Comments on Draft Pigment Violet 29 Risk Evaluation
Under the Toxic Substance Control Act

January 14, 2018

The Environmental Protection Network (EPN) is an organization comprised of over 350 EPA alumni (including scientists, policy specialists and others) volunteering their time to protect the integrity of US Environmental Protection Agency (EPA), human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current Administration efforts to undermine public health and environmental protections. We have the following comments on the draft Pigment Violet 29 (PV29) Risk Evaluation Under the Toxic Substance Control Act (TSCA).

On November 14, 2018, EPA published in the Federal Register a draft "TSCA Risk Evaluation for Colour Index (C. I.) Pigment Violet 29 (PV29)." EPA states that the purpose of this risk evaluation is to "determine whether a chemical substance presents an unreasonable risk to health or the environment under the conditions of use, including an unreasonable risk to a relevant potentially exposed or susceptible subpopulation." *EPN believes this purpose is undermined by (1) EPA's use of a flawed systematic review process and discretionary use of said process, (2) refraining from requesting additional public information under the veil of Confidential Business Information (CBI), and (3) overlooking a key pathway for children and pregnant women despite a requirement to protect vulnerable subpopulations.*

1. Use of a Flawed Process

The 2016 TSCA requires the use of the "best available science" and the "weight of the scientific evidence" (section 2625). The latter of which is defined in the regulation as "…a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." In not using a systematic review process to evaluate the weight of scientific evidence, EPA limited the science under review and therefor did not use the best available science.

EPN is deeply concerned with two issues: (1) the lack of use of appropriate systematic review methods and (2) the lack of adequate published data. EPA evaluated the relatively sparse datasets that are mainly comprised of CBI data. These datasets consisted of about two dozen studies, all of which were conducted by the chemical's manufacturer or other data owners, most in accordance with Organisation for Economic Co-operation and Development (OECD) test guidelines. EPA should follow the guidelines in the National Academy of Sciences 2017 report on the Application of Systematic Review Methods.[1]

[1]National Academies of Sciences, Engineering, and Medicine. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press; 2017. https://doi.org/10.17226/24758

EPA incorrectly describes its draft 2018 EPA guidance entitled "Application of Systematic Review in TSCA Risk Evaluations" as systematic review, but it does not meet current scientific standards. On August 16, 2018, EPN submitted detailed criticisms of that draft systematic review process. Other scientific groups have similarly criticized the EPA guidance.[2] Our comments documented EPA's failure to follow necessary internal and external peer-review procedures in developing this process, serious flaws permeating the entire TSCA systematic review process, and critical flaws in evaluating individual studies for use in toxicity assessments (such as failure to assess for bias). This draft "Application of Systematic Review in TSCA Risk Evaluation" is inconsistent with best practices in systematic review and should not be used for any purpose.

In this evaluation the agency failed to publish its systematic review protocol in advance. Additionally, minimal effort seems to have been expended on the first three steps of what it considers to be a credible systematic review: (1) *Publish the protocol*, (2) *Data Search*, during which a number of sources are queried to identify potentially useful literature, and (3) *Data Screening*, during which abstracts and full texts of potentially useful literature are examined for relevance (see page 18, paragraph 2 of the draft risk evaluation). EPA incorrectly considers it discretionary when EPA chooses to follow the best scientific practices as required by law or even all of the steps in its own draft guidance entitled "Application of Systematic Review in TSCA Risk Evaluations." EPA laid out a review process in that draft guidance (which our previous comments argue is flawed) but EPA has failed to follow in a vigorous manner said process when evaluating PV29.[3]

EPN would be supportive of using the Office of Research and Development (ORD) systematic review process in evaluating all the studies. EPA's ORD current process is endorsed by National Academy of Science (NAS) and comes closer to the (1) NAS 2014 guidance or the practices used by (2) OHAT, (3) Navigation Guide or other credible approaches to systematic review approaches.[4,5,6,7]

2. Insufficient Information

Not having access to the studies used in this review is problematic and should be remedied. EPN is concerned that EPA did not use their TSCA authority, under Sections 4 and 5, to get an appropriate release of key or critical information necessary to allow for critical review of the study methods and

[2]National Academies of Sciences, Engineering, and Medicine. Strategies and Tools for Conducting Systematic Reviews of Mechanistic Data to Support Chemical Assessments. 2018. http://dels.nas.edu/Upcoming-Workshop/Strategies-Tools-Conducting-Systematic/AUTO-5-32-82-N

[3]National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press; 2014. https://doi.org/10.17226/18764.

[4]National Academies of Sciences, Engineering, and Medicine. Progress Toward Transforming the Integrated Risk Information System (IRIS) Program: A 2018 Evaluation. Washington, DC: The National Academies Press; 2018. https://doi.org/10.17226/25086.

[5]NAS 2014

[6]U.S. Department of Health and Human Services. National Toxicological Program. OHAT Systematic Review. https://ntp.niehs.nih.gov/pubhealth/hat/review/index-2.html

[7]Woodruff, T.J., Sutton, P. An evidence-based medicine methodology to bridge the gap between clinical and environmental health sciences. Health Aff. (Millwood). 30, 931–7. 2011. https://doi.org/10.1377/hlthaff.2010.1219;

conclusions. The 2016 TSCA amendments expanded EPA's chemical testing authority to "obtain testing information for prioritizing or conducting risk evaluations on a chemical." All 24 studies used as the basis for this risk evaluation are company owned, and all data belongs to one or more manufacturing companies. In addition, many of these studies claimed CBI. TSCA section 14(b) identifies several categories of information that may not be protected as CBI, including: "health and safety studies and information from health and safety studies where the chemical or mixture has been offered for commercial distribution or for which testing is required under TSCA section 4 or notification is required under TSCA section 5." These studies must be published for a credible risk assessment and for any credible peer review.

Only the summaries of these CBI studies have been made available to the public, which are insufficient. Without adequate information, the public cannot adequately review this decision. The agency has thus failed to provide notice and comment opportunities. While advisory committees may be cleared for CBI and will have access to the studies for review, this still leaves the public in the dark. In addition, many of these committees are being challenged for conflicts of interest or limiting the usual number of panelists.

A timely example would be the recent shrinking of the Clean Air Science Advisory Committee (CASAC), limiting who may be a member of CASAC based on previous EPA grants, and the disbandment of the Particulate Matter review panel and the decision not to reinstate the Ozone review panel. A group of former CASAC chairs and former CASAC members submitted two comment letters critiquing the lack of expertise on the smaller than usual committee, dissolving additional panels, the shortened and accelerated inadequate timeline, and the new membership criteria which eliminates many qualified individuals.[8,9] They emphasized how procedural issues can have a lasting effect on science, science use, and science-based decisions.

The letter "Withholding of Public Access to Critical Studies on Pigment Violet 29 -- EPA-HQ-OPPT2018-0604" (see Appendix A) lays out similar complaints regarding the availability of industry studies being concealed from the public. On December 6, 2018, the Center for Environmental Health, Earthjustice, Environmental Defense Fund (EDF), the Environmental Health Strategy Center, Natural Resources Defense Council, and Safe Chemicals Healthy Families sent a letter on this same issue to Deputy Assistant Administrator Nancy Beck. An EDF scientist dove in even further in a series of blog posts addressing issues with evaluating exposure, evaluating hazard, and OECD studies being used for long term projections. The first post examines two 1970s studies done by the company BASF, these studies are the basis for the EPA assertion that ""no adverse effects were observed for" the inhalation route of exposure." However, BASF disregarded the adequacy and reliability of their studies due in part to major methodological deficiencies.[10] The second post discusses issues with exposure studies, mainly a questionable value for an "approximate maximum workplace air concentration" to be expected over a

[8]Frey, Chris et al. Letter to CASAC from Former Members of 2015-2018 Particulate Matter Review Panel.
[9]Frey, Chris et al. Letter to CASAC from Former Members of 2009-2014 CASAC Ozone Review Panel.
[10]Denison, Richard. "Exhibit PV29: Why this EPA can't be trusted to forthrightly assess chemical risks under TSCA." Environmental Defense Fund. 2018. http://blogs.edf.org/health/2018/12/13/exhibit-pv29-why-this-epa-cant-be-trusted-to-forthrightly-assess-chemical-risks-under-tsca/

12 hour shift at a PV29 manufacturing facility. This value came from a chemical company and while EPA uses it, they acknowledge they do not know what this workplace air value actually represents (see page 22, paragraph 1 of the draft risk evaluation). The third post expands on the second, explaining further scientific errors. The author claims EPA relied on OECD data which is explicitly not to be used for long term studies investigating chronic effects.[11] EPN agrees that data related to health and safety, addressed directly or indirectly in all 24 PV29 studies, cannot be withheld as CBI under TSCA.

3. Overlooked Pathways

Finally, EPA has not conducted a sufficient review as required by law because it has failed to assess relevant exposure pathways for sensitive populations. Specifically, EPN believes important pathways for the sensitive subpopulation of children have been left out. EPA lists PV29's "industrial and commercial activities/uses" as: processing, paints and coatings, plastic and rubber products, merchant ink for commercial printing and distribution. Paints, art supplies, toys, and food packaging and examples of possible exposure pathways for children. Some of these systematic omissions relate to the flawed "framework" prioritization and evaluation rules that inappropriately limit the exposures EPA considered. In addition, data on PV29 is already limited and sparse, exclusively observing workers likely looks only at adults who are healthy enough to work. Studying adults is not, and has never been, sufficient to understand the impact of chemical exposures for children who may have critical developmental periods when their brains, reproductive organs, and other important systems are developing. Pregnant women (fetus and mother) and children should be separately assessed. Manufacturers should demonstrate adequate data to support a claim of no unreasonable risk. No data does not equate to no risk. EPA must therefore conduct a more serious exposure screening to assess each sensitive subpopulation.

The 2016 TSCA amendments require that EPA specifically consider susceptible subpopulations, as discussed in both the legislation and the introduction of the PV29 draft risk evaluation. TSCA section 6, 15 U.S.C. 2605, requires EPA to conduct risk evaluations to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." 15 U.S.C. 2605(b)(4)(A).

As the first draft risk evaluation to be published, it is important to recognize and understand the flawed procedure used in this instance. The procedure should not be repeated moving forward with the other nine risk evaluations - or any others in the future. EPA should have a consistent procedure for conducting systematic reviews and conducting risk evaluations.[12,13]

---

[11]Denison, Richard. "Correction: The Trump EPA's first TSCA risk evaluation is a skyscraper of cards, not just a house." Environmental Defense Fund. 2018. http://blogs.edf.org/health/2019/01/08/correction-epas-first-tsca-risk-evaluation-is-a-skyscraper-of-cards-not-just-a-house/

[12]NAS 2017.

[13]National Research Council. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press; 2009. https://doi.org/10.17226/12209.

Respectfully submitted,

Michelle Roos
Executive Director, Environmental Protection Network
michelle.roos@environmentalprotectionnetwork.org

These comments were prepared by Barbara Elkus, Penny Fenner-Crisp, Trish Koman, and Betsy Southerland on behalf of the Environmental Protection Network. Questions should be addressed to Betsy Southerland, easydee420@gmail.com.

Appendix A

Letter to Deputy Assistant Administrator Dr. Nancy Beck Re: Withholding of Public Access to Critical Studies on Pigment Violet 29

December 6, 2018 Dr. Nancy Beck Deputy Assistant
Administrator Office of Chemical Safety and Pollution
Prevention U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW Washington, D.C.
20460
Re: Withholding of Public Access to Critical Studies on Pigment Violet 29 -- EPA-HQ-OPPT-2018-0604

Dear Dr. Beck:

Our organizations are deeply concerned that EPA is withholding from the public 24 studies that form the basis for its draft risk evaluation on Pigment Violet 29 (PV29). Failure to release these studies violates section 14 of the Toxic Substances Control Act (TSCA), reflects a troubling lack of transparency, and will frustrate the ability of interested parties to review and submit comments on the science EPA cites to support its risk evaluation and to participate meaningfully in the peer review process. We request that the 24 studies be placed in the docket for the draft risk evaluation without delay.

The 24 studies, conducted by PV 29's manufacturers, address its physical and chemical properties, environmental fate, human health effects and toxicity to aquatic organisms. According to the draft risk evaluation, 20 of the studies were submitted to the European Chemicals Agency (ECHA) in support of registration under the European Union (EU) REACH Regulation. The other four studies were not provided to ECHA but were apparently submitted to EPA by an unnamed data owner. EPA has made available the "robust summaries" prepared by the data owners for the 20 studies submitted to ECHA, but has withheld all 24 studies based on "a claim of business confidentiality by the data owners."

Under section 14(b)(2), the law's restrictions on disclosure of confidential business information (CBI) do not apply to "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.

Section 3(8) of TSCA defines "health and safety study" as "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and...toxicological, clinical and ecological studies..." EPA regulations at 40 CFR 716.3 state that "[i]t is intended that the term health and safety study be interpreted broadly" and encompass "[a]ny data that bear on the effects of a chemical substance on health or the environment." The regulations are explicit that tests to determine the chemical and physical properties and fate and transport behavior of a substance fall within the definition, along with studies of a chemical's human health effects and eco-toxicity.

Thus, the 24 studies on PV29 are "health and safety studies" that cannot receive CBI protection under TSCA. Moreover, EPA's obligation to disclose these studies cannot be satisfied merely by releasing "robust summaries" but requires public access to the full studies.

EPA has not described the claim(s) of confidentiality which it believes justifies withholding the 24 studies, but with respect to chemical substances, the only portion of a health and safety study that can be treated as CBI under section 14(b)(2) is information "that discloses processes used in the manufacture or processing of a chemical substance." The 24 studies likely contain little, if any, information meeting this description, and in the unlikely event any of the studies contain legitimate and substantiated CBI of this type, it can be redacted while all health and safety information is disclosed as provided for in section 14(b)(1).

It is possible that the data owners are basing their CBI claims on their "proprietary interest" in the studies under REACH. However, EPA could only honor these CBI claims if they have a basis in section 14 of TSCA. Nothing in section 14 allows EPA to avoid its unconditional obligation to disclose health and safety studies because of property right claims under European Union (EU) law.

EPA has suggested that public access to the 24 studies is unnecessary because it "has confirmed that the results of these full study reports are consistent with the corresponding robust summaries available in ECHA." However, this puts the public in the untenable position of accepting EPA's findings on faith. Without access to the full studies, the public cannot form its own judgments about the quality of the studies and the proper interpretation of the results. Thus, the public cannot meaningfully comment on whether EPA's reliance on the studies is justified and whether they in fact support the Agency's conclusion that PV29 does not present a risk of harmful effects on health and the environment. EPA's withholding of the studies effectively shuts the public out of the comment process because the 24 studies comprise the *sole* scientific basis for EPA's determination that PV29 is not toxic to humans or aquatic species.

EPA's indication that it will allow members of the Scientific Advisory Committee on Chemicals (SACC) to review the 24 studies but deny access to the public only compounds this lack of transparency. An essential element of peer review under EPA's Peer Review Handbook is a process to provide public input to the reviewers. This will be impossible if the public lacks access to the 24 studies. Moreover, by treating portions of the peer review process as CBI, EPA will deny the public full access to the peer reviewers' conclusions and recommendations on a central element of the PV29 evaluation, further blocking meaningful public participation in the review process. It also will constrain the peer reviewers' ability to engage in a robust debate and discussion during the peer review process.

It is ironic that EPA believes it can base regulatory decisions on PV29 on data that are unavailable to the public while taking a diametrically opposite position in its recent proposed rule purportedly promoting "transparency" in regulatory science. 83 Federal Register 18768 (April 30, 2018). EPA based that proposal on the principle that "[b]y better informing the public, the Agency in [*sic*] enhancing the public's ability to understand and meaningfully participate in the regulatory process" and that "EPA should ensure that the data and models underlying scientific studies that are pivotal to the regulatory action are available to the public... in a manner sufficient for independent validation." While our groups have criticized many aspects of the April 30 proposal, EPA's contradictory and selective adherence to its own transparency goals is deeply troubling.

For these reasons, we urge you to place the 24 studies in the docket for the PV29 risk evaluation without delay. We are simultaneously filing a request for the studies under the Freedom of Information Act (FOIA) to preserve our ability to access them in the event EPA does not respond favorably to this letter.

Please contact SCHF counsel Bob Sussman with any questions at bobsussman1@comcast.net.

Respectfully submitted,

Ansje Miller, Director of Policy and Partnerships **Center for Environmental Health**

Jonathan Kalmuss-Katz, Staff Attorney **Earthjustice**

Richard Denison, Lead Senior Scientist **Environmental Defense Fund**

Patrick MacRoy, Deputy Director **Environmental Health Strategy Center**

Daniel Rosenberg, Senior Attorney **Natural Resources Defense Council**

Elizabeth Hitchcock, Director **Safer Chemicals Healthy Families**

cc: Charlotte Bertrand, Acting Principal Deputy Assistant Administrator
Erik Baptist, Deputy Assistant Administrator Jeff Morris, Director OPPT Tala Henry, Deputy Director OPPT Lynn Vendinello Cathy Fehrenbacher David Fotouhi, Esq. Dr. Todd Peterson Dr. Stan Barone