Message

From: D'Amico, Louis [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=78A91F83C4414910BE286EFE02004DBC-D'AMICO, LOUIS J.]
Sent: 2/14/2019 8:29:11 PM
To: Orme-Zavaleta, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c5a111dc377411595e5b24b5d96146b-Orme-Zavaleta, Jennifer]; Dunlap, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=591eb15a268249dda0c05a7451f765c3-Dunlap, Dav]; Rodan, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Rodan, Bruce]; Robbins, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=958b4b78eb42457eacf53514e428efd6-Robbins, Chris]; Radzikowski, Mary Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2ac0a54e43bb4ac08276b57c5563c725-Radzikowski, Mary Ellen]; Hubbard, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2a93ce3245494318b109e87f7d826284-Hubbard, Carolyn]; Blackburn, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a080eb90549a453aaa6a357f5257c0b7-Blackburn, Elizabeth]
Subject: FYI Richard Denison Blog post (related to WSJ article)

http://blogs.edf.org/health/2019/02/14/the-trump-epas-actions-on-formaldehyde-can-be-summed-up-in-one-word-corrupt/

The Trump EPA's actions on formaldehyde can be summed up in one word: Corrupt

« Data visualization to drive clean air innovation and improve health
By Richard Denison / Bio / Published: February 14, 2019

Richard Denison, Ph.D., is a Lead Senior Scientist.

Today, Heidi Vogt at the *Wall Street Journal reported* on the systematic efforts by the Trump Administration to derail chemical assessments under the Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS).

Decisions are being made as I write by conflicted EPA political appointees, not only to derail the beleaguered IRIS assessment for the carcinogen formaldehyde, but to transfer any further assessment of the chemical to be under the control of those same political appointees.

The WSJ article cites an upcoming report by Congress' Government Accountability Office (GAO) that notes "EPA leadership in October directed the heads of the agency's various programs to limit the number of chemicals they wanted IRIS to study or continue researching. Nine of 16 assessments were then dropped, including one that looked at whether exposure to formaldehyde increases the risk of leukemia that 'has been drafted and is ready to be released for public comment.' " The chemical industry has long sought to undermine the findings of numerous governmental authorities that have identified the dangers posed by formaldehyde, one of the industry's biggest cash cows.

IRIS itself has also long been a target of the chemical and allied industries, including those well represented by EPA political appointees who are now able to drive the assault on IRIS from inside the agency.

This post will provide more of the backstory to the WSJ's excellent reporting. It reveals additional decisions being made as I write by conflicted political appointees, not only to derail the beleaguered IRIS assessment for formaldehyde, a known human carcinogen, but to transfer any further assessment of the chemical to be under the control of those same political appointees. What is happening here we believe is ripe for further investigation.

A brief history of IRIS and its formaldehyde assessment

IRIS, established in 1985, is situated within the science branch of EPA, the Office of Research and Development (ORD). That placement is intentional: ORD is not a regulatory branch, and placing IRIS there was intended to create an arms-length separation and a degree of independence from the EPA program offices that make regulatory decisions, decisions that necessarily consider more than science and can get caught up in political battles. As stated on EPA's website:

The placement of the IRIS Program in ORD is intentional. It ensures that IRIS can develop impartial toxicity information independent of its use by EPA's program and regional offices to set national standards and clean up hazardous sites.

The science IRIS does serves all parts of EPA – all of its program offices and its 10 EPA regions – where it is used to inform air and water pollution limits, waste site cleanup standards and other risk levels and regulatory actions. IRIS chemical hazard characterizations are also widely relied on by other federal agencies and other countries, as well as state and local governments (see this letter of support for IRIS from the Environmental Council of the States).

The IRIS assessment of formaldehyde has a long, convoluted, and contentious history that I will only touch on here before focusing on the latest chapter of this saga.

- In 2011, the National Academy of Sciences (NAS) reviewed the assessment and issued a report quite critical of the assessment's structure and its presentation and analysis of evidence, though not of its conclusions regarding formaldehyde's hazards. The report made numerous recommendations for improving the assessment and the IRIS process. That report led EPA to undertake a major overhaul of IRIS, in addition to redoing its formaldehyde assessment.
- In 2014, the NAS reviewed IRIS' progress in implementing its recommendations, and issued a new report that gave the program high marks, noting it had made more progress at a faster pace than had been expected.
- Also in 2014, the NAS affirmed a separate finding by the National Toxicology Program (NTP) that formaldehyde is a known human carcinogen and linked to nasopharyngeal cancer, sinonasal cancer, and myeloid leukemia. In response to that finding, the chemical industry's main trade association, the American Chemistry Council (ACC), issued a press release smearing the NTP.

- In 2017, EPA's Science Advisory Board (SAB) also reviewed IRIS' progress and issued a highly favorable report.
- In April 2018, the NAS conducted yet another review of IRIS and again specifically assessed the extent to which EPA had made progress in responding to its earlier 2011 and 2014 recommendations, yielding yet another positive report. In response, ACC issued a press release claiming it knows better than the nation's most august scientific body.
- In January 2018, EPA's IRIS report to Congress indicated that "IRIS plans to deliver an External Review of its Formaldehyde Assessment for public comment and peer review in FY18."

Enter the Trump EPA

First let me introduce the main EPA players in this latest chapter, in addition to the Office of the Administrator:

- Nancy Beck, Principal Deputy Assistant Administrator for the EPA Office of Chemical Safety and Pollution Prevention (OCSPP), which administers the Toxic Substances Control Act (TSCA). Beck came to EPA in April 2017 directly from a senior position at the American Chemistry Council (ACC), many of whose member companies are major producers and users of formaldehyde. While at ACC, one of Dr. Beck's main activities was a sustained assault on the IRIS program on behalf of ACC members; e.g, see here and here.
- David Dunlap, Deputy Assistant Administrator of ORD, who came to EPA in September 2018 directly from Koch Industries. Among other polluting companies, Koch owns the pulp and paper giant Georgia-Pacific, which is a major producer and user of formaldehyde.

Despite the fact that IRIS resides in ORD, Beck in OCSPP has been extensively involved in agency activities involving the IRIS program. As one measure of this, consider Dr. Beck's calendar for the first 10 months she was at EPA, which was recently released in response to an EDF FOIA request. During that short time, Beck's calendar shows 19 call or meeting entries involving IRIS.

Efforts last year by the Administration and EPA political appointees to defund IRIS (see last entry on p. 19), followed by a Senate majority appropriations bill that included language to dismantle IRIS entirely and relocate parts of it to OCSPP, were thwarted. The enacted FY18 appropriations bill continues to fund the IRIS program at FY17 levels and mandates that the program stay within ORD (see page 578).

Bear in mind that a draft of the revised IRIS formaldehyde assessment itself has been ready for review since the fall of 2017. In anticipation of its release for review, both chambers of Congress in reports accompanying the Consolidated Appropriations Act of 2017 directed EPA to contract with the NAS to conduct an external peer review of the revised IRIS assessment and they appropriated the needed funding.

Despite all of this, Trump appointees at EPA have steadfastly blocked release of the IRIS assessment.

Killing off the IRIS formaldehyde assessment

Meanwhile, efforts were being ramped up to kill off the assessment entirely. The most recent IRIS multi-year agenda, which was released in December 2015, listed the formaldehyde assessment as in progress. And it remains listed on the IRIS Tracker, with its status noted (optimistically, it turns out) as "Step 4. Public Comment and External Peer Review." But formaldehyde has now mysteriously disappeared from the most recent IRIS program outlook document (published December 19, 2018). What happened?

In August 2018, ORD initiated a process to identify EPA program office priorities for IRIS assessments (see response to question 117, here). David Dunlap, immediately upon his arrival at EPA from Koch Industries, oversaw the completion of that effort, which led to the December IRIS outlook document from which formaldehyde is absent. Dunlap then issued a prospectively applicable EPA recusal statement that includes a voluntary recusal from any matters related to the IRIS formaldehyde assessment, due to his deep conflicts of interest based on his prior employment. Miraculously, his recusal statement was dated the same day as the IRIS program outlook document.

EPA Acting Administrator Andrew Wheeler was asked about the status of the formaldehyde assessment in questions for the record submitted by Senator Ed Markey subsequent to Wheeler's January 16, 2019, Senate Environmental and Public Works Committee's hearing on his nomination to become EPA Administrator. In his response, Wheeler wrote (see responses to question 116, emphasis added):

Because IRIS assessments are major investments in both time and resources, in an August 10, 2018 Memorandum to Agency program offices I requested an update of top priorities for IRIS assessments. *Formaldehyde was not identified as a top priority.*

With this decision, Step 1 of the Trump EPA's strategy on formaldehyde appears to have been completed. Now it's onto Step 2.

Formaldehyde is expected to be resurrected as a top agency priority – but now under OCSPP's control

On January 29, the American Chemistry Council (ACC) posted a public notice of a meeting it will hold on February 20. The meeting notice follows an ACC letter dated January 7, 2019, sent to "formaldehyde stakeholders" announcing the creation of a formaldehyde consortium to plan for the anticipated imminent proposal by EPA to designate formaldehyde as a "high-priority substance" under TSCA:

Importantly, in January 2019, EPA is expected to announce the next 20 chemical substances that will undergo review by its TSCA risk evaluation program. Based on EPA's guidance for selecting chemicals for risk evaluation, formaldehyde is a prime candidate for selection by EPA as a high priority chemical in this next round of reviews due to its widespread use in the production of consumer products and its inclusion on EPA's TSCA work plan.

While EPA's announcement has been delayed in part by the government shutdown, it simply defies credulity that ACC would have scheduled such a meeting unless ACC at least knew about, if not had a hand in, EPA's plan to propose to designate formaldehyde as a TSCA high-priority chemical.

ACC's stated purpose for the meeting is to prepare "to engage with EPA on its formaldehyde risk evaluation activities" in order to "to ensure that formaldehyde remains a sustainable chemistry for use in various product applications."

(Given that the ACC meeting notice was made public and addressed to "formaldehyde stakeholders," EDF and other NGOs active in TSCA implementation and with high interest in formaldehyde RSVP'd for the meeting, as instructed in the meeting notice. Each of us quickly received an email from ACC indicating we were not welcome to attend the meeting.)

Should EPA finalize its high-priority designation, OCSPP will then initiate a risk evaluation of formaldehyde. Under normal circumstances, OCSPP could be expected to rely heavily on an IRIS assessment of a chemical in preparing its TSCA risk evaluation – rather than reinvent the wheel and waste precious EPA resources in duplicative efforts. But we are not facing normal circumstances.

To summarize, in the span of a few weeks, it appears we will move from EPA's Acting Administrator declaring formaldehyde *not to be* a high priority for the agency – and on that basis halting the finalization of the IRIS assessment – to EPA declaring formaldehyde *to be* a high priority for the agency – thereby resurrecting assessment of the chemical, but now under the direction of political appointees with a long history of antagonism toward IRIS' science and with conflicts of interests on this chemical.

Now that is a corrupt process.

It doesn't have to end this way

It would be a shame if this travesty plays out as the first major decision made under the leadership of the newly appointed OCSPP Assistant Administrator Alexandra Dunn, who has suggested she is looking to set a new and more balanced course for TSCA implementation. It's not too late to remedy the situation:

- IRIS could be allowed to complete the formaldehyde assessment through regular order, promptly releasing the current draft for agency, public and NAS review.
- Beck could step back into her lane at OCSPP and stop interfering with IRIS.
- If OCSPP still decides to designate formaldehyde as a high-priority substance, it should certainly rely on the completed IRIS assessment in conducting its risk evaluation, rather than having conflicted political appointees redo to their own liking the science IRIS has already done.

Deliberative Process / Ex. 5

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 | Mob Personal Matters / Ex. 6 | email: damico.louis@epa.gov