

June 16, 2018

Letter to Oppose the EPA Proposed Rule on Strengthening Transparency in Regulatory Science from Environmental Health Professionals and Organizations

RIN: 2080-AA14

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Dear EPA Administrator,

We are environmental health professionals and organizations with expertise and interest in protecting children and their families from exposures to toxic chemicals that could lead to neurodevelopmental harm. We strongly support EPA's mission to protect human health and the environment, including by setting exposure limits and clean-up standards for environmental pollutants.

This letter is to voice our opposition to the EPA Proposed Rule, *Strengthening Transparency in Regulatory Science*.¹ We are opposed to this proposal because it will hamstring the Agency's use of scientific information, which can only harm EPA's work quality and public credibility. The proposed rule prohibits the Agency from setting regulations that are supported, in part or whole, by data that is not publicly available for re-analysis or that cannot be replicated. Since the proposed rule is retroactive, it could lead to the dismantling of many important existing EPA regulations.

Moreover, its claims of increasing transparency are disingenuous because the Proposal may allow EPA to consider significant amounts of information submitted by industry to the agency, even though the information will be protected as Confidential Business Information (CBI) and shielded from the public. Because industry data are associated with CBI claims more so than public health researchers' work, the Proposal reveals its industry bias.

EPA regulations that reduce exposure to pollutants and chemicals that are toxic to the developing brain have for decades relied on studies that included data and information that was not made fully public, including longitudinal epidemiologic studies, human clinical studies, and animal toxicologic studies. In many cases, the original raw data does not exist or is no longer accessible. In other cases, individual participant's data cannot be made public because of confidentiality requirements legally mandated by Institutional Review Boards and/ or the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In some cases, the original studies cannot be replicated because the high exposure conditions no longer exist, thanks to successful EPA safeguards.

Some examples of existing EPA actions that have reduced people's exposures to toxic chemicals, that may be rolled back because of this rule are below:

Air pollution

Most air pollution is the result of burning fossil fuels, such as coal, oil, natural gas, and gasoline to produce electricity and power vehicles.² Prenatal and early childhood exposure to air pollution increases the risk of developmental delays, reduced IQ, symptoms of anxiety, depression and inattention. Air pollution may also increase children's risk of developing autism. Thanks to EPA regulations since 1997 that relied on the Harvard Six Cities study (a longitudinal epidemiologic study of thousands of individuals begun in the 1970s) and American Cancer Society study, among others, EPA has determined that over 230,000 premature deaths will be prevented by 2020, with benefits exceeding the costs of the Clean Air Act by 30-fold.³

The Six Cities study has been reanalyzed many times, including by the Health Effects Institute (a public non-profit co-funded by EPA and the regulated industry) and the American Cancer Society, in published reports.⁴ Despite rigorous and transparent expert review and approval, the Six Cities findings continue to be disputed by polluters and their allies in Congress.^{5,6}

Lead in drinking water

The damaging effects of early childhood lead exposure can last a lifetime, so prevention is the only effective and meaningful solution. EPA's Lead and Copper Rule (LCR) of 1991 does just that by establishing drinking water limits, monitoring, and protective actions if needed. The rules are based on epidemiology studies published in the 1990's that correlate childhood blood lead levels with impaired brain function and adverse behavioral effects.⁷ Many of the published studies are longitudinal cohort studies that include measurements of lead in blood from children decades ago, and then follow them out over time to observe lasting effects.

Thanks to important EPA regulations and effective lead-reduction measures in gasoline and paint, overall blood lead levels have been reduced in many people. This makes it impossible to replicate the exposure conditions at the time the original children in the study cohort had their blood lead levels measured, nor would it be ethical to seek to do so.

Neurotoxic pesticides like chlorpyrifos

Organophosphate pesticides like chlorpyrifos are widely used in agriculture, with over 5 million pounds of the insecticide applied annually across the U.S to a variety of crops including apples, oranges, broccoli and berries.⁸ Symptoms of acute poisoning include nausea and vomiting, headaches, dizziness, seizures, paralysis, and in extreme cases, even death. Due to risks to children's health, in 2000, EPA banned household use of chlorpyrifos and most other organophosphate pesticides.⁹ The studies can no longer be reproduced because – thanks to the Food Quality Protection Act (FQPA) and the ban on residential uses – pregnant women and

young children are no longer poisoned by indoor use of organophosphate pesticides at such high levels.

Conclusion

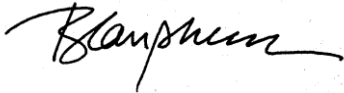
As scientists and health professionals we recognize the importance of data sharing and replicability in scientific practice and discourse. We would welcome an open dialogue to improve science-based decisions across the federal government, including at EPA. However, as The Economist pointed out in an editorial last month, this proposed rule is about stifling science used by EPA, not improving it.¹⁰ The editors of Science, Nature, the PLOS journals and the Proceedings of the National Academies of Science have issued a joint statement of opposition of the Proposed Rule.¹¹ The EPA Chartered Science Advisory Board (SAB) identified many of the problems we've detailed in this letter, and recommended that it merits review by the SAB.¹² We share many of these concerns, and therefore strongly oppose the proposal.

Thank you for the opportunity to provide comments.

Respectfully,



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