:** McPherson, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraf3de097]; Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]  
**Subject:** RE: Items for your review

Hi Chris,

Thank you for the quick reviews.

# Deliberative Process / Ex. 5

Best,  
Megan

Megan Christian, MPH  
Office of Research and Development  
U.S. Environmental Protection Agency  
[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)  
202-564-6184

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**From:** Robbins, Chris  
**Sent:** Thursday, May 31, 2018 9:44 AM  
**To:** Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>  
**Cc:** McPherson, Mark <[McPherson.Mark@epa.gov](mailto:McPherson.Mark@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** RE: Items for your review

Hi Megan,

I've reviewed all of these documents **Deliberative Process / Ex. 5** thx

Christopher S. Robbins  
Deputy Assistant Administrator for Management (Acting)  
Office of Research and Development  
**Personal Matters / Ex. 6**

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**From:** Christian, Megan  
**Sent:** Wednesday, May 30, 2018 4:54 PM  
**To:** Robbins, Chris <[Robbins.Chris@epa.gov](mailto:Robbins.Chris@epa.gov)>  
**Cc:** McPherson, Mark <[McPherson.Mark@epa.gov](mailto:McPherson.Mark@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>;

Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>

**Subject:** Items for your review

Good afternoon Chris,

Since we have a variety of items circulating around the IO for review, I wanted to consolidate all items in your wheelhouse into one email:

# Deliberative Process / Ex. 5

# **Deliberative Process / Ex. 5**

# **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

Megan Christian, MPH  
Office of Research and Development  
U.S. Environmental Protection Agency  
[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)  
202-564-6184

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Message

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**From:** Blackburn, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A080EB90549A453AAA6A357F5257C0B7-BLACKBURN, ELIZABETH]  
**Sent:** 9/10/2018 3:43:02 PM  
**To:** Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]  
**CC:** Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Christian, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a0f5e0e9d94271b23cad28db653851-Lizotte, Me]  
**Subject:** Re: invitation to Jennifer Orme-Zavaleta for SEJ panel

Sorry. Come to talk to you now.

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192  
Cell Personal Matters / Ex. 6

Sent from my iPhone

On Sep 10, 2018, at 11:42 AM, Hubbard, Carolyn <[Hubbard.Carolyn@epa.gov](mailto:Hubbard.Carolyn@epa.gov)> wrote:

Hi just to follow up- Deliberative Process / Ex. 5

**Deliberative Process / Ex. 5**

Let me know what you think.

Carolyn Hubbard  
Communications Director  
EPA Office of Research and Development  
202-564-2189  
Personal Matters / Ex. 6

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**From:** Orme-Zavaleta, Jennifer  
**Sent:** Friday, September 07, 2018 12:25 PM  
**To:** Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Cc:** Hubbard, Carolyn <[Hubbard.Carolyn@epa.gov](mailto:Hubbard.Carolyn@epa.gov)>; Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>  
**Subject:** Re: invitation to Jennifer Orme-Zavaleta for SEJ panel

Separate i think

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US EPA  
Cell Personal Matters / Ex. 6  
DC  
RTP

On Sep 7, 2018, at 11:47 AM, Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)> wrote:

9:30?

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192  
Mobile: Personal Matters / Ex. 6

---

**From:** Orme-Zavaleta, Jennifer  
**Sent:** Friday, September 7, 2018 11:47 AM  
**To:** Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Cc:** Hubbard, Carolyn <[Hubbard.Carolyn@epa.gov](mailto:Hubbard.Carolyn@epa.gov)>; Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>  
**Subject:** Re: invitation to Jennifer Orme-Zavaleta for SEJ panel

**Deliberative Process / Ex. 5** Lets discuss Monday

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US EPA  
Cell Personal Matters / Ex. 6  
DC 2  
RTP

On Sep 7, 2018, at 11:38 AM, Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)> wrote:

**Deliberative Process / Ex. 5**

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192  
Mobile: Personal Matters / Ex. 6

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**From:** Hubbard, Carolyn  
**Sent:** Friday, September 7, 2018 11:18 AM  
**To:** Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>  
**Cc:** Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>; Christian, Megan <[Christian.Megan@epa.gov](mailto:Christian.Megan@epa.gov)>  
**Subject:** RE: invitation to Jennifer Orme-Zavaleta for SEJ panel

Yes, it's been with OPA. Nancy is asking me about it. If you are interested, I think they would be ok with you doing it- otherwise she was wondering if you could suggest someone else.

Carolyn Hubbard

Communications Director  
EPA Office of Research and Development  
202-564-2189

Personal Matters / Ex. 6

**From:** Orme-Zavaleta, Jennifer  
**Sent:** Friday, September 07, 2018 11:04 AM  
**To:** Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>  
**Cc:** Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov>; Christian, Megan <Christian.Megan@epa.gov>  
**Subject:** Re: invitation to Jennifer Orme-Zavaleta for SEJ panel

I think we have seen this and it has been w opa. I also believe Francesca is speaking at it. Lets get some guidance.

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US EPA  
Cell  
DC 2  
RTP

Personal Matters / Ex. 6

On Sep 7, 2018, at 10:45 AM, Hubbard, Carolyn  
<Hubbard.Carolyn@epa.gov> wrote:

Hi Jennifer- were you aware of this request? This is the first I've seen it. Is this something you're interested in doing?

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Original request-from Elizabeth Shogren, Science Reporter, sent to Thomas Carpenter:

I'm moderating a panel on October 5 about science in Trump administration as part of the Society of Environmental Journalism's annual conference, which this year will be in Flint, Michigan.

I would greatly appreciate if Jennifer Orme-Zavaleta would participate in the panel.

The conference will be in Flint Michigan. Each panelist will be asked to give a brief opening statement and then we will field questions from the audience and I will likely ask some questions as well. Panelists will be encouraged to engage each other as well. Perhaps

Orme-Zavaleta could speak briefly about why the Trump administration proposed its secret science rule: <https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations>.

I would be very grateful if you would relay the invitation.

Thank you.

Best wishes,

Elizabeth Shogren

Message

**From:** Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALITA, JENNIFER]  
**Sent:** 3/16/2018 7:20:29 PM  
**To:** Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]  
**Subject:** Re: EPA: Pruitt is expected to restrict science. Here's what it means

Doesn't it tho!

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US EPA  
Cell: Personal Matters / Ex. 6  
DC 202-564-6620  
RTP 919-541-2283

On Mar 16, 2018, at 3:14 PM, Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov> wrote:

**Deliberative Process / Ex. 5**

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192  
Cell: Personal Matters / Ex. 6

Sent from my iPhone

On Mar 16, 2018, at 2:52 PM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

Yes, saw this.

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Sigh

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development  
US EPA  
Cell: Personal Matters / Ex. 6  
DC 2  
RTP

On Mar 16, 2018, at 2:46 PM, Blackburn, Elizabeth <Blackburn.Elizabeth@epa.gov> wrote:

I guess you saw this.

## Deliberative Process / Ex. 5

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192

Cell: [Personal Matters / Ex. 6](#)

Sent from my iPhone

Begin forwarded message:

**From:** "McGuinness, Moira"  
<[McGuinness.Moira@epa.gov](mailto:McGuinness.Moira@epa.gov)>  
**Date:** March 16, 2018 at 2:27:03 PM EDT  
**To:** "Hubbard, Carolyn" <[Hubbard.Carolyn@epa.gov](mailto:Hubbard.Carolyn@epa.gov)>,  
"Blackburn, Elizabeth" <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** EPA: Pruitt is expected to restrict science.  
Here's what it means

### EPA: Pruitt is expected to restrict science. Here's what it means

U.S. EPA chief Scott Pruitt is expected to roll out plans soon to restrict the agency's use of science in rulemakings, pitting him against critics who say it would threaten public health and environmental protections.

In a closed-door meeting at the Heritage Foundation on Monday, Pruitt told a group of conservatives that he has plans for additional science reform at the agency, according to multiple attendees. EPA hasn't formally shared details of the plan, but it's widely expected to resemble an effort that Republican lawmakers and conservative groups have been pushing for years. It's been met with staunch resistance from Democrats and many scientists.

The plan could come "sooner rather than later," said Steve Milloy, who served on Trump's EPA transition team and attended the meeting at the Heritage Foundation.

EPA did not respond to a request for comment. And Milloy cautioned that he did not know the specifics of the plan and said he was not authorized to discuss the meeting.

The initiative is expected to require EPA — when issuing rules — to rely only on scientific studies where the underlying data are made public. It's an idea that House Science, Space and Technology Chairman Lamar Smith (R-Texas) has been championing for years. He and others argue that EPA has been crafting regulations based on "secret science" to advance its regulatory agenda.

Smith, one of the leading opponents of mainstream climate science in Congress, has repeatedly accused federal climate scientists of engaging in a massive conspiracy to falsify climate data. And he has repeatedly introduced bills that would require EPA to publicize data it uses when crafting regulations.

Those efforts died when President Obama was in the White House, and Smith's newest legislative push doesn't appear to be moving even though Republicans control both chambers of Congress. The House passed a bill dubbed the "Honest and Open New EPA Science Treatment (HONEST) Act" — requiring that EPA rules be based on science for which underlying data is publicly available and reproducible — last March. But the measure has gone nowhere since it was referred to the Senate Environment and Public Works Committee.

Smith has tried to push the idea elsewhere, too. In comments on the 2019 budget proposal, the GOP majority on the Science panel led by Smith suggested that EPA's funding should be contingent on the administrator's "requiring that all scientific and technical information and data relied on to support a risk, exposure, or hazard assessment; criteria document; standard; limitation; regulation; regulatory impact analysis; or guidance issued by the EPA is made publicly available."

Smith did not respond to a request for comment.

Critics on the left and in the scientific community see the effort as an attempt to hinder EPA from issuing rules.

"A lot of the data that EPA uses to protect public health and ensure that we have clean air and clean water relies on data that cannot be publicly released," said Yogin Kothari with the Union of Concerned Scientists.

Many scientific studies rely on data that can't be made public for reasons like patient privacy concerns or industry confidentiality.

"If EPA doesn't have data to move forward with a public protection for a safeguard, it doesn't have to do that at all," said Kothari. "It really hamstring the ability of the EPA to do anything, to fulfill its mission."

Publishing raw data also opens scientists up to attacks from industry, which can twist or distort data to shape a deregulatory agenda, said Betsy Southerland, a former senior EPA official in the Office of Water who worked on a staff analysis of the "HONEST Act."

Southerland, who left EPA last summer, said the effort is deceptive and is not about transparency, but about sidelining peer-reviewed science that supports regulation of pollution. She said there are numerous examples of groundbreaking studies that are not replicable, such as human health studies after the dropping of atomic bombs in Hiroshima or the ecological effects of the BP PLC Gulf of Mexico oil spill. In many of the older studies, there are a plethora of people, including some who are dead, who could no longer be tracked down.

"This is just done to paralyze rulemaking," she said. "It's another obstacle that would make it so hard and so difficult to go forward with rulemaking that in the end, the only thing that would happen — in the best case you would greatly delay rulemaking; in the worst case you would just prevent it. It would be such an obstacle you couldn't overcome it."

Publicizing the data in some EPA actions, which often come after years of research, could be extensive. For example, risk assessments for certain chemicals sometimes cite hundreds or even thousands of studies, all of which would have to be tracked down for data collection, according to the EPA analysis of the "HONEST Act."

Requiring data transparency would cost hundreds of millions of dollars because it would require EPA staff to track down data from study authors and create an online management system to store and present those data, the analysis found. In addition, EPA staff would have to spend time redacting personally identifiable information in the studies, and study authors would likely require payments for preparing and sending their data.

EPA career staff estimated that Smith's legislation would add \$250 million in costs annually for the first few years after it was implemented, Southerland said. That estimate was dismissed by senior EPA officials who said those costs were inflated and that the agency would not use many studies to which the rule would apply, but they did not provide evidence, she said. EPA's analysis of Smith's bill was published by the radio program "Marketplace."

Milloy, who has long pushed for EPA to stop issuing regulations unless the underlying scientific data are made public, said the science reform effort could be done through a directive, in the same way that Pruitt reshaped EPA's science advisory panels.

The overhaul of those committees is another area where Pruitt came through on one of Smith's longtime priorities.

In October, Smith was seated front and center at an event where Pruitt announced that he would reform the advisory panels to bar researchers who take government funding. Critics said that move skewed the advice EPA is getting by making it tough for researchers who rely on public funding to participate, but keeping industry-funded scientists on board.

Pruitt then appointed as science advisers a number of researchers whose work is funded by industry, energy lobbying groups and conservative think tanks, while forcing out academics from major research institutions.

"Pruitt did a great job in cleaning up the science advisory boards, and if he does that kind of work on this, that's fantastic," Milloy said of the expected science data reform effort. "My goal is to make sure EPA does not rely on scientific studies unless the data is made available for replication by somebody."

Kothari of the Union of Concerned Scientists called it "alarming" that the Trump administration's science agenda "is being run by the chairman of the Science Committee, given that he has continued to not care about how science informs policymaking."

"This is the second thing now that this administrator will be implementing based on legislation that was never enacted," Kothari said. "It's just another excuse for Pruitt's EPA to really abrogate EPA's responsibility to protect human health and the environment."

Moira

---

Moira McGuinness  
EPA Research Editor in Chief  
202-564-1507—desk  
202-590-0010—mobile  
[mcguinness.moira@epa.gov](mailto:mcguinness.moira@epa.gov)

**Meeting with  
Chairman Lamar Smith (R-TX-21)  
Tuesday, January 9<sup>th</sup> 2018  
11:00AM, EPA HQ, Administrator's Office**

**Main Topics of Discussion:**

- HONEST Act, number one priority he wants to discuss
- Potential invitation to testify before House Science, Space, and Technology Committee
- Thanks you for SAB Reform and kind word in National Journal article

**NOTE:** Rep. Smith is the Chairman of the House Science, Space, and Technology Committee which has a limited jurisdiction over some of EPA science programs.

**Background:** The HONEST Act, which would prohibit the Environmental Protection Agency from proposing, finalizing, or disseminating regulations or assessments based upon science that is not transparent or reproducible, has been a priority for Chairman Smith. It passed the House but is not likely to move in the Senate. The Congressman would like to discuss potential ways EPA could implement the principals of the bill without legislative action along the lines of the SAB reform effort recently undertaken.

**Taking Points:**

- **HONEST Act:** Happy to have our staff at EPA work with committee staff on identifying potential areas you think we might be able to implement the transparency initiatives outlined in the HONEST Act using our regulatory/guidance authority.
- **Invitation to Testify:** We have seen a number of our political appointees confirmed by the Senate recently and are happy to work with your staff on identifying witnesses for Committee Hearings.

**Decision Points/Objectives:** This meeting is occurring at the request of Chairman Lamar Smith. His main objective for the meeting is to find a way to have the EPA implement the HONEST Act objectives outside of the legislative process since it is unlikely to pass in the Senate.

**Attendees:**

Troy Lyons, AA OCIR  
Aaron Ringel, DAA OCIR

Appointment

---

**From:** Doa, Maria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99E502A905374B0B890DB9B22E18D92E-MDOA02]  
**Sent:** 7/6/2018 3:28:54 PM  
**To:** Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Hetes, Bob [Hetes.Bob@epa.gov]; Lowit, Anna [Lowit.Anna@epa.gov]; Camacho, Iris [Camacho.Iris@epa.gov]; Sheppard, Tracy [Sheppard.Tracy@epa.gov]; Raffaele, Kathleen [raffaele.kathleen@epa.gov]; Birchfield, Norman [Birchfield.Norman@epa.gov]; Foster, Stiven [Foster.Stiven@epa.gov]; Peffers, Mel [Peffers.Mel@epa.gov]; Dockins, Chris [Dockins.Chris@epa.gov]; Flaherty, Colleen [Flaherty.Colleen@epa.gov]; Scozzafava, MichaelE [Scozzafava.MichaelE@epa.gov]; Schappelle, Seema [Schappelle.Seema@epa.gov]; Teichman, Kevin [Teichman.Kevin@epa.gov]; Shao, Nicole [Shao.Nicole@epa.gov]  
**CC:** Burden, Susan [Burden.Susan@epa.gov]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Suero, Maryann [suero.maryann@epa.gov]  
**Subject:** First Workgroup Meeting: Strengthening Transparency In Regulatory Science (83 Fr 18768); SAN 6781  
**Attachments:** Proposed rule.pdf; Extension of comment period and notice of public meeting.pdf; Provisional timeline of rule schedule overview 1st workgroup meeting.pdf; Standard Schedule for rule 1st workgroup meeting.pdf; COMMENT SUMMARY TOPICS\_StrenTrans. rev6.docx; Agenda 1st workgroup meeting.docx; Workgroup Members.docx  
**Location:** DCRoomRRB51161; Call-in number: **Personal Matters / Ex. 6**  
**Start:** 7/12/2018 7:00:00 PM  
**End:** 7/12/2018 8:00:00 PM  
**Show Time As:** Busy

Attached are the materials for the meeting. The agenda is attached and also shown below.

Agenda

- I. Introduction of workgroup members (*current list attached to meeting invite*)
- II. Overview of action
- III.
- IV.
- V.

# Deliberative Process / Ex. 5

- VI. Other items
- VII. Next steps

Strengthening Transparency In Regulatory Science Rulemaking  
1<sup>st</sup> Workgroup Meeting – July 12, 2018  
Agenda

- I. Introduction of workgroup members (*current list attached to meeting invite*)
- II. Overview of action

- III.
- IV.
- V.

**Deliberative Process / Ex. 5**

- VI. Other items
- VII. Next steps

Workgroup Members:

Workgroup Chair: ORD

Workgroup Chair Alternate: ORD

OAR Primary: Bob Hetes/RTP/OAR/OAQPS/HEID/RBG (919-541-1589)

OCSPP Primary: Anna Lowit/DC/OCSPP/OPP/HED (703-308-4135)

OCSPP Secondary: Iris Camacho/DC/OCSPP/OPPT/RAD (202-564-1229)

OCSPP Secondary: Seema Schappelle/DC/OCSPP/OSCP/ (202-564-8006)

OGC Primary: Tracy Sheppard/DC/OGC/SWERLO (202-564-1305)

OLEM Primary: Kathleen Raffaele/DC/OLEM/OPM (202-566-0301)

OLEM Secondary: Norman Birchfield/DC/OLEM/ORCR (703-347-0174)

OLEM Secondary: Stiven Foster/DC/OLEM/OAA, OPM (202-566-1911)

OP Primary: Mel Peffers/DC/OP/ORPM/PRAD

OP Secondary: Chris Dockins/DC/OP/NCEE (202-566-2286)

OW Primary: Colleen Flaherty/DC/OW/OST/HECD (202-564-5939)

OW Primary: Michael Scozzafava/DC/OW/OST/EAD (202-566-2858)

Message

**From:** Doa, Maria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99E502A905374B0B890DB9B22E18D92E-MDOA02]  
**Sent:** 8/22/2018 8:55:14 PM  
**To:** Flowers, Lynn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1a4411c874d041b9a8badfc32b91bd70-Flowers, Lynn]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Vallero, Dan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=338898e9462940748baa103863a000c7-Vallero, Dan]; Wade, Tim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5cd67598ea624da8bfd1b53bdfb4e9d4-Wade, Timothy J.]; Nelson, Daniel K. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9bd641d949d4a96b2d6c307be288afa-Nelson, Dan]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Updike, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920571ed9264c93b7bc670b0a498d04-Updike, David]; Noel, Glenda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4b623a1613b46af874225422c979326-Noel, Glenda]  
**CC:** Shao, Nicole [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=36641c9d93784a1899d4e3640f8c6ac3-Shao, nicole]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]  
**Subject:** ORD Team on Strengthening Transparency in Regulatory Science  
**Attachments:** Strengthening Transparency in Regulatory Science presentation v2.pptx; Strengthening Transparency in Regulatory Science 04-24-2018 (002).pdf; Transparency Comment Outline Aug 22 2018 ORD Team Focus.pdf

Hi -

Welcome to the ORD team addressing the science issues raised in comments on the proposed rule - Strengthening Transparency in Regulatory Science. You will receive an invitation to a meeting on September 5, 2018. I wanted to provide you with some background and some materials in advance. ORD's role in this rulemaking is quite different from the role we take in most other rulemakings. ORD is leading this rulemaking.

**Deliberative Process / Ex. 5**

## Deliberative Process / Ex. 5

Attached is an overview powerpoint and a copy of the proposed rule in case you have not seen it. Also attached is an outline of the public comment categories for the rulemaking. The sections in normal font are the areas we will discuss (starting with section III on page 2).

**Deliberative Process / Ex. 5**

Deliberative Process / Ex. 5

I will follow up before the meeting by sending you some public comments to illustrate some of the issues.

## Deliberative Process / Ex. 5

If you have any questions or would like additional information, please give me a call or email me.

I look forward to working with you all on this.

Thanks,  
Maria

Maria J. Doa, Ph.D.  
Office of Science Policy  
Office of Research and Development  
Environmental Protection Agency  
Tel. 202.566.0718

Message

**From:** Doa, Maria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99E502A905374B0B890DB9B22E18D92E-MDOA02]  
**Sent:** 6/19/2018 1:08:54 PM  
**To:** Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0d8bb05ce06d694985e-Hawkins, CherylA]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]  
**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort  
**Attachments:** COMMENT SUMMARY TOPICS\_StrenTrans. rev2 mjd.docx

Hi All,

Will we be discussing the outline with the contractor tomorrow? **Deliberative Process / Ex. 5**

## Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

Thanks,  
Maria

---

**From:** Doa, Maria  
**Sent:** Monday, June 18, 2018 4:22 PM  
**To:** Sinks, Tom <Sinks.Tom@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>; Hawkins, CherylA <Hawkins.CherylA@epa.gov>; Greene, Mary <greene.mary@epa.gov>  
**Cc:** Hauchman, Fred <hauchman.fred@epa.gov>  
**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Hi Tom,

## Deliberative Process / Ex. 5

As more of the comments come in the outline will branch out a bit more. Please note that in the schedule there is a step after the public meeting (on August 6) in which an updated version of the outline will be generated.

-Maria

---

**From:** Sinks, Tom  
**Sent:** Monday, June 18, 2018 4:13 PM  
**To:** Doa, Maria <Doa.Maria@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>; Hawkins, CherylA

<Hawkins.CheryLA@epa.gov>; Greene, Mary <greene.mary@epa.gov>

Cc: Hauchman, Fred <hauchman.fred@epa.gov>

**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Nice job Maria – this looks good.

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

**From:** Doa, Maria

**Sent:** Monday, June 18, 2018 3:55 PM

**To:** Sinks, Tom <Sinks.Tom@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>; Hawkins, CheryLA <Hawkins.CheryLA@epa.gov>; Greene, Mary <greene.mary@epa.gov>

Cc: Hauchman, Fred <hauchman.fred@epa.gov>

**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Hi Tom,

Attached is a draft of the response to comments outline.

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Let me know if you have any questions.

Thanks,  
Maria

**From:** Sinks, Tom

**Sent:** Thursday, June 14, 2018 4:08 PM

**To:** Doa, Maria <Doa.Maria@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>; Hawkins, CheryLA <Hawkins.CheryLA@epa.gov>; Greene, Mary <greene.mary@epa.gov>

Cc: Perry, Dale <Perry.Dale@epa.gov>

**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Thanks Maria – that works for me. I will be here until Tuesday at 11:00 am and then run to DCA for flight(s) to Sitka AK. I'll be back in the office on Friday 6/29.

**Deliberative Process / Ex. 5**

**From:** Doa, Maria

**Sent:** Thursday, June 14, 2018 2:55 PM

**To:** Sinks, Tom <Sinks.Tom@epa.gov>; Clarke, Robin <Clarke.Robin@epa.gov>; Dale Wells <dale.wells@state.co.us>; Hawkins, CheryLA <Hawkins.CheryLA@epa.gov>; Greene, Mary <greene.mary@epa.gov>

**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Hi Tom,

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5** think it will take me until Monday COB to share a synthesized outline for us within ORD (I know you will be off soon).

-Maria

---

**From:** Sinks, Tom

**Sent:** Thursday, June 14, 2018 10:52 AM

**To:** Joanne O'Loughlin <[joloughlin@scainc.com](mailto:joloughlin@scainc.com)>; Clarke, Robin <[Clarke.Robin@epa.gov](mailto:Clarke.Robin@epa.gov)>; Doa, Maria <[Doa.Maria@epa.gov](mailto:Doa.Maria@epa.gov)>; Dale Wells <[dale.wells@state.co.us](mailto:dale.wells@state.co.us)>; Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>; Greene, Mary <[greeney.mary@epa.gov](mailto:greeney.mary@epa.gov)>

**Cc:** Phil Norwood <[pnorwood@scainc.com](mailto:pnorwood@scainc.com)>; Nanishka Albaladejo <[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)>

**Subject:** RE: Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Thanks for sharing. Maria now has this version and a similar effort we had started as well.

---

**From:** Joanne O'Loughlin [<mailto:joloughlin@scainc.com>]

**Sent:** Wednesday, June 13, 2018 3:59 PM

**To:** Clarke, Robin <[Clarke.Robin@epa.gov](mailto:Clarke.Robin@epa.gov)>; Doa, Maria <[Doa.Maria@epa.gov](mailto:Doa.Maria@epa.gov)>; Dale Wells <[dale.wells@state.co.us](mailto:dale.wells@state.co.us)>; Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>; Greene, Mary <[greeney.mary@epa.gov](mailto:greeney.mary@epa.gov)>; Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>

**Cc:** Phil Norwood <[pnorwood@scainc.com](mailto:pnorwood@scainc.com)>; Nanishka Albaladejo <[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)>

**Subject:** Draft Preliminary Comment Summary Topics List - Strengthening Transparency in Regulatory Science ((83 FR 18768) Comment Summary Effort

Good Afternoon Robin/Team,

At our meeting this morning we noted that we jotted down some preliminary draft comment summary topics based on the subject Federal Register Notice (FRN) proposal. The preliminary draft list of topics is attached.

# Deliberative Process / Ex. 5

Regards,

*Joanne O'Loughlin*

Environmental Scientist

1414 Raleigh Road, Suite 450

Chapel Hill, North Carolina 27517

(984) 234-3970

[joloughlin@scainc.com](mailto:joloughlin@scainc.com)

[www.scainc.com](http://www.scainc.com)



---

This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

Message

---

**From:** Joanne O'Loughlin [joloughlin@scainc.com]  
**Sent:** 7/30/2018 6:52:54 PM  
**To:** Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]  
**CC:** Nanishka Albaladejo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdef62e4e]; Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]  
**Subject:** For August 1 Weekly Status Meeting: Comment Summary Discussion Items (Strengthening Transparency in Regulatory Science) – August 1, 2018  
**Attachments:** Comment Response Discussion Items\_Aug 1\_v1.0.docx

Good Afternoon Robin,

I have attached a short list of comment summary discussion items for the August 1 weekly status meeting. We thought it would be helpful to provide ahead of time. We are looking forward to our meeting with you on Wednesday.

Regards,

*Joanne O'Loughlin*

Environmental Scientist  
Work Phone: (984) 234-3970  
Cell Phone: (919) 452-1575  
Chapel Hill, North Carolina  
[joloughlin@scainc.com](mailto:joloughlin@scainc.com)  
[www.scainc.com](http://www.scainc.com)



This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

Message

---

**From:** Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]  
**Sent:** 5/17/2018 12:37:07 PM  
**To:** Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Pope, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41baa5adcd7045d3872762b9cae6478f-Pope, Danielle]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]  
**CC:** Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** Transparency in Regulatory science.contract.scope of work.draft.05172018 .docx  
**Attachments:** Transparency in Regulatory science.contract.scope of work.draft.05172018 .docx

Thanks for sharing the document yesterday Robin. I've made edits up until

**Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

Message

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**From:** Sinks, Tom [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=001007B7D256453A8A19B91DF704E22C-SINKS, TOM]  
**Sent:** 5/31/2018 5:29:55 PM  
**To:** Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Teichman, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20074f3f79c444a4b324cfbb890c7f56-Teichman, Kevin]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Hauchman, Fred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8bf9785f32048ccad5f60b25a72017d-Hauchman, Fred]  
**CC:** Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** organizing comments on transparency in regulatory science.draft05312018.docx  
**Attachments:** organizing comments on transparency in regulatory science.draft05312018.docx

# Deliberative Process / Ex. 5

I developed the attached based on the NPRM, comments we are receiving, and an understanding of the issues.

I'd love to get any constructive feedback ( ) you'd like to provide.

Message

---

**From:** Clarke, Robin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=568E817318E242B0A709E0DB888A0310-CLARKE, ROBIN]  
**Sent:** 5/23/2018 9:57:20 PM  
**To:** Reddick, Lorraine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14ff14b45eae417fa1db45cb36962e7e-LReddick]  
**CC:** Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Pope, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41baa5adcd7045d3872762b9cae6478f-Pope, Danielle]  
**Subject:** Re: Final Documents for SOW for WA 3-05 under contract EP-D-14-033  
**Attachments:** Transin RegulatorECRIGCEEP-D-14-033OP3.xls; CORForm1900.pdf; Final PWSWA3-05TransinRegsci.contract.docx

Hi Lorraine,

I have attached the new PWS, IGCE, and my signed COR Form, with your added changes, please proceed in submitting this forward to your contracts office. **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5** If you have any questions, please feel free to give me a call at the number below, or you can reach me by email. Again, I appreciate all of your help during this process.

Thanks

Robin R. Clarke

U.S. EPA | Office of Research and Development  
Immediate Office of the Assistant Administrator

(202) 564-6493 (wk)

(202) 564-2070 (fax)

clarke.rob@epa.gov

*"The true meaning of life is to plant trees, under whose shade you do not expect to sit"*

Message

---

**From:** Greene, Mary [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9AAA7190F96E4BFCA7B06F8BE3F35D45-GREENE, MARY]  
**Sent:** 5/17/2018 8:33:39 PM  
**To:** Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]  
**CC:** Pope, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41baa5adcd7045d3872762b9cae6478f-Pope, Danielle]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** Transparency in Regulatory science.contract.scope of work.draft.05172018  
**Attachments:** Transparency in Regulatory science.contract.scope of work.draft.05172018 .docx

**Importance:** High

Hi Robin,

I made several changes in the previous version to address edits and other comments provided. Please note.

Deliberative Process / Ex. 5

# Deliberative Process / Ex. 5

I think you can use this version to cost out the support.

Message

---

**From:** Joanne O'Loughlin [joloughlin@scainc.com]  
**Sent:** 6/26/2018 8:52:46 PM  
**To:** Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0d9b05ce06d694985e-Hawkins, CherylA]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]  
**CC:** Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]; Nanishka Albaladejo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdef62e4e]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere1144e76]  
**Subject:** Draft Approach for Summarizing "Level 3" Complexity Comments: "Strengthening Transparency in Regulatory Science" Comment Summary Effort  
**Attachments:** Draft Example\_RegScien\_L3 CommAppr.docx

Good Afternoon Robin, et. al.,

Attached is a draft approach for Deliberative Process / Ex. 5 that we will briefly discuss tomorrow at our 9:30 AM weekly status meeting.

Regards,

*Joanne O'Loughlin*

Environmental Scientist  
1414 Raleigh Road, Suite 450  
Chapel Hill, North Carolina 27517  
(984) 234-3970  
[joloughlin@scainc.com](mailto:joloughlin@scainc.com)  
[www.scainc.com](http://www.scainc.com)



Message

---

**From:** Clarke, Robin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=568E817318E242B0A709E0DB888A0310-CLARKE, ROBIN]  
**Sent:** 6/20/2018 7:10:22 PM  
**To:** Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere1144e76]; Nanishka Albaladejo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdef62e4e]  
**CC:** Doa, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99e502a905374b0b890db9b22e18d92e-MDoa02]; Greene, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aaa7190f96e4bfca7b06f8be3f35d45-Greene, Mary]; Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** FW: Updated outline for the response to comments  
**Attachments:** COMMENT SUMMARY TOPICS\_StrenTrans. rev3 mjd.docx

Hi Phil,  
Attached is the updated outlined per our meeting this morning.

---

**From:** Doa, Maria  
**Sent:** Wednesday, June 20, 2018 11:26 AM  
**To:** Clarke, Robin <Clarke.Robin@epa.gov>  
**Subject:** Updated outline for the response to comments

Hi Robin,

Attached please find the updated outline for the response to comments doc for the contractor.

Thanks,  
Maria

Message

**From:** Hawkins, CherylA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D917BEE23E774E0DBB05CE06D694985E-HAWKINS, CHERYLA]  
**Sent:** 8/7/2018 4:30:39 PM  
**To:** Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Nanishka Albaladejo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userdef62e4e]  
**CC:** Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=usere1144e76]; Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]  
**Subject:** RE: Strengthening Transparency in Regulatory Science - Draft Transcript  
**Attachments:** Full EPA 07.17.18 (RLSO) CAH.DOC

Hi Nan,

Attached is a copy of the draft transcript with my redline edits and comments. Also Tom has provided some comments below.

# Deliberative Process / Ex. 5

Cheryl A. Hawkins, Ph.D.  
US EPA/ORD/Office of the Science Advisor  
RRB 41259  
(202)564-7307  
hawkins.cheryla@epa.gov

---

**From:** Sinks, Tom  
**Sent:** Tuesday, August 07, 2018 11:22 AM  
**To:** Hawkins, CherylA <Hawkins.CherylA@epa.gov>  
**Cc:** Sinks, Tom <Sinks.Tom@epa.gov>  
**Subject:** RE: Strengthening Transparency in Regulatory Science - Draft Transcript

Cheryl – this looks great. **Deliberative Process / Ex. 5**

# Deliberative Process / Ex. 5

---

**From:** Hawkins, CherylA  
**Sent:** Monday, August 06, 2018 11:43 AM  
**To:** Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** FW: Strengthening Transparency in Regulatory Science - Draft Transcript

Hi Tom,

In case you want to take a look at the draft public comments document, it is attached.

So far, I found that they changed the EPA address in the red-line edits to the hearing room address and it should be changed back to the Pennsylvania Ave. address and there are places in the redline edits where I think they need to go back and check the recording.

Cheryl A. Hawkins, Ph.D.  
US EPA/ORD/Office of the Science Advisor  
RRB 41259  
(202)564-7307  
[hawkins.cheryla@epa.gov](mailto:hawkins.cheryla@epa.gov)

---

**From:** Nanishka Albaladejo [<mailto:nalbaladejo@scainc.com>]  
**Sent:** Friday, August 03, 2018 11:58 AM  
**To:** Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>  
**Cc:** Phil Norwood <[pnorwood@scainc.com](mailto:pnorwood@scainc.com)>; Joanne O'Loughlin <[joloughlin@scainc.com](mailto:joloughlin@scainc.com)>  
**Subject:** RE: Strengthening Transparency in Regulatory Science - Draft Transcript

Good afternoon Cheryl,

I hope you are having a great Friday. Attached is a redline strike out of the transcript. As previously mention we focused on things like misspellings of people's names and organizations, along with some formatting changes (to make the transcript more consistent; since we had 2 reporters).

Please let me know if you have any questions or concerns. Thank you.

Nanishka (Nan) Albaladejo  
LEED Green Associate/Environmental Scientist  
1414 Raleigh Rd., Ste. 450  
Chapel Hill, NC 27517  
Office: (919) 484-0222, ext 959  
Direct: (984) 243-3959  
[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)  
[www.scainc.com](http://www.scainc.com)



---

**From:** Clarke, Robin <[Clarke.Robin@epa.gov](mailto:Clarke.Robin@epa.gov)>  
**Sent:** Thursday, August 2, 2018 6:23 PM  
**To:** Nanishka Albaladejo <[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)>; Perry, Dale <[Perry.Dale@epa.gov](mailto:Perry.Dale@epa.gov)>  
**Cc:** Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>; Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>; Joanne O'Loughlin <[joloughlin@scainc.com](mailto:joloughlin@scainc.com)>; Phil Norwood <[pnorwood@scainc.com](mailto:pnorwood@scainc.com)>; Greene, Mary <[greenemary@epa.gov](mailto:greenemary@epa.gov)>  
**Subject:** RE: Strengthening Transparency in Regulatory Science - Draft Transcript

Hi Nanishka,

I have spoken with Dale Perry in reference to her receiving the draft transcript.

**Deliberative Process / Ex. 5**

## **Deliberative Process / Ex. 5**

**Deliberative Process / Ex. 5**

If you have any questions, by all means, let me know.

Thanks

Robin R. Clarke

U.S. EPA | Office of Research and Development  
Immediate Office of the Assistant Administrator  
(202) 564-6493 (wk)  
(202) 564-2070 (fax)  
[clarke.robin@epa.gov](mailto:clarke.robin@epa.gov)

*"The true meaning of life is to plant trees, under whose shade you do not expect to sit"*

---

**From:** Nanishka Albaladejo [<mailto:nalbaladejo@scainc.com>]

**Sent:** Tuesday, July 31, 2018 10:27 AM

**To:** Perry, Dale <[Perry.Dale@epa.gov](mailto:Perry.Dale@epa.gov)>; Clarke, Robin <[Clarke.Robin@epa.gov](mailto:Clarke.Robin@epa.gov)>

**Cc:** Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>; Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>; Joanne O'Loughlin <[joloughlin@scainc.com](mailto:joloughlin@scainc.com)>; Phil Norwood <[pnorwood@scainc.com](mailto:pnorwood@scainc.com)>

**Subject:** Strengthening Transparency in Regulatory Science - Draft Transcript

Good morning,

I hope you 'll are having a good day. I wanted to let you know that we received the draft transcript for the July 17 public hearing. With your permission we plan to review the transcript (433 pages) for any possible errors, such as spelling mistakes (e.g., EPA and speaker names and organizations), punctuation and grammar mistakes. After our initial review, we plan to forward the redline strike-out draft transcript to you for final review and approval.

Please let me know if you have any questions. Thank you and have a great day.

Nanishka (Nan) Albaladejo

LEED Green Associate/Environmental Scientist

1414 Raleigh Rd., Ste. 450

Chapel Hill, NC 27517

Office: (919) 484-0222, ext 959

Direct: (984) 243-3959

[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)

[www.scainc.com](http://www.scainc.com)



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This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

ED\_002389\_00029002-00003

Message

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**From:** Nanishka Albaladejo [nalbaladejo@scainc.com]  
**Sent:** 8/20/2018 1:37:32 PM  
**To:** Hawkins, CherylA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d917bee23e774e0dbb05ce06d694985e-Hawkins, CherylA]  
**CC:** Clarke, Robin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=568e817318e242b0a709e0db888a0310-Clarke, Robin]; Joanne O'Loughlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user1144e76]; Phil Norwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf809dbab]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** RE: EPA Strengthening Transparency in Regulatory Science  
**Attachments:** ATT00001.txt; 071718 EPA Public Hearing Full w Index.pdf; Full EPA 07.17.18 (RLSO) CAH REV081718.doc

Morning Cheryl,

I hope you had a nice weekend. Before we uploaded the "Strengthening Transparency in Regulatory Science" transcript to FDMS I wanted to re-confirm that you did not need to review the transcript a second time?

Thank you and have a great day.

Sincerely,

Nanishka (Nan) Albaladejo  
LEED Green Associate/Environmental Scientist  
1414 Raleigh Rd., Ste. 450  
Chapel Hill, NC 27517  
Office: (919) 484-0222, ext 959  
Direct: (984) 243-3959  
[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)  
[www.scainc.com](http://www.scainc.com)

---

**From:** Nanishka Albaladejo  
**Sent:** Friday, August 17, 2018 3:20 PM  
**To:** 'Hawkins, CherylA' <Hawkins.CherylA@epa.gov>; 'Sinks, Tom' <Sinks.Tom@epa.gov>  
**Cc:** 'Clarke, Robin' <Clarke.Robin@epa.gov>; Joanne O'Loughlin <joloughlin@scainc.com>; Phil Norwood <pnorwood@scainc.com>  
**Subject:** EPA Strengthening Transparency in Regulatory Science

Good afternoon Cheryl,

Attached are the revised, corrected transcripts, along with a redline strike out version (that include comments from the reporter; specifically noting area that are unchanged due to the commenter stating specifically what was transcribe).

We plan to upload the transcripts to the Docket, but before we do I wanted to re-confirm that you 'll did not need to review the transcript a second time?

Thank you and have a great day.

Nanishka (Nan) Albaladejo

LEED Green Associate/Environmental Scientist

1414 Raleigh Rd., Ste. 450

Chapel Hill, NC 27517

Office: (919) 484-0222, ext 959

Direct: (984) 243-3959

[nalbaladejo@scainc.com](mailto:nalbaladejo@scainc.com)

[www.scainc.com](http://www.scainc.com)



This email may contain privileged and confidential information intended only for the use of the specific entity named herein.

Message

---

**From:** Linkins, Samantha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B7A94AA2975D4933981A8A9BF12AAA40-LINKINS, SAMANTHA]  
**Sent:** 6/18/2018 4:16:53 PM  
**To:** Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]; Cawiezell, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb3be5507fbc4947bf3ac3d03af1f3ab-Cawiezell,]  
**Subject:** RE: Transparency Rule Docket Comments Mouse AL-18-000-8190 6-11-18.doc  
**Attachments:** Transparency Rule Docket Comments House AL-18-000-8190 6-13-18.doc; 18-000-8190.pdf

Attached is the final, approved by OCIR and Jennifer/Richard. Thomas, you can put this back into CMS/CCU to have them make the rest of the letter and print out for Tom to sign.

Samantha Linkins  
Science Communication  
Office of Research and Development, US EPA  
Washington, DC  
Office: 202-564-1834  
Cell: Personal Matters / Ex. 6

---

**From:** Sinks, Tom  
**Sent:** Thursday, June 14, 2018 9:53 AM  
**To:** Cawiezell, Thomas <Cawiezell.Thomas@epa.gov>  
**Cc:** Linkins, Samantha <Linkins.Samantha@epa.gov>  
**Subject:** FW: Transparency Rule Docket Comments Mouse AL-18-000-8190 6-11-18.doc

Tom – this was the latest draft – but it isn't final

---

**From:** Sinks, Tom  
**Sent:** Monday, June 11, 2018 4:09 PM  
**To:** Linkins, Samantha <Linkins.Samantha@epa.gov>  
**Cc:** Hawkins, CherylA <Hawkins.CherylA@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>; Greene, Mary <greene.mary@epa.gov>; Sinks, Tom <Sinks.Tom@epa.gov>  
**Subject:** Transparency Rule Docket Comments Mouse AL-18-000-8190 6-11-18.doc

Thanks Sam. Looked good. I made some minor edits. Since this is coming from me, I'd like to include the url for the regulations.gov posting Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Message

---

**From:** Bowman, Liz [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3D4D94D3E4B4B1F80904056703EBC80-BOWMAN, ELI]  
**Sent:** 4/26/2018 3:09:35 PM  
**To:** Grantham, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12a3c2ed7158417fb0bb1b1b72a8cfb0-Grantham, Nancy]  
**CC:** Bolen, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31e872a691114372b5a6a88482a66e48-Bolen, Brit]; Nickerson, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=148f2c1c05b54f358e29c59b841664aa-Wnicker]; Letendre, Daisy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b691cccca6264ae09df7054c7f1019cb-Letendre, D]; Wilcox, Jahan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88fd588e97d3405d869bcae98d391984-Wilcox, Jah]; Konkus, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=555471b2baa6419e8e141696f4577062-Konkus, Joh]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]  
**Subject:** RE: SIGNED: Strengthening Transparency in Regulatory Science

Awesome, thank you!

---

**From:** Grantham, Nancy  
**Sent:** Thursday, April 26, 2018 10:53 AM  
**To:** Bowman, Liz <Bowman.Liz@epa.gov>  
**Cc:** Bolen, Brittany <bolen.brittany@epa.gov>; Nickerson, William <Nickerson.William@epa.gov>; Letendre, Daisy <letendre.daisy@epa.gov>; Wilcox, Jahan <wilcox.jahan@epa.gov>; Konkus, John <konkus.john@epa.gov>; Yamada, Richard (Yujiro) <yamada.richard@epa.gov>; Hubbard, Carolyn <Hubbard.Carolyn@epa.gov>  
**Subject:** Re: SIGNED: Strengthening Transparency in Regulatory Science

Doing now

Sent from my iPhone

On Apr 26, 2018, at 10:47 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

I just talked to Brittany – Can we just add a link to the press release, with a PDF of the proposal? Until it's up on ORD's site?

---

**From:** Bolen, Brittany  
**Sent:** Thursday, April 26, 2018 10:34 AM  
**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>  
**Subject:** FW: SIGNED: Strengthening Transparency in Regulatory Science

---

**From:** Bolen, Brittany  
**Sent:** Thursday, April 26, 2018 10:24 AM  
**To:** Nickerson, William <[Nickerson.William@epa.gov](mailto:Nickerson.William@epa.gov)>; Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>; 'Daisy Letendre ([letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov))' <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Wilcox, Jahan

<[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>

**Subject:** RE: SIGNED: Strengthening Transparency in Regulatory Science

Hello Nancy - as you may have seen, the point of contact for this proposal is ORD. I do not know the ORD communications staff, but copying Richard here for awareness.

Thank you,

Brittany

---

**From:** Grantham, Nancy

**Sent:** Thursday, April 26, 2018 10:19 AM

**To:** Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>

**Cc:** Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>; Nickerson, William <[Nickerson.William@epa.gov](mailto:Nickerson.William@epa.gov)>; Germann, Sandy <[Germann.Sandy@epa.gov](mailto:Germann.Sandy@epa.gov)>

**Subject:** Re: SIGNED: Strengthening Transparency in Regulatory Science

Op - is there a suggested place on your pages? Thx ng

Sent from my iPhone

On Apr 26, 2018, at 10:15 AM, Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)> wrote:

Yes, that would be great. Can we put it on the appropriate place on the website?

---

**From:** Grantham, Nancy

**Sent:** Thursday, April 26, 2018 10:14 AM

**To:** Block, Molly <[block.molly@epa.gov](mailto:block.molly@epa.gov)>; Letendre, Daisy <[letendre.daisy@epa.gov](mailto:letendre.daisy@epa.gov)>; Bowman, Liz <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>; Wilcox, Jahan <[wilcox.jahan@epa.gov](mailto:wilcox.jahan@epa.gov)>; Konkus, John <[konkus.john@epa.gov](mailto:konkus.john@epa.gov)>

**Cc:** Nickerson, William <[Nickerson.William@epa.gov](mailto:Nickerson.William@epa.gov)>; Germann, Sandy <[Germann.Sandy@epa.gov](mailto:Germann.Sandy@epa.gov)>; Grantham, Nancy <[Grantham.Nancy@epa.gov](mailto:Grantham.Nancy@epa.gov)>

**Subject:** Fwd: SIGNED: Strengthening Transparency in Regulatory Science

Folks are looking for a link

on line for this - and op is saying we don't have yet - do we want to post this pdf someplace so we can link Tom it?

Thx ng

Sent from my iPhone

Begin forwarded message:

**From:** "Johnson, Laura-S" <[Johnson.Laura-S@epa.gov](mailto:Johnson.Laura-S@epa.gov)>

**To:** "Jackson, Ryan" <[jackson.ryan@epa.gov](mailto:jackson.ryan@epa.gov)>, "Bowman, Liz" <[Bowman.Liz@epa.gov](mailto:Bowman.Liz@epa.gov)>, "Lyons, Troy" <[lyons.troy@epa.gov](mailto:lyons.troy@epa.gov)>, "Bennett, Tate" <[Bennett.Tate@epa.gov](mailto:Bennett.Tate@epa.gov)>, "White, Elizabeth"

<[white.elizabeth@epa.gov](mailto:white.elizabeth@epa.gov)>, "Bodine, Susan" <[bodine.susan@epa.gov](mailto:bodine.susan@epa.gov)>, "Minoli, Kevin" <[Minoli.Kevin@epa.gov](mailto:Minoli.Kevin@epa.gov)>, "Leopold, Matt"

<Leopold.Matt@epa.gov>, "Bowman, Liz" <Bowman.Liz@epa.gov>, "Wheeler, Andrew" <wheeler.andrew@epa.gov>, "Bolen, Brittany" <bolen.brittany@epa.gov>, "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Yamada, Richard (Yujiro)" <yamada.richard@epa.gov>  
**Cc:** "Wooden-Aguilar, Helena" <Wooden-Aguilar.Helena@epa.gov>, "Grantham, Nancy" <Grantham.Nancy@epa.gov>, "Richardson, RobinH" <Richardson.RobinH@epa.gov>, "Hope, Brian" <Hope.Brian@epa.gov>, "Fonseca, Silvina" <Fonseca.Silvina@epa.gov>, "Hewitt, James" <hewitt.james@epa.gov>, "Abboud, Michael" <abboud.michael@epa.gov>, "Wilcox, Jahan" <wilcox.jahan@epa.gov>, "Gaines, Cynthia" <Gaines.Cynthia@epa.gov>, "Nickerson, William" <Nickerson.William@epa.gov>, "Lovell, Will (William)" <lovell.william@epa.gov>, "Kime, Robin" <Kime.Robin@epa.gov>, "Maguire, Kelly" <Maguire.Kelly@epa.gov>, "Blackburn, Elizabeth" <Blackburn.Elizabeth@epa.gov>  
**Subject: SIGNED: Strengthening Transparency in Regulatory Science**

Good afternoon

Today, the Administrator signed the proposed rule "Strengthening Transparency in Regulatory Science."

This proposed regulation is intended to strengthen the transparency of EPA regulatory science. The proposed regulation provides that when EPA develops regulations, including regulations for which the public is likely to bear the cost of compliance, with regard to those scientific studies that are pivotal to the action being taken, EPA should ensure that the data underlying those are publicly available in a manner sufficient for independent validation.

In this notice, EPA solicits comment on this proposal and how it can best be promulgated and implemented in light of existing law and prior Federal policies that already require increasing public access to data and influential scientific information used to inform federal regulation.

Attached is the signed and dated proposed rule. For your convenience, please go to p. 19 for the Administrator's signature.

Please contact me if you have any questions.

Sincerely,  
Laura

Laura S. Johnson | U.S. Environmental Protection Agency  
Special Assistant, Office of the Administrator | Cell | Personal Matters / Ex. 6  
Office (202) 566-1273 | [johnson.laura-s@epa.gov](mailto:johnson.laura-s@epa.gov)

Message

**From:** Orme-Zavaleta, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3C5A111DC377411595E5B24B5D96146B-ORME-ZAVALITA, JENNIFER]  
**Sent:** 5/16/2018 10:06:19 PM  
**To:** Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]  
**CC:** Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Yamada, Richard (Yujiro) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c34a1e0345e4d26b361b5031430639d-Yamada, Yuj]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Radzikowski, Mary Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac0a54e43bb4ac08276b57c5563c725-Radzikowski, Mary Ellen]; Christian, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a0f5e0e9d94271b23cad28db653851-Lizotte, Me]; Kuhn, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be20941b4c1144b8b3635e4df015924a-Kuhn, Kevin]; McPherson, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=useraf3de097]; Fleming, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14b4c2e10bf84f1fa9a3f91f5ca1c4c0-Fleming, Megan]; Branch, Danielle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=642b26a0fe0c45eb86cfd504b2d0b195-Branch, Dan]; Bhandari, Pradnya [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=590061335898471baf770048c5a794cf-Bhandari, P]; Perry, Dale [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8d297f23ce449d0b3f20780c9f94583-DPerry02]; Sinks, Tom [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=001007b7d256453a8a19b91df704e22c-Sinks, Tom]  
**Subject:** Re: SAB workgroup memo on proposed rule

Thanks. adding tom

Jennifer Orme-Zavaleta, PhD  
Principal Deputy Assistant Administrator for Science  
Office of Research and Development

US EPA

Cell  
DC  
RTI  
Personal Matters / Ex. 6

On May 16, 2018, at 5:58 PM, Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)> wrote:

All

As per Tom Carpenter, this is what will happen with the SAB work group memo –

**Deliberative Process / Ex. 5**

Liz Blackburn  
Chief of Staff  
EPA Office of Research and Development  
202-564-2192  
Mobile [Personal Matters / Ex. 6](#)

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**From:** Carpenter, Thomas  
**Sent:** Wednesday, May 16, 2018 5:30 PM  
**To:** Blackburn, Elizabeth <[Blackburn.Elizabeth@epa.gov](mailto:Blackburn.Elizabeth@epa.gov)>  
**Subject:** FW: Meeting Material Request approved for the Web site

FYI

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**From:** Carpenter, Thomas  
**Sent:** Tuesday, May 15, 2018 1:04 PM  
**To:** Muellerleile, Caryn <[Muellerleile.Caryn@epa.gov](mailto:Muellerleile.Caryn@epa.gov)>; Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** RE: Meeting Material Request approved for the Web site

Th path the Toms discussed:

## Deliberative Process / Ex. 5

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**From:** Muellerleile, Caryn  
**Sent:** Tuesday, May 15, 2018 12:32 PM  
**To:** Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>; Carpenter, Thomas <[Carpenter.Thomas@epa.gov](mailto:Carpenter.Thomas@epa.gov)>  
**Subject:** RE: Meeting Material Request approved for the Web site

## Deliberative Process / Ex. 5

Either of you: feel free to call if any questions.

thanks,  
Caryn  
564-2855

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**From:** Sinks, Tom  
**Sent:** Tuesday, May 15, 2018 11:16 AM  
**To:** Muellerleile, Caryn <[Muellerleile.Caryn@epa.gov](mailto:Muellerleile.Caryn@epa.gov)>; Feeley, Drew (Robert) <[Feeley.Drew@epa.gov](mailto:Feeley.Drew@epa.gov)>  
**Cc:** Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>; Yamada, Richard (Yujiro) <[yamada.richard@epa.gov](mailto:yamada.richard@epa.gov)>; Orme-Zavaleta, Jennifer <[Orme-Zavaleta.Jennifer@epa.gov](mailto:Orme-Zavaleta.Jennifer@epa.gov)>; Hawkins, CherylA <[Hawkins.CherylA@epa.gov](mailto:Hawkins.CherylA@epa.gov)>  
**Subject:** FW: Meeting Material Request approved for the Web site

I need some guidance. This is a memo from a working group of the EPA SAB related to their assessment of the EPA regulatory agenda and the need for the SAB to discuss this rule. This memo is on the SAB website at

[https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp\\_memo\\_2080-AA14\\_final\\_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf)

What are the standard operating procedures for including this in the official docket? How is it categorized?

Thanks

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**From:** Carpenter, Thomas  
**Sent:** Tuesday, May 15, 2018 9:52 AM  
**To:** Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** RE: Meeting Material Request approved for the Web site

Sorry – sent the secondary info to you. Attached is the memorandum. Direct link is provided in case you need to forward that. I will look for a time today.

[https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp\\_memo\\_2080-AA14\\_final\\_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf)

Tom

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**From:** Sinks, Tom  
**Sent:** Monday, May 14, 2018 1:52 PM  
**To:** Carpenter, Thomas <[Carpenter.Thomas@epa.gov](mailto:Carpenter.Thomas@epa.gov)>  
**Subject:** RE: Meeting Material Request approved for the Web site

Thanks – went to the site and didn't see anything that specified the NPRM

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**From:** Carpenter, Thomas  
**Sent:** Sunday, May 13, 2018 7:32 PM  
**To:** Brennan, Thomas <[Brennan.Thomas@epa.gov](mailto:Brennan.Thomas@epa.gov)>; Sinks, Tom <[Sinks.Tom@epa.gov](mailto:Sinks.Tom@epa.gov)>  
**Subject:** FW: Meeting Material Request approved for the Web site

Tom:

I posted the SAB Work Group Memorandum to the Board regarding Strengthening Transparency in Regulatory Science RIN (2080-AA14). It is available at the link below. I will be back in the office Tuesday (5/15).

Tom

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**From:** Thomas Carpenter [<mailto:Carpenter.Thomas@epamail.epa.gov>]  
**Sent:** Sunday, May 13, 2018 7:24 PM  
**Subject:** Meeting Material Request approved for the Web site

**The *Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)* Meeting Material, for the Chartered Science Advisory Board Meeting, for 5/31/2018 to 6/1/2018, has been posted to the SAB Web site at this location:**

<https://yosemite.epa.gov/sab/sabproduct.nsf/0/7D239353BCECF85B852582600058B716?OpenDocument&Date=5/31/2018>

The ***Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)*** Meeting Material, is also available in the product database:

**[Click here to open the Meeting and view the Meeting Material under Meeting Materials](#)**