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EPN Comments on EPA's Draft Revision to the Toxic Substances Control Act (TSCA) Risk Determination for Pigment Violet 29

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Founded in 2017, the Environmental Protection Network (EPN) harnesses the expertise of more than 550 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators with decades of historical knowledge and subject matter expertise.

EPN's comments address two overarching issues as well as some specifics that are relevant to the draft revision to Chapter 5: Unreasonable Risk Determination of the Risk Evaluation for Colour Index Pigment Violet 29 (PV29) (hereafter, cited as PV29).

Overarching Issues

Recent months have seen EPA's reconsideration and revision of policies and practices related to implementation of the TSCA-mandated Existing Chemicals Review Program. Coupled with this exercise was a commitment to make limited revisions to several of the first 10 risk evaluations before risk management options are developed and proposed. At this time, EPA has proposed a Part 1 risk management rule for chrysotile asbestos and targeted revisions to the risk evaluations for cyclic aliphatic bromide cluster (HBCD) and PV29. These comments address the proposed risk evaluation revisions for PV29. We focus on three issues raised in the PV29 Federal Register notice: (1) EPA's decision to no longer assume use of Personal Protective Equipment (PPE) in determining whether occupational exposures present unreasonable risks of injury; 2) EPA's shift to whole chemical unreasonable risk determinations as opposed to only use-by-use determinations; and 3) Expansion of Consideration of Exposure Pathways to be integrated into the review process. Of course, all of these issues are also critical for consideration across the board for all existing chemicals undergoing review.

PPE

In their earlier comments on the first 10 chemicals, EPN and many other commenters stated repeatedly and vigorously that the assumption of the use of PPE (either respirators and/or gloves) should NOT be a factor in determining if a worker's exposure related to a specific occupational use does or does not constitute an unreasonable risk. While some facilities may have the commitment and capacity to comply with Occupational Safety and Health Administration (OSHA) standards and National Institute for Occupational Safety and Health (NIOSH) recommendations, many others do not. Therefore, EPN and others argued that it would be more appropriate and health-protective to make unreasonable risk judgments based upon no PPE. Needless to say, to us, it makes sense that

the agency is removing PPE as a factor in the unreasonable risk determination process and shifting that discussion to the risk management realm. We commend the agency for making this change. Doing so has no substantive impact upon the construction or content of the existing final risk evaluation (except for Chapter 5) as risk estimates for no PPE are already included in the document. In the case of PV29, the draft revised Chapter 5 reaffirms, but does not change, any condition-of-use (COU)-specific unreasonable risk finding.

As the agency shifts its attention to the development of risk management options for PV29, the other chemicals in the first batch of 10 and beyond, the role, if any, that PPE plays in risk mitigation will be an important component of the decision-making process.

In Section 5.2.4 of the PV29 draft revised Chapter 5, the agency makes the point that "when undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied …" We would argue that the agency must make the same assumption when considering risk *management* options.

For many years, OSHA has had in place a hierarchy of controls that is used to determine how to implement feasible and effective controls on exposure to chemical hazards and toxic substances in occupational settings. This long standing policy (albeit without the force of law and not uniformly implemented) posits that, "where possible, *elimination or substitution* is the most desirable [choice] followed by *engineering controls*. *Administrative or work practice controls* may be appropriate in some cases where engineering controls cannot be implemented or when different procedures are needed after implementation of the new engineering controls. *Personal protection equipment* is the least desirable but may still be effective."[1]

Imposition of requirements for the use of PPE should be the absolute last option selected. If we haven't become sufficiently aware of the many occasions of, and reasons for, failure to adequately protect workers across the many business sectors over the long term, the last two years certainly have shown everyone how hard it can be to wear masks or respirators for hours at a time, while maintaining adequate and effective protection throughout.

The Whole Chemical Approach

The TSCA Chemical Substances Inventory ("TSCA Inventory") currently lists over 85,000 existing chemicals, about half of which are actively involved in the chain of commerce. Section 6 of TSCA "provides EPA with the authority to prohibit or limit the manufacture (and import), processing, distribution in commerce, use, or disposal of an existing chemical if EPA concludes that the chemical presents an unreasonable risk to human health or the environment."[2] In the 46 years since

[1] https://www.osha.gov/chemical-hazards/controlling-exposure
[2] https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/regulation-chemicals-under-section-6a-toxic-substances

TSCA was first passed, EPA has moved to regulate only a very small number of existing chemicals (single, class, or mixture) under this provision of the law. In these relatively few cases, EPA has proposed to ban or modify the uses of an existing chemical/class. This has been done primarily on a case-by-case, use-by-use basis, meaning that even if just some or all uses of a chemical were the subject of a risk evaluation, risk reduction measures were determined on a use-by-use basis. There were two exceptions: the polychlorinated biphenyl total ban, as mandated in the law, and the proposed total ban on all existing uses of asbestos, which failed in the courts, resulting in some uses remaining on the market.

EPA's risk evaluation procedural rule did not clearly specify whether the agency had to evaluate all COUs in a risk evaluation or could opt for evaluation of only a subset. However, in EPN's view, the wording of TSCA requires EPA to make unreasonable risk determinations for the whole chemical, whether or not all COUs were evaluated in the risk evaluation and/or were declared an unreasonable risk. EPA first signaled that it would apply the whole chemical approach in its proposed December 2021 revisions to the HBCD evaluation. A quick screen of the comments received on the HBCD draft suggests that there are divergent opinions on this matter, from supportive to questioning to objecting. However, EPN believes that the whole chemical approach is not only required by TSCA, but is the soundest and most health-protective approach.

The first 10 risk evaluations included risk determinations based only upon the historical case-by-case, use-by-use approach. The new policy reflects an intention to make a risk determination, as and when appropriate, for the chemical as a whole, presumably informed in whole or in part upon the individual COU findings.

While EPN is strongly supportive of the implementation of the whole chemical approach conceptually, we believe it deserves more robust discussion and clarification. At the moment, the agency appears to be planning a case-by-case decision on when to apply the whole chemical approach, which implies a "we'll know it when we see it" approach. Admittedly, application of the whole chemical approach for making risk determinations is in its early stages, with only two examples available for public comment to date (HBCD and PV29).

Even though the agency does provide a rationale for choosing the whole chemical approach for PV29 (Section 5.1.1, page 2, paragraph 4), we recommend that the agency develop general guidance that would articulate, in greater detail, the decision logic to be used when making a whole chemical risk determination. What factors/criteria would be considered? Number/percentage of COUs determined to present an unreasonable risk? Position of unreasonable risk COU(s) in the chain of commerce/life cycle of the chemical: manufacture/import, processing, distribution, use, disposal? Greater or lesser weight given to occupational/occupational non-user (ONU) uses vs. consumer/bystander uses? Impacts of exposures on the general population? Identification of number/nature (*i.e.*, demographics) of exposed and affected subpopulations? Others?

Or alternatively, the agency could simply issue a blanket statement, declaring that any chemical/class/mixture that has been subjected to a prioritization process and received a final designation of High Priority will automatically receive a single risk determination based upon the whole chemical approach. In the prioritization process rule finalized in 2017, priority designations are also based upon the chemical substance "as a whole." Information on each potential candidate is assembled and evaluated against a set of criteria and considerations including:

1. The chemical substance's hazard and exposure potential;
2. The chemical substance's persistence and bioaccumulation;
3. Potentially exposed or susceptible subpopulations;
4. Storage of the chemical substance near significant sources of drinking water;
5. The chemical substance's conditions of use or significant changes in conditions of use;
6. The chemical substance's production volume or significant changes in production volume; and
7. Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

Although selection of the first 10 chemicals occured after the passage of the 2016 TSCA amendments, nine of the ten (excluding PV29) were listed on the Office of Pollution Prevention and Toxic's (OPPT's) Work Plan: 2014 Update[3], which had been created using similar selection criteria. It was shown in these cases that each met a sufficient number and variety of criteria to be deemed a chemical of concern that "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator."

Expanding Consideration of Exposure Pathways

We have noted above two circumstances in which the whole chemical approach will/could be implemented in the Existing Chemicals Review Program. The first is during prioritization for designation as a High or Low Priority chemical (or neither) before any risk evaluation is begun. The second is when making a single risk determination for the chemical after the actual risk evaluation (assessment) is completed and COU-specific risk estimates and determinations are made for both human health and environmental targets. In between, there is a vast under-explored desert that fails to appropriately and adequately discern the potential risks to human health and the environment from exposures to the chemical/class/mixture being evaluated, uniformly leading to an underestimate of risk which could be significant and pivotal.

[3] https://www.epa.gov/sites/default/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf

The agency acknowledges one of these failures in the June 30, 2021, Path Forward statement[4], which says,

> "Under the previous administration, the first 10 risk evaluations did not assess air, water or disposal exposures to the general population because these exposure pathways were already regulated, or could be regulated, under other EPA-administered statutes….The approach to exclude certain exposure pathways also resulted in a failure to consistently and comprehensively address potential exposures to potentially exposed or susceptible subpopulations,…including fenceline communities (i.e., communities near industrial facilities)."

To remedy this misstep, we recommend that the agency:

- **As the default**, conduct a multi-route exposure and risk assessment for both the general population and any relevant subpopulations. Any proposed opt-out would require detailed justification subject to public review and comment.
- **Combine (aggregate) the total exposure** determined in the general population assessment with that directly related to each of the chemical's COUs, using that aggregated value when estimating the risk related to each COU—this step to occur **BEFORE** the COU's risk determination is made.

Justification for taking this approach is that each individual who is involved in a COU is also a member of the general population most of their time and would be subject to exposures in both realms.

There are other systemic issues related to the exposure assessment practices employed in the first 10 risk evaluations, which likewise lead to a possibly significant and pivotal underestimation of risk. The most prominent—and most weakly justified—was the determination of risk separately for each expected route of exposure related to a specific COU. The excuses were creative, to say the least.

For example, HBCD: "For the purposes of this evaluation, inhalation and dermal routes of exposure were not combined to evaluate occupational risks to HBCD. Dermal and inhalation exposure were considered independently. Combining exposure routes would entail too much uncertainty given the lack of a usable PBPK model." A similar argument was made in the methylene chloride risk evaluation, as well as others.

The second example is 1,4-Dioxane: "As a result of the limited nature of all routes of exposure to individuals (i.e., occupational) resulting from the conditions of use of 1,4-dioxane, a consideration of aggregate exposures of 1,4-dioxane was deemed not to be applicable for this risk evaluation."

EPN provided counter arguments to each of these refusal statements during review of each risk evaluation, including the possibility/likelihood that the degree of uncertainty inherent in the

[4] https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations

aggregation process was outweighed by uncertainties in other choices made in the assessment, but the agency chose to proceed with their use nonetheless.

We also recommended that OPPT consult with the Office of Pesticides Program (OPP), which has managed to conduct credible multi-route occupational exposure and risk assessments for decades, and has developed, on its own or in partnership with the Office or Research and Development (ORD) and other parties, a series of well-vetted, peer-reviewed models that can easily be tailored to the assessment of non-pesticide chemicals.

Our recommendations related to COU-specific assessments are:

1. Combine exposure estimates from all relevant routes of exposure for each occupational/ONU and consumer/bystander COU BEFORE making COU-specific human health risk determinations.
2. Combine exposure estimates from all relevant routes of exposure for each ecological target BEFORE making COU-specific environmental risk determinations. While this might not apply to aquatic species, it would, for instance, be relevant for terrestrial mammals and birds.
3. Determine whether or not there is a subpopulation of humans or ecological targets that may be exposed via more than one COU over the same relevant time frame. If so, combine their exposure to all of them and make the risk determination on the combination.

PV29-Specific Comments

The agency has stated that, in the event that it decides to revise Chapter 5 "Unreasonable Risk Determination" for any of the first 10 chemicals for which a final risk evaluation was issued in 2020 or 2021, the revision would supersede all previous versions of the Chapter. The subject of the present request for public review and comment is the second example of this choice. What is not clear is how and where the final revised Chapter 5 would be made available to the public. We would suggest that the final revised Chapter be inserted into a new document to be entitled ***Revised Final Risk Evaluation for C.I. Pigment Violet 29 (Anthra [2,1,9-def:6,5,10-d'e'f'] diisoquinoline-1,3,8,10 (2H,9H)-tetrone) CASRN: 81-33-4.*** This new document would also contain all of the unchanged chapters found in the (final) Risk Evaluation issued in January 2021.

That being said, EPN has recommendations for modifications to be made in the draft revised Chapter 5 for PV29. Some of them relate to bringing additional information forward from Chapter 5 in the 2021 Risk Evaluation in order to provide a more complete picture and buttress the agency's choice of implementing the whole chemical approach in a revised Chapter 5.

1. Page 1, paragraph 3 of the draft lists the 10 COUs for which EPA identified unreasonable risks and which were drivers for the unreasonable risk determination for the whole chemical. But, unlike the 2021 Chapter 5, there is no mention anywhere of the four COUs that did not meet the unreasonable risk standard, forcing the reader to go back to the 2021 version if they want to know what they were. By leaving out reference to the four, it deprives the reader of the whole picture. To assist the reader in

understanding why EPA is implementing the whole chemical approach for PV29, it is helpful to see, in one place, that unreasonable risk was determined for over 70% (10 out of 14) of the COUs and to know where each fits in the life cycle of the chemical.

Therefore, EPN recommends that EPA insert appropriately edited text from the 2021 Section 5.4.1 No Unreasonable Risk Determination (pp 99-100) into this document as a new Paragraph 4 on Page 1(see below). The current Paragraph 4 will then become Paragraph 5.

> "EPA has determined that the following conditions of use of C.I. Pigment Violet 29 do not present an unreasonable risk of injury to health or the environment:
>
> • Distribution in commerce;
>
> • Industrial and commercial use in plastic and rubber products for automobile plastics ~~(Section 5.2.1.10, Section 5.1.1, Section 5.1.2, Section 4)~~;
>
> • Industrial and commercial use in plastic and rubber products for industrial carpeting ~~(Section 5.2.1.10, Section 5.1.1, Section 5.1.2, Section 4)~~;
>
> • Consumer use in professional quality watercolor and acrylic artist paint ~~(Section 5.2.1.13, Section 5.1.1, Section 5.1.2, Section 4)~~."

And, for those readers who benefit from visuals to confirm their interpretation of text addressing the whole chemical approach, we would recommend including in the revised Chapter 5 a figure, which would be a slightly modified, updated version of Figure 1-2. C.I. Pigment Violet 29 Life Cycle Diagram from the 2021 Final Risk Evaluation. It could be modified to add "Distribution in Commerce" as text in a box either along the top line between "Processing" and "Industrial, Commercial and Consumer Uses" with an arrow pointing down to the line between the Processing boxes and the Use boxes in the middle of the diagram, or a text box with "Distribution in Commerce" within it right on the line between the Processing boxes and the Use boxes. This editing should be coupled with shading in the boxes for all COUs deemed to constitute an unreasonable risk to highlight the distinction between the problematic and seemingly acceptable COUs.

2. Page 7, Section 5.2.1, Paragraph 1, lines 3-4: The draft refers to Table 4.4 from the final risk evaluation as providing "health risk estimates for all conditions of use." That is literally correct but makes the title of the table somewhat misleading. The title is "Risk Estimations for Occupational Inhalation Exposure Scenarios." While true, the table also includes reference to the single consumer use that was evaluated in the risk evaluation, even though no quantitative estimates were derived. We would recommend removing "Occupational" from the table title to minimize confusion, especially since there is also a second COU lacking quantitation (Industrial/Commercial Use: Plastic, Rubber Products, Industrial Carpeting).

3. EPA needs to highlight the consequences of shifting the consideration of application of PPE from the process of making unreasonable risk determinations to the development of risk management options.

   As noted above in our general comments, EPN wholeheartedly supports the agency's decision to remove application of PPE as a factor in making unreasonable risk determinations and moving it to the risk management process. In the final risk evaluation, EPA determined that 10 use scenarios constituted an unreasonable risk at high-end exposures, most of which assumed use of respirators of at least APF=10. Obviously, if EPA shifts to determinations made in the absence of any PPE, those unreasonable risk determinations would continue for the high-end exposure scenarios, but those which had been deemed not unreasonable at central tendency exposures would now also warrant an unreasonable risk determination. The resulting changes are captured in draft Table 5-1 Supporting Basis for the Unreasonable Risk Determination for Human Health in the two columns entitled "Human Health Effects/Chronic Non-Cancer, High End and Central Tendency."

   Once again, for those readers who benefit from visuals to confirm their understanding of the consequences of removing PPE as a factor in making unreasonable risk determinations in a risk evaluation, we would recommend a modest addition to draft Table 5-1. As noted in the table below, this addition would be two columns, placed to the left of the existing columns on the Chronic Non-Cancer High End and Central Tendency risk determinations. Displaying these before and after scenarios would impressively highlight the differences that result, in this case when PPE is removed as a determining factor, especially for central tendency exposures.

   [Note: the column at the far left of the table below should not be included in a new Table 5-1. Its purpose was simply to assist the authors of these comments in creating the proposed revisions to the table.]

Proposed Amended Table 5-1

Human Health Effects				
Chronic Non-Cancer				
	2021 Final RE		2022 Revised Final RE	
Life Cycle Stage	High End	Central Tendency	High End	Central Tendency
Manufacture	✔§#	OK	✔	✔
	✔	✔	✔	✔
Import	✔	OK	✔	✔
	✔	✔	✔	✔
Process - Paints/Coatings	✔	OK	✔	✔
	✔	✔	✔	✔
Process - Rubber/Plastics	✔	OK	✔	✔
	✔	✔	✔	✔
Process - Intermediates	✔	OK	✔	✔
	✔	✔	✔	✔
Automobile (OEM and refinishing)	✔ (APF=25)	OK (APF=25)	✔	✔
	✔	✔	✔	✔
Coatings/Basecoats	✔ (No PPE)	OK (No PPE)	✔	✔
	✔	✔	✔	✔
Merchant Links	✔ (No PPE)	OK (No PPE)	✔	✔
	✔	✔	✔	✔
Disposal	✔	OK	✔	✔
	✔	✔	✔	✔

§ Denotes unreasonable risk; #Assumes PPE at APF = 10, unless otherwise noted