Message

From: Bahadori.Tina@epa.gov [Bahadori.Tina@epa.gov]
Sent: 5/18/2018 12:23:02 PM
To: Mazza, Carl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ef03c34ecaf4e219c037be57464ecf9-CMazza]; scho
Subject: Fwd: InsideEPA

Tina Bahadori
Director EPA/ORD/NCEA

Begin forwarded message:

From: "Bahadori, Tina" <Bahadori.Tina@epa.gov>
Date: May 18, 2018 at 8:12:50 AM EDT
To: "Orme-Zavaleta, Jennifer" <Orme-Zavaleta.Jennifer@epa.gov>, "Robbins, Chris" <Robbins.Chris@epa.gov>, "Blackburn, Elizabeth" <Blackburn.Elizabeth@epa.gov>, "Hubbard, Carolyn" <Hubbard.Carolyn@epa.gov>
Cc: "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Champlin, Anna" <Champlin.Anna@epa.gov>
Subject: InsideEPA

Does Richard need to be alerted?

EPA Again Finds Formaldehyde Poses Leukemia Risks But Stalls Study

May 17, 2018

After years of additional study and scientific review, EPA has again found that formaldehyde poses leukemia and other cancer risks, though Democratic senators say the draft finding has prompted Trump EPA appointees to block release of the assessment and they are urging Administrator Scott Pruitt to quickly release it.

Pointing to Pruitt's "back to basics" agenda for EPA, Sens. Tom Carper (DE), Ed Markey (MA) and Sheldon Whitehouse (RI) say in a May 17 letter to Pruitt that in their opinion, "assessing chemicals for their effects on human health is a basic part of EPA's mission to protect human health" and urge the administrator to "ensure there are no further efforts to delay or block the publication of this assessment that has serious implications for public health."

The senators say they have learned that the latest draft Integrated Risk Information System (IRIS) assessment of formaldehyde was completed "during the fall of 2017," but has yet to proceed through the regular intra-agency review process normally undertaken before the document is released for inter-agency review, public comment, and peer review.

They argue that "EPA by now should have published the assessment for public comment," but that it has not because "multiple political appointees within EPA have expressed reluctance to move the assessment through the agency review process, have repeatedly set up briefings on the assessment

only to later cancel them, and/or have insisted that IRIS first set up briefings for industry stakeholders before completing agency review."

The senators name Pruitt's chief of staff, Ryan Jackson, air office chief Bill Wehrum and toxics office appointee Nancy Beck, as among those delaying the formaldehyde assessment's public release.

The news marks the second time in a week that the agency is facing reports that it sought to delay conservative chemical assessments. *Inside EPA* first reported May 11 that Trump administration officials' concerns

are blocking release of the Agency for Toxic Substances and Disease Registry's toxicological profile of four PFAS chemicals that included risk estimates stricter than EPA's for two of the chemicals.

The senators say they believe the administration is delaying the draft formaldehyde assessment because it found the substance to be "carcinogenic, presenting evidence for nasopharyngeal cancer and leukemia, among other risks to human health."

Such a finding, while controversial, is not surprising -- EPA's last publicly available draft IRIS assessment, issued in 2010, also linked formaldehyde exposure to leukemia and nasopharyngeal risks.

But EPA never finalized the draft assessment after the National Academy of Sciences (NAS) strongly criticized its conservative risk estimates that would likely have driven a host of new regulatory requirements.

In addition, the NAS panel strongly faulted IRIS' methodology in crafting its draft assessment, warning of a pattern of problems in how the agency creates assessments for its IRIS database that have forced the program into years of reforms and continuing criticisms from industry and GOP critics.

But later NAS reports balanced the critique provided in the formaldehyde review. A 2014 NAS review concurred with the National Toxicology Program's (NTP) 2012 monograph that formaldehyde exposure could cause myeloid leukemia, while also waving aside some of industry and other critics' longtime arguments that formaldehyde exposure is unlikely to lead to systemic cancers like leukemia.

And NAS' 2014 and 2018 reviews of the IRIS program have largely praised the agency's efforts to implement the recommended reforms.

Industry Concerns

While industry officials acknowledge that formaldehyde exposure can cause nasopharyngeal risk, they say that type of cancer is much rarer and of less concern to the public than leukemia.

As a result, they have raised doubts about the agencies' conclusions and have also funded multiple studies trying to find a biological process by which formaldehyde causes leukemia.

They also sought to reanalyze a key 2010 study -- by University of California-Berkeley professor Luoping Zhang and colleagues that EPA, the National Toxicology Program and the International Agency for Research on Cancer -- have all relied upon in their conclusions that formaldehyde exposure can cause leukemia.

The Zhang study compared blood samples of Chinese workers exposed to formaldehyde with other unexposed Chinese factory workers, and concluded that chromosomal abnormalities in the exposed workers' cells were indicative of leukemia.

But last year, for example, the American Chemistry Council (ACC) touted new findings and a new award for a 2015 study it funded that re-analyzes raw data underlying the Zhang study. Authored by Ramboll Environ consultant Kenneth Mundt and colleagues, ACC's study points to flaws in the Zhang study's methods that the authors say should lead EPA and other agencies to alter their conclusions.

ACC in a press release about the studies argued that the reanalysis' findings "are important because they call into question the validity of all these recent formaldehyde assessments. The original paper failed to meet its own data quality standards and the scientific standard of reproducibility. Relying on it consequently led to unsubstantiated regulatory decisions and unwarranted outcomes."

ACC's findings also appear to have translated into industry advocacy. According to the senators' letter, ACC and Exxon Mobil "have been pressuring EPA not to release the assessment for public comment as drafted. ACC, ExxonMobil and other industry actors are said by the individuals we have communicated with to particularly object to findings related to leukemia," the senators write.

"Unfortunately, it appears that the agency may be succumbing to pressure from industry ... This is exceptionally disturbing, and lends further credence to the belief, already widely held, that EPA has been captured by industry," they say.

Such advocacy is likely responsible for delaying an assessment that was completed last fall. For example, Tina Bahadori, director of EPA's National Center for Environmental Assessment, told the agency's Science Advisory Board at its last meeting, in August 2017, that the IRIS program is working to soon release a new draft assessment of formaldehyde.

And last February, agency research officials sought to include formaldehyde as a topic of discussion at the next chartered SAB meeting, now scheduled for May 31 in Washington, D.C. Internal emails released to the Union of Concerned Scientists in response to a Freedom of Information Act request indicate that the acting head of SAB's staff office, Tom Brennan, sought to schedule a meeting with Beck, Brittany Bolen, the acting policy office associate administrator, and Richard Yamada, the deputy research office chief, to discuss the agenda for the next meeting of the chartered SAB.

In a Feb. 13 email, Brennan tells Beck, Bolen and Yamada that Jackson asked them to meet to discuss "potential topics" for the upcoming Spring SAB meeting. "We have a couple of potential items we can discuss including the war on lead, PFAS, crossagency activities and formaldehyde."

But the agenda for the SAB's May meeting -- the first since Pruitt took the helm at EPA -- includes the federal lead strategy and "EPA approaches on perfluoroalkyl substances."

Formaldehyde is not mentioned, though Bahadori and IRIS chief Kris Thayer are slated to present an IRIS "update." EPA has already contracted with NAS to review the next draft formaldehyde assessment, the senators' letter notes, but it cannot do so until the assessment completes a series of internal, inter-agency and public reviews.

But one environmentalist says it is clear that the draft assessment is being held back at EPA. It "has been stuck in [EPA] for so long it will take laxatives to get it out," says a source with the Natural Resources Defense Council.-- *Maria Hegstad* (mhegstad@iwpnews.com)