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To the US EPA TSCA Science Advisory Committee on Chemicals (SACC)

TSCA SACC Website: http://www.epa.gov/tsca-peer-review
Docket No. EPA–HQ–OPP–2018–0604

White House E.O. (June 14th) slashing federal advisory committees by at least one-third by September 30th. You may have thought that this SACC was the first meeting of such a committee after the order was issued, but I think that honor may go to a committee that I am on – the NIEHS NTP-BSC – whose meeting started Monday of this week. In any case, this makes your task all the more important.

Scientific peer review is the cornerstone of scientific activities, and carries all the responsibilities that go with such an important task. Rush Holt, chief executive of the American Association for the Advancement of Science, was reported in TIME magazine a few days ago as saying , "he was concerned about the move to cut back on advisory panels, especially ones involved with health and the environment (underline not in original). 'Advisory committees help the government become better informed, and making smart decisions should not be seen as optional or dispensable'." I agree.

The work of this advisory committee is so important because EPA is setting an important precedent with its risk evaluation of Pigment Violet 29 (CAS 81-33-4), and – most distressing – with its determination of 'no unreasonable risk' to human health or the environment. EPA determined that PV29, under all conditions of use, poses a low hazard to human health and environmental receptors, low solubility, low vapor pressure, low bioaccumulation potential, low absorption, limited environmental releases and low potential for resulting exposures. None of these findings is adequately supported by data – and several of the conclusions reached by

EPA were done so by ignoring the Agency's own risk assessment methods and guidelines. Due to the lack of reliable data, the European assessment recently concluded that, "a reliable conclusion on the bioavailability of this substance is not possible based on the currently available data."[1] (see blog by Dr. Richard Denison for a discussion of the details).[2] The SACC should similarly advise EPA that it cannot make a 'no unreasonable risk' determination based on the current database and that it needs to obtain credible data in a number of areas, over the next year, before it finalizes its risk evaluation.

EPA's finding is based on two-dozen industry-sponsored studies that have not been made public (in violation of TSCA Section 14(b) requiring disclosure of health and safety studies)[3], most of them incompletely reported out and some having substantial portions withheld from the public. There are no verifiable exposure or monitoring data, no hazard study lasting 90 days or longer, no reliable inhalation toxicity studies, and no reliable solubility information.

The lack of chronic hazard data is particularly disturbing. Using acute and sub-chronic data to predict chronic effects, particularly to sensitive or vulnerable populations, cannot be done with scientific confidence. It would be like trying to predict hyponatremia by extrapolating from drowning – both can kill you, but you couldn't predict one from observing the other.

There are approximately 40 thousand chemicals in commerce, with about 3,300 (excluding polymers) of them high production volume chemicals, like PV29, used and /or imported at over 1 million pounds annually in the US.[4] Less than 1 percent (several hundred) have been fully tested for toxicity. Amended TSCA was passed by Congress to address exactly that problem.[5] And, PV29 is the first – and therefore the most important and precedent setting – test case. That's why the work you do on this committee matters so much – it matters for the other 39 thousand chemicals, most of which will be like PV29 with very little toxicity data.

In yesterday's meeting, in response to a query from a committee member, EPA stated that it has 'lots of experience' using read-across, bridging, and QSAR methods to fill data gaps. While EPA is correct that it has plenty of experience in filling data gaps without data – largely in its New Chemicals Program – EPA has no evidence that its efforts result in a correct outcome. How would it know, since it never tracks or reviews its approvals? We only learn about problems when things go terribly wrong like with Dupont's GenX Chemicals which EPA approved in 2008 through its New Chemicals Program based on industry-sponsored studies.[6] *Now*, EPA says, "Animal studies have shown health effects in the kidney, blood, immune system, developing fetus, and especially in the liver following oral exposure. The data are suggestive of cancer."[7] Too bad for about all the people who have now been exposed to PFAS in their drinking water. Wouldn't it have been smarter to get those animal studies before approving it for food containers and other consumer products? Amended TSCA gives EPA the authority to request these data for PV29 and other chemicals – Congress *intended* for EPA to obtain these data – the SACC should direct them to do so, before making a risk determination.

A determination of no unreasonable risk under TSCA must be supported by substantial evidence establishing that exposure to a substance will not result in adverse human or

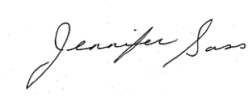
environmental effects under its conditions of use. Such determinations should be based on multiple lines of evidence from well-designed and well-conducted studies of adequate statistical power, adequate time to follow up (latency period), sufficiently sensitive life-stages, and sensitive species and strains of animal models in both sexes. Conjecture or limited data are not enough to support this determination. Instead, EPA must make an affirmative showing that no unreasonable risk exists.

You are the Agency's scientific peer reviewers. The public, workers and organized labor, consumers, parents, and environmental advocates are looking to you to be thorough, thoughtful, rigorous, and scientifically accurate in your response to EPA.

Dr. Lorenzo Tomatis, former Director of the International Agency for Research on Cancer, warned that serious public health consequences may follow if chemicals are misclassified as less toxic or non-toxic based on untested mechanistic hypotheses, poorly validated tests, or incomplete data sets.[8] Retired NIEHS toxicologist Dr. Ron Melnick wrote that, "declaring a chemical as not hazardous, or reducing a level of health protection, should require validation, not speculation".[9]

The SACC should direct EPA that it cannot make a 'no unreasonable risk' determination without a substantial, reliable, defensible database. This is not simply a matter of how one sees the color purple – it is about how EPA will address the tens of thousands of chemicals that will follow.

Thank you,



[1] Justification Document for the Selection of a CoRAP Substance. Group Name: Diisoquinoline tetrones. See discussion of perylenes, p. 12-14. https://echa.europa.eu/documents/10162/387374b8-62fa-c857-e60f-65e1cd9fd821

[2] EPA says PV29 is perfectly safe. The EU, citing concerns and a dearth of data, begs to differ. By Richard Denison, May 7, 2019
http://blogs.edf.org/health/2019/05/07/epa-says-pv29-is-perfectly-safe-the-eu-citing-concerns-and-a-dearth-of-data-begs-to-differ/

[3] Section 14(b) of TSCA is titled "Information Not Protected from Disclosure." Section 14(b)(2) provides that the law's restrictions on the release of confidential business information (CBI) do not "prohibit the disclosure . . . of any health and safety study which is submitted under this Act" for a chemical substance which "has been offered for commercial distribution." The absence of CBI protection extends to both the study itself and "any data reported to, or otherwise obtained by, the Administrator from" the study.

[4] http://scorecard.goodguide.com/chemical-profiles/def/hpv.html

[5] http://www.cnn.com/2010/HEALTH/10/26/senate.toxic.america.hearing/

[6] Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as GenX Chemicals. EPA Document Number: 823-P-18-001. Nov 2018
https://www.epa.gov/sites/production/files/2018-11/documents/genx_public_comment_draft_toxicity_assessment_nov2018-508.pdf

[7] EPA Fact Sheet: Draft Toxicity Assessments for GenX Chemicals and PFBS, Nov 2018. https://www.epa.gov/sites/production/files/2018-11/documents/factsheet_pfbs-genx-toxicity_values_11.14.2018.pdf

[8] Tomatis L. 2002. The IARC Monographs program: changing attitudes towards public health. Int J Occup Environ Health 8:144–152

[9] Melnick RL, Kamel F, Huff J. Declaring chemicals "not carcinogenic to humans" requires validation, not speculation. Environ Health Perspect. 2003 Apr;111(4):A203-4.