



NATURAL RESOURCES DEFENSE COUNCIL

Comments from the Natural Resources Defense Council
To the US EPA Children's Health Protection Advisory Committee
October 11, 2018

NRDC shares the concerns raised by many environmental health professionals, the American Academy of Pediatrics, pollution-impacted communities, and environmental protection groups on the recent placement of the Director of the Office of Children's Health Protection (OCHP) on Administrative Leave.

The [OCHP Website](#) describes its mission as "assuring all EPA actions and programs address the unique vulnerabilities of children" and says it seeks to "reduce negative environmental impacts on children through involvement in EPA rulemaking, policy, enforcement actions, research and applications of science that focuses on prenatal and childhood vulnerabilities" and to "protect children through safe chemicals management."

This raises serious questions about whether the EPA leadership remains committed to protecting children from the threats posed, for example, by lead in drinking water, by brain toxic pesticides like chlorpyrifos, and by other hazardous chemicals like perchlorate, Teflon-like chemicals (poly- and per-fluorinated alkyl substances, or PFAs) in our tap water, and toxics in consumer products.

The OCHP and its Advisory Committee has historically provided a critical science-based voice within the Agency on children's behalf, to attest to the fact that children typically require a higher degree of protection than adults, due to the vulnerable nature of their developing brains and bodies, and their higher exposure than adults to many toxics. OCHP has often acted as an internal EPA clearinghouse for expertise and science on environmental risks specific to children.

Input from the OCHP and this Advisory Committee will be especially important with the upcoming EPA "pre-prioritization" comment periods under TSCA. By the end of 2019, TSCA requires EPA to select at least 20 high priority and 20 low priority chemicals. The high priority chemicals will be the focus of risk evaluations for three years. There are 73 chemicals on the agency's initial list of potential high priority chemicals, based on the 2014 TSCA Work Plan for Chemical Assessments. EPA is taking comment on these until December 1, 2019. Priority chemicals will be selected in the next 9 to 12 months, and sometime early in 2019 EPA will identify proposed lists of high and low priority chemicals. Industry wants EPA to list more low priority chemicals than the 20 that the law requires. The OCHP should provide a perspective and recommendations on TSCA chemical prioritization consistent with its mission to "protect children through safe chemicals management."

OCHP and this Advisory Committee should recommend that TSCA chemical evaluations use mechanistic information or alternative testing to upgrade a chemical hazard, but not to weaken a hazard evaluation. While mechanistic or adverse outcome pathway (AOP) information may be useful as

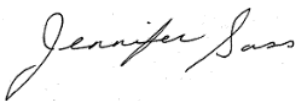
organizing principles, pathway-based processes (e.g., modes of action, mechanisms of action) can lead to false negatives (fail to protect human health) when used to evaluate the toxicity of chemicals with unknown and/or multiple ways to disrupt a cellular process. Chemicals can act via different pathways depending upon the organ or system exposed to the agent being tested (e.g., tamoxifen inhibits cell proliferation in breast cancer cells but can stimulate proliferation in the uterus). Pathway-based approaches can also lead to increased amounts of bias – i.e., by favoring one mechanism over another – which can result in the exclusion of data and alternative mechanisms by which a chemical can cause harm. For these reasons, these approaches are not appropriate for downgrading or dismissing evidence of toxicity, exposure, or risk.

OCHP and this Advisory Committee should recommend that the use of models for TSCA chemical assessments must be critically evaluated. Toxicologic models are promoted as one way to generate conclusions in TSCA chemical assessments in the presence of inevitable gaps in understanding. Modelled outputs are in many important ways like a meta-analysis or review article in that they incorporate the results of many studies to generate an overall summary of the data. In fact, dozens or even hundreds of different pieces of information are put together to build such models. Choices of which pieces of information to use, how to use them, and how they are presumed to fit together can all reflect the biases of the modeler, thereby leading to bias or error in the model's output. It is thus critical to document the assumptions built into the framework of any model used by EPA and policy-makers. As such, models can be highly subjective, especially when the sponsor and any financial interests they might have in the resulting regulations have not been divulged or made fully transparent. For all these reasons, it is critical that toxicological models be made public available, full transparent, and most importantly that they be fully tested and critically evaluated for accuracy as to bias.

The EPA Toxics Office should not proceed with its TSCA chemical evaluations until it incorporates recommendations from the OCHP and this Advisory Committee.

Put kids first. TSCA requires EPA to fully consider potential harm to vulnerable populations, including children. As EPA proceeds with prioritization and risk evaluations under TSCA, it should confer with and consider the recommendations of the OCHP and this Advisory Committee.

Respectfully,



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