

May 15, 2017

Comments from Academics, Scientists, and NGOs on the Evaluation of Existing Regulations

EPA-HQ-OA-2017-0190
FRL-9961-60-OP

Comments submitted to EPA-HQ-OA-2017-0190 and by email to Sarah Rees, Director, Office of Regulatory Policy and Management, Office of Policy, 1200 Pennsylvania Avenue N.W., Mail Code 1803A, Washington, DC 20460, Phone: (202) 564-1986; Laws-Regs@epa.gov.

These comments are submitted on behalf of the undersigned academic, scientists, and clinicians from universities and non-governmental organizations (NGOs) across the U.S. We collectively declare that we have no direct or indirect financial or fiduciary conflicts of interest relevant to the evaluation of existing regulations.

We appreciate the opportunity to provide written comments on the Agency's proposal regarding the evaluation of existing regulations. In response to Executive Order 13777 signed February 24, 2017, the Environmental Protection Agency (EPA) is soliciting input from the public to inform its Task Force's evaluation of existing regulations. EPA previously held a public meeting on May 1, 2017 in Washington D.C. and several of the undersigned submitted oral comments at that time. We appreciate this subsequent follow-up opportunity to submit further comments to EPA's Office of Pollution Prevention and Toxics (OPPT) regarding regulatory reform under the Toxic Substances Control Act (TSCA) Subchapters I (Control of Toxic Substances), II (Asbestos Hazard Emergency Response), VI (Formaldehyde Standards for Composite Wood Products) and the Emergency Planning and Community Right-to-Known Act (EPCRA) Subchapter II §11023 (Toxic chemical release forms), commonly referred to as the Toxics Release Inventory (TRI) (Docket No. EPA-HQ-OA-2017-0190-0042).

We strongly support EPA in its efforts to fulfill its mission "to protect human health and the environment." In fulfillment of these statutory mandates, we would like to take this opportunity to make the following recommendations to EPA as they consider options for regulatory reform:

- 1. Implement the strongest human health protections as consistent with EPA's mission;**
- 2. In the risk management phase, fully consider the public health and environmental benefit of each regulation in addition to their costs to identify regulations that achieve environmental and public health protection without imposing financial burdens on the economy;**
- 3. EPA should strive to eliminate or minimize financial conflicts of interest (COI) from any and all individuals involved in the regulatory process. In the event that financial COI exists, EPA should collect information in an effort for complete transparency regarding any financial conflicts of interest (COI) that potentially bias individuals—such as those with a financial interest or who profit from decisions—toward undervaluing the scientific information related to health effects of industrial chemicals. Any and all existing financial COI should be made explicit and transparent to the public;**
- 4. Ensure the continued health protection for all potential susceptible populations in existing regulations;**
- 5. Ensure that existing regulations fully account for aggregate and cumulative exposure to chemicals and also non-chemical stressors as representative of real-world scenarios.**

Attached please find additional details with respect to each of these comments. We are very appreciative for the opportunity to provide public input and we are looking forward to continuing to participate in such opportunities in the near future. Please feel free to contact us with any questions regarding these comments.

Respectfully,

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1. Implement the strongest human health protections as consistent with EPA's mission.

EPA's mission is to protect human health and the environment. The Agency accomplishes this through a variety of activities, including providing information to the public (e.g., informing communities of nearby industry chemical emissions through the TRI (EPCRA, Subchapter II §11023)¹), protecting people from harm caused by others (e.g., implementation of pollution control programs setting wastewater standards for industry)², and implementing societal interventions through regulations that protect public health (e.g., lead in paint)³. These critical societal interventions are critical to ensuring public health protection, particular in cases where it is beyond the individual to avoid exposures to protect their own health (e.g., clean air regulations). As such, public health interventions including regulations have repeatedly been credited with greatly improving the health of the American public.^{4,5}

In considering options for regulatory reform, EPA must above all ensure that its ability to protect public health is not compromised through the removal of any such regulation. Removing restrictions on environmental chemicals that have been scientifically shown to be linked with adverse health effects will deleteriously undermine efforts to protect the health of Americans and people around the world.

2. In the risk management phase, fully consider the public health and environmental benefit of each regulation in addition to their costs to identify regulations that achieve environmental and public health protection without imposing financial burdens on the economy.

Following the risk assessment phase where the scientific evidence regarding exposures and health effects are considered, the risk management phase typically renders every major regulation proposed by EPA subject to an evaluation of both its costs (to industry, manufactures, distributors, etc.) as well as its anticipated benefits (medical costs saved from avoided illness, quantified benefits from avoiding adverse health effects, etc.). We strongly encourage EPA to fully consider both quantitative and qualitative benefits of each regulation when considering regulatory reform action during the risk management process. When the benefits of a regulation outweigh the costs, this is indicative of an effective means to protect public health without hindering the economy. For instance, below we list several examples comparing the costs and benefits of certain key regulations, illustrating the point that these regulations provide both significant benefits in protecting environmental and public health while also avoiding placing undue financial burdens on the economy.

- **National Ambient Air Quality Standards for Ozone** (40 CFR Parts 50 & 58; 80 FR 65291; RIN 2060-AP38). Annual cost of rule is estimated at \$1.4 billion until 2025, whereas overall net health benefits in 2025 are estimated at \$4.5 billion.⁶ The annual health benefits in 2025 include up to 660 less premature deaths, 230,000 fewer child asthma attacks, 160,000 less missed school days, 28,000 less missed work days, 630 fewer emergency room visits, and 340 fewer acute bronchitis cases among children.⁷
- **EPA and National Highway Traffic Safety Administration, Department of Transportation** Greenhouse Gas Emissions and Fuel Efficiency Standards for Medium- and Heavy-Duty Engines and Vehicles-Phase 2 (81 FR 73478; RIN 2060-AS16; RIN 2127-AL52). Annual cost of rule is estimated at \$11 billion whereas overall net benefits are estimates at \$229 billion, a reduction of fuel consumption up to 82 billion gallons, and a reduction of greenhouse gas emissions by 1,098 million metric tons over the lifetime of vehicles with model years 2018 to 2029.⁸ Health benefits in

¹ 42 U.S. Code §11023

² Code of Federal Regulations, Title 40, Chapter 1, Subchapter N

³ Code of Federal Regulations, Title 40, Chapter 1, Subchapter R, Part 745

⁴ Ten Great Public Health Achievements — United States, 1900–1999. MMWR Morb Mortal Wkly Rep 1999;48:241-243

⁵ Ten Great Public Health Achievements — United States, 2001–2010. MMWR Morb Mortal Wkly Rep 2011;60:619-623

⁶ U.S. Government Accountability Office. (2015). <http://www.gao.gov/assets/680/673757.pdf>

⁷ U.S. Environmental Protection Agency. (2015). https://www.epa.gov/sites/production/files/2015-10/documents/20151001_bynumbers.pdf

⁸ U.S. Government Accountability Office. (2016). <http://www.gao.gov/assets/690/681242.pdf>

2030 estimated at \$1.1 million from reducing one ton of PM2.5 emission from on-road vehicles as well as a reduction of premature deaths and cardiovascular disease associated with diesel PM exposure.⁹

- **Clean Air Interstate Rule** (70 FR 25161; RIN 2060-AL76). Annual cost of rule is estimated at \$4 billion whereas the overall net benefits estimated at \$71 billion in 2010 and up to \$98 billion in 2015 annually, with benefits substantially outweighing the costs in 2015 by 39:1.¹⁰ Annual health benefits in 2015 include a reduction of 17,000 premature deaths; 8,700 chronic bronchitis cases; 22,000 heart attacks; 15,500 hospitalizations; and 1.7 million lost work days.¹¹

Furthermore, often the argument is made that the cost to industry for compliance is higher than that which EPA and other government agencies have calculated. However, reviews of past regulations reveals the just the opposite—that often the revised cost estimate subsequent to passing a regulation is much lower than the cost estimate calculated by industry during the development of the regulation and the benefits are much higher.¹² For instance, the 1970 Clean Air Act contained mandates regarding automotive emission reductions, which was met by pushback by several carmaker companies. Estimates provided by industry for the cost of adding catalytic converters to achieve these emission reductions were initially \$860 per vehicle. However, a 1972 report by the National Academy of Sciences later priced them at \$288 per vehicle.¹² This is but one example of how the costs to industry are often overestimated and provide further support in most instances, the advantages of regulations greatly outweigh expenses. Furthermore, overall the benefits of environmental regulations greatly exceed their associated costs—a recent report by the Office of Management and Budget (OMB) evaluated the 32 major federal rules issued by EPA between October 1, 2004 – September 30, 2014 and reported that the overall annual costs were estimated between \$37.6-45.4 billion (2014\$) whereas the benefits were \$160.2-787.7 billion (2014\$),¹³ demonstrating that attainment of a clean and safe environment that protects public health is indeed achievable without placing an undue burden on the economy.

- 3. EPA should strive to eliminate or minimize financial conflicts of interest (COI) from any and all individuals involved in the regulatory process. In the event that financial COI exists, EPA should collect information in an effort for complete transparency regarding any financial conflicts of interest (COI) that potentially bias individuals—such as those with a financial interest or who profit from decisions—toward undervaluing the scientific information related to health effects of industrial chemicals. Any and all existing financial COI should be made explicit and transparent to the public.**

EPA must strive to eliminate or minimize to the greatest extent possible financial conflicts of interest (COI) from individuals participating in the regulatory decision-making process, such as political appointees or members of advisory committees. We strongly believe that there is a need to completely and transparently vet individuals for any financial conflicts of interest that could potentially bias them in

⁹ Federal Register. (2016). p 73580, 73836. <https://www.federalregister.gov/documents/2016/10/25/2016-21203/greenhouse-gas-emissions-and-fuel-efficiency-standards-for-medium--and-heavy-duty-engines-and#footnote-572-p73836>

¹⁰ Federal Register. (2005). p 25166. <https://www.federalregister.gov/documents/2005/05/12/05-5723/rule-to-reduce-interstate-transport-of-fine-particulate-matter-and-ozone-clean-air-interstate-rule>

¹¹ Office of Management and Budget. (2016). Table B-1, p 81.

¹² The Pew Charitable Trust. 2015. Fact Sheet: Government Regulation: Costs Lower, Benefits Greater than Industry Estimates. <http://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2015/05/government-regulation-costs-lower-benefits-greater-than-industry-estimates>

¹³ 2015 Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act. https://obamawhitehouse.archives.gov/sites/default/files/omb/inforeg/2015_cb/2015-cost-benefit-report.pdf

undervaluing the scientific evidence on health effects from exposure to hazardous chemicals, such as those who currently or have previously worked for or have been financially supported by industry.

By law, EPA committees in particular must be composed in a way so as to ensure that industry bias is publicly disclosed, minimized, and eliminated if possible. The Federal Advisory Committee Act (FACA)¹⁴ requires federal agencies to ensure the advisory committee is "in the public interest" and is "fairly balanced in terms of points of view represented and the function to be performed," and does not contain members with inappropriate special interests. We encourage EPA to exclude financially conflicted members, so that committees are composed of individuals who are able to provide a fair and complete review of all relevant data or issues.

In other public health regulatory situations, it is customary to set a health benchmark or risk assessment based only on health and scientific considerations and then to consider costs, leads time or market considerations in the risk management or implementation phase. This risk management phase would be an appropriate avenue for industry consultation and advisement to the Administrator. In this manner, industry members or others with financial conflicts of interest are given the opportunity to directly provide advice on considerations that impact their operations, but this separation would not allow for these economic considerations to intrude on the scientific risk assessment process.

Effective disclosure policies play an essential role in protecting EPA and committee work products. If such interests are discovered later, it may seem that either the EPA or the individual was intentionally hiding this information from the public, thereby casting doubt on the regulatory process itself, and on EPA's ability to identify conflicts and enforce its own policies. Declarations of financial conflicts of interest are a routine part of many scientific proceedings and conferences because of the importance of transparency. Other scientific committees (e.g., the National Academy of Sciences and Institute of Medicine) all require complete transparency of financial COI and similar guidelines should be adopted and consistently applied by EPA.

4. Ensure the continued health protection for all potential susceptible populations in existing regulations.

Pregnant women, developing fetuses and young children represent sensitive time periods of development where exposures to harmful contaminants can pose potential serious consequences for health outcomes and lasting consequences for brain development, cognition and behavior in children. Other susceptible populations include those with vulnerability due to either elevated chemical exposures or to heightened susceptibility to their effects, such as workers, the elderly, individuals with co-existing diseases, or communities simultaneously exposed to a myriad of co-occurring chemical and social stressors. There is increasing recognition that these susceptible populations must specifically be considered in regulation and to ensure the protection of their health. For instance, the recent Lautenberg Amendments to the Toxic Substances Control Act (TSCA)¹⁵ expressly requires that evaluation of chemicals specifically consider and ensure protection of such susceptible populations. We strongly recommend that EPA must identify existing susceptible subpopulations of concern and ensure that any proposed regulatory reform actions will not jeopardize the protection of the health of these individuals.

¹⁴ The Federal Advisory Committee Act. 5 U.S.C. App. II

¹⁵ 15 U.S. Code, Chapter 53

5. Ensure that existing regulations fully account for aggregate and cumulative exposure to chemicals and also non-chemical stressors as representative of real-world scenarios.

People are simultaneously exposed to a multitude of chemicals in the real world, many of which contribute to similar adverse health effects, and they can be exposed to the same chemical through multiple exposure pathways. Not accounting for these well-documented scientific facts inherently biases EPA's assessment, in the direction of systematic underestimation of individual and population risk, which in turn undermines science-based decisions. The federal pesticide law passed in 1996¹⁶ and the European framework for chemical management (REACH)¹⁷ require aggregate risk assessments. Under these laws, regulators must consider all sources of possible exposure to a chemical even when only considering the risk from any one source of that chemical. Assessing "cumulative exposures," i.e., accounting for the fact that people are exposed to a multitude of chemicals simultaneously, because these exposures can have (an) additive effect(s) on increasing the risk of an adverse health effect, was codified in the Food Quality Protection Act (FQPA)¹⁶ and recommended by the National Academy of Sciences (NAS) in 2008.¹⁸ This concept was expanded on in *Phthalates and Cumulative Risk*¹⁸ in which NAS recommended that chemicals that contribute to the same common adverse health outcome (not just the same - mechanism) should be considered as additive to the risk. While *Phthalates and Cumulative Risk* focused on the need to do this for phthalates, the NAS did not limit its recommendation to phthalates. For example, it pointed to the fact that lead and mercury can have an additive effect collectively on brain development.¹⁸

Biomonitoring data clearly support that people are exposed to a myriad of chemicals simultaneously—for instance NHANES data has documented that virtually 100% of pregnant women in the U.S. are simultaneously exposed to measurable levels of at least 43 different chemicals.¹⁹ EPA should ensure that existing and future regulations incorporate practices to consider aggregate exposures from all relevant pathways to develop risk metrics that are adequately representative of the true risks faced by the population. When data are lacking, EPA should rely on a default approach to account for all chemicals that contribute to the same common adverse health outcome considered as additive to the risk. EPA has broached this issue in the past in its draft dioxin risk assessment, which considered the impact of background and cumulative exposure to dioxin-like compounds and the potential impact on low-dose response.²⁰ We strongly recommend that EPA continue to actively address this important issue in its regulations to increase the accuracy of these assessments and ensuring public health protection.

We are very appreciative for the opportunity to provide public input and we are looking forward to continuing to participate in such opportunities in the near future. Please feel free to contact us with any questions regarding these comments.

¹⁶ Food Quality Protection Act, [Pub.L. 104–170](#). Approved 1996-08-03.

¹⁷ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

¹⁸ National Research Council, *Phthalates and cumulative risk assessment: the task ahead*. 2008, Washington, D.C.: National Academies Press. 188 p.

¹⁹ Woodruff, T.J., et al., *Estimating risk from ambient concentrations of acrolein across the United States*. Environ Health Perspect, 2007. **115**(3): p. 410-5.

²⁰ U.S. Environmental Protection Agency, *Exposure and human health reassessment of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) and related compounds National Academy of Sciences (NAS) review draft*. 2004, U.S. Environmental Protection Agency: Washington, DC.