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Environmental Protection Agency
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Re: Draft Guidelines for Human Exposure Assessment

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Improved risk assessment practices at the Environmental Protection Agency (EPA) have the potential to drive policy decisions that would alleviate many of the threats to children's health from environmental exposures. EPA's risk assessment practices, including exposure assessment, need substantial updates to reflect current science and ensure that EPA fully evaluates, and then addresses, the real-world risks to children and communities. It is positive that EPA is updating the Guidelines for Human Exposure Assessment and we urge EPA to complete these important updates this year.

There is increasing evidence that environmental exposures are jeopardizing the health and well-being of children across the country. Preventing these exposures can result in significant decreases in diseases which take an extraordinary toll on our communities:

- Asthma – reducing toxic exposures could alleviate 1 in 3 cases of asthma requiring medical attention¹;
- Childhood Cancers – 10-20% of the 3 most common childhood cancers can be prevented by reducing environmental hazards¹;
- Neurobehavioral Disorders (Autism, ADHD, Intellectual Disability) – an estimated 10% can be prevented by reducing toxic exposures. In California, this was estimated to equal 1800 children each year¹;
- Healthier kids equal significant cost savings
 - California estimate = \$254 million annually and \$10 to \$13 billion over the lifetime of children born within a single year¹
 - US estimate = \$76.6 Billion in 2008².

But from the impacts of pesticides in agricultural communities to air toxics from industrial sources in overburdened communities, EPA's risk assessments have failed to properly address the vulnerability of the developing fetus, infant and child, thus likely contributing to an increasing burden of disease.

With the proposed revisions and updates to EPA's Guidelines for Exposure Assessment, EPA has the opportunity to correct and strengthen outdated and scientifically unsupported practices that lead to

¹ California Environmental Health Tracking Program & Public Health Institute, 2015. Costs of Environmental Health Conditions in California Children. Available at: http://www.phi.org/uploads/files/2015ROI_CEHTP.pdf.

² Trasande, L. & Liu, Y., 2011. Reducing The Staggering Costs Of Environmental Disease In Children, Estimated At \$76.6 Billion In 2008. Health Affairs, 30(5), pp.863–870.

underestimations of risk, ultimately hampering the protection of the developing fetus and children from environmental and consumer product exposures. In order to prevent disease and improve health, it is not enough for EPA to simply finalize these draft guidelines; the guidelines must result in changes to the *actual practices* used at EPA to evaluate health threats from environmental exposures. Bridging the gap between these guidelines and how EPA conducts risk assessments is critical in order to see assessments that more accurately and completely account for real-world health risks, leading to informed risk management and public health protections.

Currently, the draft guidance summarizes important principles that are not routinely incorporated into the assessments conducted by EPA programs. EPA programs need clear directives, methods, and deadlines for incorporating the following principles expressed in the draft guidelines into their risk assessment practice:

- (1) **Accurate assessment of aggregate exposures.** EPA acknowledges the importance of evaluating aggregate exposures of contaminants of concern that may impact an individual, or community, via multiple pathways of exposure but assessments often fail to accurately assess aggregate exposures. If there are insufficient data to quantify aggregate exposures, a default should be used to account for these exposures. The guidelines need to ensure that when exposures can occur via multiple pathways (i.e. inhalation and oral), the combined exposure is included in any risk analysis, from the start. Exposures add up, and different exposures may add up to an unsafe level—that is the fundamental premise behind an aggregate assessment, so each risk from one route individually must be considered together in context with all other exposures, and all types of carcinogenic risks must be, at least, added together. This is important for children in agricultural communities, for example, who may be exposed to pesticides from food, water, and off-target drift from fields. It is also critical for children who breathe air near major air toxics sources like refineries, and also drink the breast milk of their mothers who breathe such air, and play on playgrounds nearby, ingesting soil that is contaminated with persistent bioaccumulative toxicants deposited from those refineries' air emissions.
- (2) **Accounting for cumulative exposures and effects.** EPA acknowledges that there are additional significant health threats for individuals and communities facing: multiple sources of contaminants; multiple contaminants that together pose a larger health threat because they act through a common pathway or impact similar health endpoints; and the combined impact of contaminant exposure with social stressors. EPA should use default factors to account for the known additional risk coming from these types of exposures where they cannot be more explicitly quantified. These health threats often fall disproportionately on disadvantaged communities where there are more sources of chemicals and greater levels of stress. The guidelines need to provide clear methods to factor these health threats into existing risk assessment protocols, starting with an interim measure until EPA completes full new cumulative risk guidelines. Scammell et al. describe how tools including indexes, maps, and combined approaches can provide an important first step towards evaluating background exposures and delineating the cumulative context for an assessment³. EPA should also use available data to quantitatively inform variability and vulnerability factors in risk assessments.

³ Scammell, M.K., Montague, P. & Raffensperger, C., 2014. Tools for Addressing Cumulative Impacts on Human Health and the Environment. *Environmental Justice*, 7(4), pp.102–109.

- (3) **Consideration of vulnerable groups and populations of concern.** EPA acknowledges the need to consider differential exposure profiles based on life-stage and population characteristics, such as ethnicity, dietary preferences, socioeconomic status, or cultural practices. Although updates have been made to the Exposure Factors handbook to provide additional values to account for unique exposures to children and the developing fetus, including placental transfer, breastmilk and object-to-mouth ingestion, considering these routes of exposure has not yet been incorporated into risk assessments performed by many of the EPA programs. Another example of inadequately accounting for exposures to populations of concern is the consideration of dietary intake of bioaccumulative chemicals, which would be much higher for indigenous and some low-income communities that rely on subsistence fishing or traditional foods such as marine mammals.
- (4) **Use of accurate exposure models.** EPA discusses the importance of the rigorous evaluation, and validation, of exposure models and algorithms (including traditional and high-throughput models and algorithms) to ensure that there is sufficient predictive capacity to meet the objectives of the risk assessment. EPA programs must be directed to use the best-available methods and to reject the use of models and algorithms that do not meet the criteria described in the guidance document and are found not to align with observational or experimental data.

The following issues are not adequately addressed in the draft guidelines and revisions should be made to incorporate:

- (5) **The science on early-life vulnerability.** These guidelines must incorporate the science documenting that early-life exposures present greater risks to the developing fetus and child due to increased susceptibility and vulnerability. Age-dependent adjustment factors should be used for all carcinogens, not only those that act by a mutagenic mode of action. Adjustment factors should also be used to account for increased susceptibility to carcinogens due to prenatal exposures, which the draft guidelines currently do not cover. For chronic non-cancer risks, increased susceptibility of children (including prenatally) should be accounted for through use of child-specific reference values or additional uncertainty/ safety factors where reference values are not available. Scientific findings over the last decade clearly indicate that the prenatal period is a particular window of susceptibility to multiple adverse health outcomes in addition to cancer, including neurodevelopmental and respiratory effects^{4, 5}. These need to be accounted for in the guidelines.
- (6) **A systematic literature review as a key first step in planning and scoping.** EPA's exposure assessments should be informed by the body of scientific evidence. It is important that the literature review use elements of a systematic review process in order to transparently conduct a comprehensive literature search, document and evaluate evidence. Systematic review methods for chemical assessments have been developed and implemented through various case studies by the National Toxicology Program (NTP) Office of Health Assessment and Translation

⁴ Grandjean, P.; Landrigan, P. J., Neurobehavioural effects of developmental toxicity. 701 Lancet Neurol. 2014, 13, (3), 330-338.

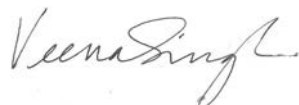
⁵ Pinkerton, K.E. & Joad, J.P., 2000. The mammalian respiratory system and critical windows of exposure for children's health. Environmental health perspectives, 108 Suppl , pp.457–62.

(OHAT), the EPA Integrated Risk Information System (IRIS) program, the University of California San Francisco, and others. ⁶

To protect people from unsafe exposures to toxicants in the environment and consumer products, EPA needs to finalize the draft exposure guidelines in 2016, release and then implement a plan to transform risk assessment practice according to these guidelines. This will be a critical piece of larger risk assessment reforms that are needed to more comprehensively address early life vulnerabilities and move towards the practices recommended in the National Academies Report *Science and Decisions*⁷. Bringing these guidelines up to date with current science is a critical step towards ensuring safer, healthier communities where children can live, learn and play.

Thank you for the opportunity to comment on this guideline document. We look forward to seeing EPA ensure that families are protected from toxic chemical exposures in their homes, workplaces and communities.

Sincerely,



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⁶ Rooney AA, Boyles AL, Wolfe MS, Bucher JR, Thayer KA. Systematic review and evidence integration for literature-based environmental health science assessments. *Environ Health Perspect*. 2014 Jul;122(7):711–8. Thayer KA, Wolfe MS, Rooney AA, Boyles AL, Bucher JR, Birnbaum LS. Intersection of systematic review methodology with the NIH reproducibility initiative. *Environ Health Perspect*. 2014 Jul;122(7):A176–7. Birnbaum LS, Thayer KA, Bucher JR, Wolfe MS. Implementing systematic review at the National Toxicology Program: status and next steps. *Environ Health Perspect*. 2013 Apr;121(4):A108–9. Woodruff TJ, Sutton P. The Navigation Guide systematic review methodology: a rigorous and transparent method for translating environmental health science into better health outcomes. *Environ Health Perspect*. 2014 Oct;122(10):1007–14.

⁷ National Research Council, 2009. *Science and Decisions: Advancing Risk Assessment*, Washington, D.C.: National Academies Press.

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