



May 29, 2019

Dr. Thomas Armitage,
Designated Federal Officer (DFO),
EPA Science Advisory Board
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Re: EPA's request for SAB advice regarding upcoming actions related to an update to the "2005 EPA Guidelines for Carcinogen Risk Assessment" and creation of guidelines for non-cancer risk assessment. Meeting of June 5-6, 2019

Dear Members of the EPA Science Advisory Board,

NRDC recognizes that scientific advances in the fields of cancer and non-cancer risk assessment may support the need for updates to EPA guidelines and policies, and as scientists and policy experts we are happy to offer our expertise and support to help guide this endeavor.

NRDC appreciates that the SAB is being asked to provide its expert recommendations to EPA. However, we have concerns regarding the willingness of the current EPA leadership to develop and follow a deliberate, transparent and inclusive process for updating its guidelines. Further, we are concerned that EPA's intentions are not consistent with the Agency's stated mission, "to protect human health and the environment".¹ We believe in this mission, but it cannot be achieved without transparency and accountability. This will require a credible process, public participation and accurate information.

Is EPA leadership committed to a credible, transparent and public process, and is its goal to gather accurate information for the purpose of carrying out its mission to protect human health and the environment? We raise this question in light of EPA's recent demonstrated willingness to repeatedly disregard scientific consensus, and even its own Agency scientists, on important environmental health issues. For example:

Science Transparency Rule. The 2018 proposed Science Transparency Rule² was opposed by academic health experts, scientific journal editors, and this SAB.³ Main concerns raised by the SAB included: "the proposed rule appears to have been developed without a public process for soliciting input specifically from the scientific community," and that it, "proposes constraints to

¹ EPA website. <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>

² <https://www.epa.gov/osa/strengthening-transparency-regulatory-science>

³ See list of opposing groups with links to original authors here: <https://www.nrdc.org/experts/jennifer-sass/health-experts-rebut-trump-epa-censoring-science-rule>

the use of scientific studies in particular contexts," including the use of epidemiology, dose-response models, and mechanism of action information.⁴

TSCA Systematic Review implemented without scientific review or consensus. The TSCA Systematic Review has been strongly criticized by experts in the field, and yet EPA is using it without having subjected it to SAB review or a public peer review process.⁵ This circumvents EPA's peer review process and avoids SAB review of a document that surely fails scientific scrutiny.

Withholding the IRIS program's formaldehyde assessment from SAB and public review. The IRIS program's formaldehyde hazard assessment has been finished in draft form for well over a year, but has been withheld by the Administrator, as reported in a March 2019 GAO report.⁶

Stripping resources from IRIS chemical assessment program. The March 2019 GAO report found that, "between June and December 2018, EPA leadership directed the program to stop the assessment process ...", and instead moved staff into the TSCA program.⁷ The IRIS program supports many other EPA and Agency programs in addition to the TSCA program, as well as states, local governments, and impacted communities. This shift in resources leaves those many Agency programs and scientists unsupported.⁸

EPA's leadership is not only disregarding recommendations of its expert staff, but seems also to be circumventing the SAB. For example, in his April 19 letter to the SAB, Administrator Wheeler wrote that, on the Strengthening Transparency in Regulatory Science proposed regulation, SAB will be consulted only on mechanisms for securing access to confidential business information and personally identifiable information. This limited issue is only one among many scientific and science-policy issues relevant to the proposed rule that would benefit from SAB consultation. If the SAB is to be meaningfully involved in reviewing EPA's planned actions to amend the Agency's Cancer Guidelines, and formally establish non-Cancer Guidelines, the Board should not be constrained by limited and narrow charge questions that do not take full advantage of SAB expert input. Agency science and science policies should not be shielded from outside expert review and public participation.

Although little information about EPA's intentions or process have yet been made public, what has been reported or gleaned from Agency staff is concerning. For example, Administrator Wheeler has indicated his intent to have draft versions by late fall, and to finalize both revisions to the Cancer Guidelines, establishment of non-cancer Guidelines, as well as a Hazard Communication plan by the end of 2020

⁴ Science Advisory Board (SAB) Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science. EPA-SAB-18-003. June 28, 2018. [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/4ECB44CA28936083852582BB004ADE54/\\$File/EPA-SAB-18-003+Unsigned.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebProjectsCurrentBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf)

⁵ Comments from Academics, Scientists and Clinicians on: The Application of Systematic Review in TSCA Risk Evaluations. Submitted online via Regulations.gov to docket EPA-HQ-OPPT-2018-0210-0107
Comment submitted by Juleen Lam, Assistant Professor, Department of Health Sciences, California State University, East Bay et al EPA-HQ-OPPT-2018-0210-0081

Comment submitted by Jennifer Sass, Senior Scientist. Natural Resources Defense Council (NRDC) et al EPA-HQ-OPPT-2018-0210-0103

⁶ GAO. Status of EPA's Efforts to Produce Assessments and Implement the Toxic Substances Control Act. Report of the US Government Accountability Office, GAO-19-270: Published: Mar 4, 2019. <https://www.gao.gov/products/GAO-19-270>

⁷ <https://www.gao.gov/products/GAO-19-270>

⁸ <https://www.gao.gov/products/GAO-19-270>

“but sooner if possible.”⁹ This is an alarmingly short amount of time for such a serious and technical undertaking, and suggests that consideration, deliberation and consultation may all be sacrificed to meet an arbitrary deadline – with potentially serious consequences for scientific integrity, the Agency’s credibility, and public health.

We have also been troubled to hear that the Administrator has raised the possibility of circumventing EPA’s Risk Assessment Forum and instead assigning the work of developing revisions to the Cancer Guidelines and non-cancer guidelines to third-party sources. Such an approach would raise very serious concerns regarding public input, openness of the process and potential conflicts. The apparent rush to revise the Cancer Guidelines, and establish non-cancer guidelines – including potentially circumventing EPA’s long-established process for doing so -- deserves serious scrutiny by the SAB. As noted above, we recognize that the advance of scientific understanding, the development of new technologies and other factors may warrant a period revisiting and updating of Agency Guidelines, but it will be important for the SAB to learn what changes in science or policy the Administrator sees as driving its unusual and problematic approach.

If EPA is to move forward, we recommend that a process be put in place to ensure that there are opportunities for meaningful public engagement early in the process and continuing throughout. To be meaningful, public engagement must be done early and at intervals through the document development period, so that the public is fully informed, and its recommendations and concerns can be addressed and, where appropriate, integrated into the development process. To be inclusive and truly public, it should also include webinar and dial-in participation at public meetings. This will better facilitate participation and input from pollution-impacted communities, academic experts, health and science policy organizations, Tribal representatives, and others who may not have the ability to easily travel to Washington DC to participate in meetings and other related activities. EPA does this for many but not all of its public meetings, indicating that it is feasible to do so for all public meetings.

An early step should include identifying issues that new or updated risk assessment guidelines should address, with extensive SAB involvement, as well as meaningful public engagement. We suggest the following issues as areas that would benefit from SAB and public discussion:

Chemical classes – Guidelines should be updated to describe how chemicals can be grouped together in a risk assessment so as to address all or many members of a chemical class. This approach was recommended in the recent National Academies (NAS) report on organohalogen flame retardants; the National Academies Committee backed a class-based approach for non-cancer hazards as the “only possible practical” one for such a large class of hazardous chemicals.¹⁰

Using mechanistic information – Guidelines should be updated to address how EPA can use key characteristics of carcinogens¹¹ to group agents together and to determine their carcinogenicity. These characteristics could be gleaned from mechanistic information, quantitative structure-

⁹ Inside EPA. EPA Seeks To Update Cancer Risk Guide, Plans New Non-Cancer Guide. Maria Hegstad. April 24, 2019

¹⁰ National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25412>.

¹¹ Smith MT, Guyton KZ, Gibbons CF, Fritz JM, Portier CJ, Rusyn I, et al. (2016). Key characteristics of carcinogens as a basis for organizing data on mechanisms of carcinogenesis. *Environ Health Perspect.* 124(6):713–21. <https://doi.org/10.1289/ehp.1509912> PMID:26600562

activity information, and read-across information. We recommended consistency with the approach described in the recently updated 2019 IARC Preamble and the 2019 IRIS Handbook.

Dose-response curves – There are many reasons why an exposure-response relationship may not be evident in a study, including poor exposure data and exposure misclassification. Guidelines should clarify this fact. Random exposure misclassification biases the risk estimates toward zero; both the direction and magnitude of bias should be noted whenever possible.

Early life susceptibility – Guidelines should expand early life sensitivity protections to account for the risks posed by prenatal exposures.

Non-mutagenic carcinogens – Guidelines regarding increased susceptibility of early life-stages and sensitive populations to mutagens should be expanded to also include non-mutagenic carcinogenic agents.

No threshold for population risks – Guidelines should expand dose-response analysis to better account for environmental exposure levels, exposure to multiple hazardous agents, exposures in the presence of existing processes and other real-world scenarios. This would address recommendations from numerous National Academies reports including ‘Science and Decisions’ and be a considerable advancement to providing a reference dose that is far too simplistic to ever be accurate, or adequately protective across a diverse population that includes vulnerable subpopulations.¹²

Hazard ID must be informative - A proper hazard identification should describe target endpoints for cancer and non-cancer effects. A simple reference dose doesn’t tell the public what specific hazards are associated with an exposure. For example, it is important to know that perfluoroalkyl substances (PFAS) are linked to asthma in children, so that parents can take increased precautions if there are asthmatic children in the home.¹³ Similarly, it is important to know what kind of cancer, organ, or system toxicity is associated with exposure to a particular chemical so that individuals and communities with special sensitivities can be informed and protected.

Avoid paralysis by analysis - Updated Guidelines should clarify that EPA should provide an analysis of all relevant available information, and not all information, to avoid endless delays and facilitate completion of robust assessments.

Additionally, we strongly recommend that EPA and the SAB consider the scientific consensus as presented in the recently updated IARC Monographs Preamble¹⁴ and by the EPA IRIS Program in its draft Handbook for Developing IRIS Assessments (April 2019). Both documents have benefited from extensive scientific input from a broad range of experts.

¹² National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12209>.

¹³ Rappazzo KM, Coffman E, Hines EP. Exposure to Perfluorinated Alkyl Substances and Health Outcomes in Children: A Systematic Review of the Epidemiologic Literature. *Int J Environ Res Public Health*. 2017;14(7):691. Published 2017 Jun 27. doi:10.3390/ijerph14070691

¹⁴ IARC Monographs on the Identification of Carcinogenic Hazards to Humans, Preamble. January 2019. <https://monographs.iarc.fr/preamble-to-the-iarc-monographs/>

In conclusion, EPA's risk assessment guidelines of any sort are highly influential and extremely important for the protection of public health. The process to review and revise existing guidelines, or establish new ones, should ensure that the best available science is incorporated, and include full and meaningful engagement with the public and with the SAB early and throughout the process, as well as review by the National Academies.

Thank you for the opportunity to provide comments.

Respectfully,

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