April 21, 2022

Todd Coleman
Office of Pollution Prevention & Toxics (7404T)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC. 20460-0001

Re: Comments on Draft Revised Risk Determination for C.I. Pigment Violet 29; EPA-HQ-OPPT-2016-0725

Dear Mr. Coleman:

The Color Pigments Manufacturers Association (CPMA) is pleased to present these comments on the Agency's draft revision of the risk determination for C.I. Pigment Violet 29 (PV29).[1]

CPMA is the national trade association representing the color pigments industry. CPMA represents companies in the value chain that are engaged in the production or selling of color pigments in North America. Color pigments are important components in a wide range of applications, including printing inks, paints and coatings, plastics, building materials, cosmetics, personal care products, pharmaceuticals and agricultural products. Formed in 1925, CPMA provides programs to enhance regulatory compliance and support the manufacture and use of color pigments.

As explained more fully in the balance of these comments,

- EPA's "whole chemical" approach to risk determination is inconsistent with TSCA and is prohibited by EPA's current risk evaluation framework rule. EPA is not free to act at variance with its own procedural rules. Taken as a whole, PV29 does not pose an unreasonable risk. If EPA retains the whole chemical approach, it may only impose risk management requirements on conditions of use (COUs) that drive the unreasonable risk determination, directly or indirectly.
- The scope of EPA's new policy regarding worker protection assumptions is unclear. Moreover, that policy violates TSCA, which requires EPA to make risk evaluation and risk determination decisions based on the particular circumstances of each condition of use of the relevant chemical, guided by the best available science. In any event, this issue is irrelevant to the PV29 risk evaluation, as the final risk evaluation did not make any 'no unreasonable risk' determinations based on assumptions that workers used personal protective equipment.
- CPMA's recently-conducted study of airborne particles at the sole U.S. plant where PV29 is manufactured demonstrates definitively that workers and occupational non-users there are not exposed to PV29 particles in the ultrafine range that EPA found to present health hazards.

[1] 87 Fed. Reg. 12690 (March 7, 2022).

Based on the scientific information now available to EPA regarding exposures to PV29 at particle sizes of concern, EPA can (indeed, must) conclude that PV29 no longer presents an unreasonable risk at that facility. Accordingly, no additional risk management requirements are required (or authorized) for the manufacturing condition of use.

- The draft revised risk determination opines that alveolar hyperplasia is an "irreversible" effect. But the final risk evaluation says nothing about whether that or other non-carcinogenic effects observed in rodent studies of carbon black are reversible in rodents or humans. If EPA wants to supplement the final risk evaluation to further address this issue, it needs to reopen the risk evaluation for public comment.
- EPA should integrate any new Section 5 into what would become a revised final risk evaluation so that the entire document is complete and internally consistent.

CPMA also endorses comments of the American Chemistry Council on the draft revised risk determination.

I. Problems with EPA's Proposed "Whole Chemical" Approach

EPA's "whole chemical" approach to making unreasonable risk determinations violates TSCA. Section 6(a) speaks in terms of *conditions of use* presenting unreasonable risk, as it is triggered where the "manufacture, processing, distribution . . ., use, or disposal of a chemical substance . . . or any combination *of such activities*, presents an unreasonable risk . . . ."[2] Section 6(a) then authorizes restrictions on one or more of those activities, listed in the disjunctive.[3] Consistently, in support of those determinations, Section 6(b)(4) directs risk evaluations to determine whether a chemical substance presents an unreasonable risk "under the conditions of use."[4] The statute thus does not authorize "whole chemical" risk determinations.

The whole chemical approach is also prohibited by the Agency's risk evaluation framework rule, which unambiguously states that EPA will make unreasonable risk determinations for "each condition of use[], either in a single decision document or in multiple decision documents."[5] As result, any final risk management rule premised on a "whole chemical" risk determination will have been issued "without observance of procedure required by law,"[6] and hence will be illegal – unless and until EPA revises the framework rule to provide for whole chemical risk determinations. As just noted, however, we believe such a revised rule would be contrary to law.

We also disagree even more strongly with EPA's proposed determination of unreasonable risk for PV29 taken as a whole chemical. As we have explained in our comments on the revised draft risk evaluation,[7]

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[2] 15 U.S.C. § 2605(a)(emphasis added).
[3] *See esp. id*. § 2605(a)(1)-(3).
[4] *Id*. § 2605(b)(4)(A).
[5] 40 C.F.R. § 702.47. Making unreasonable risk determinations on a COU-by-COU basis is essential to the mechanisms outlined in the rule, whereby EPA can make "early" unreasonable risk determinations for some but not all COUs, and can issue "no unreasonable risk" orders for COUs that don't present unreasonable risk. *See id.* § 702.49; *see also* 82 Fed. Reg. 33726, 33744 (July 20, 2017).
[6] 5 U.S.C. § 706(2)(D).
[7] EPA-HQ-OPPT-0604-0105.

and in our December 15, 2021 submission on the topic,[8] the best available scientific evidence shows that PV29 does not present unreasonable risk in the workplace, most importantly because the particle size observed in the workplace is 50 times larger than the ultrafine particles (of carbon black) that EPA found to present unreasonable risk. But – as we explained in our December 15 submission – EPA can address this issue satisfactorily in its forthcoming risk management rulemaking. See Part III below.

Finally, CPMA takes specific issue with EPA's statement that it "is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk."[9] EPA's application of risk management to a COU must be linked to, and diminish, unreasonable risk posed by that or another COU. Stated in terms of the Agency's current "whole chemical" formulation, risk management may only be applied to a COU that drives the unreasonable risk, directly or indirectly. This conclusion flows from the language of TSCA, which only authorizes risk management requirements "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk."[10] It also flows from the reasoned decisionmaking requirement of arbitrary and capricious review under the Administrative Procedure Act, which requires agencies to demonstrate "a rational connection between the facts found and the choice made."[11] So, as EPA described at GlobalChem, it could permissibly require a manufacturer of tubes of glue containing a chemical substance – the processor of a chemical – to print warning labels on the tubes in order to protect do-it-yourselfer consumers. But in the case of PV29, EPA could not impose requirements on manufacturers of plastic or rubber products containing PV29 since the Agency has concluded that those conditions of use do not pose unreasonable risk, directly or indirectly.[12] EPA should confirm it agrees with this view.

II. Problems with EPA's "Worker Protection" Assumptions

A. Confusion Regarding Scope

The draft revised risk determination says: "EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied," and that, "[t]herefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE.[13] Likewise, the draft risk evaluation for HBCD refers to "an applicable OSHA requirement or industry practice," and declares "EPA['s] inten[t] to make its determination of unreasonable risk from a baseline scenario that does not assume compliance with OSHA standards, including any applicable

[8] "Ramboll US Consulting's Attached Report on 'Airborne Particle Size Characterization of C.I. Pigment Violet 29 (PV29)' and its Relevance to EPA's Risk Management Rulemaking on PV29, EPA-HQ-OPPT-2021-0277." This document does not appear to have been posted yet in the docket.
[9] Draft for Public Comment at 1.
[10] 15 U.S.C. § 2605(a).
[11] *See, e.g., Public Citizen, Inc. v. Mineta*, 340 F.3d 39, 56 (2d Cir. 2003).
[12] *See* the Final Risk Evaluation at 94-95.
[13] Draft for Public Comment at 7-8.

exposure limits or requirements for use of respiratory protection or other PPE."[14] On the other hand, the Federal Register notice announcing availability of the draft revised risk determination focuses on PPE:

> EPA proposes that the risk determination should be explicit that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE would be considered during risk management.[15]

Similarly, at GlobalChem on April 11, Niva Kramek was clear that EPA's assumption was "very specifically" limited to non-use of *PPE*, and not any to other forms of worker protection, like engineering controls.

What does EPA intend? The Agency should clarify this issue in writing promptly.

B. EPA's New Assumption Is Contrary to Statute

In any event, EPA's assumption is illegal. As just noted, the draft revised risk determination says that "EPA cannot assume as a general matter that an applicable OSHA requirement or industry practice is consistently and always properly applied." So, instead, EPA is assuming that these requirements or practices will *never* be applied. The statute does not require either assumption, and likely does not authorize either assumption "as a general matter." Rather, TSCA requires EPA to evaluate the risks posed by the chemical substance "under the conditions of use,"[16] defined as "the circumstances, as defined by the Administrator, under which a chemical substance is intended, known, or *reasonably foreseen* to be manufactured, processed, distributed in commerce, used, or disposed of."[17] This language requires EPA to make decisions based on the particular circumstances of each condition of use of the relevant chemical – a series of fact-based decisions. Those decisions are to be based, moreover, on "the best available science."[18] Clearly, what is "reasonably foreseeable" regarding use of the industrial hygiene controls can differ depending on the chemical substance and the type of workplace. In the case of a widely-used solvent like methylene chloride, for example, it may well be reasonably foreseeable that home repair contractors may not supply their employees with PPE, or that those employees may not use it, especially when working unsupervised at a customer site. It may therefore be reasonable for EPA to assume nonuse of PPE in such cases. But an industrial chemical may only be used at sophisticated manufacturing sites to make other chemicals. In that case, it would not be reasonable for EPA to assume nonuse of workplace controls – particularly engineering controls – absent some data showing, for example, that ventilation is regularly turned off. The statute does not allow EPA to simply adopt a "protective" assumption that ignores the reality of how a particular chemical is used at categories of workplaces.

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[14] 86 Fed. Reg. 74086.
[15] 87 Fed. Reg. 12692.
[16] 15 U.S.C. § 2605(b)(4)(A).
[17] *Id.* § 2602(4) (emphasis added).
[18] *Id.* § 2626(h).

PV29 is only made at one plant in the United States, and 90% of the production is consumed onsite to make other pigments. EPA's risk evaluation staff visited that site as part of the risk evaluation, and have seen first-hand the effectiveness of practices used there to minimize the generation of, and worker exposure to, PV29 particles. These practices consist of engineering controls (fans and bay doors open to the outdoors), administrative controls (restricting employees not wearing specified PPE from areas where PV29 is handled) and PPE (including half-mask negative pressure air purifying respirators equipped with N95 filters). It is "known" to EPA that worker protections are used in the manufacture of PV29, and under the administrative record in this rulemaking it is "reasonably foresee[able]" that worker protections will continue to be used in that manufacture. Virtually all the rest of the PV29 production is used to make plastic pellets, paints and inks – all examples of large, sophisticated manufacturing operations where worker protection is the norm. Thus, EPA acted reasonably in assuming, in the revised draft risk evaluation for PV29 issued in October 2020, that workers at automobile coating and refinishing workplaces would wear APF25 respirators.[19]

C. EPA's Assumption Makes No Difference in the Case of PV29

In the Federal Register notice regarding the redrafted risk determination, EPA stated correctly that "[r]emoving the assumptions of PPE use in making the whole chemical risk determination for PV 29 would not alter the conditions of use or worker subpopulations that drive the unreasonable risk determination for PV 29."[20] This is because, for every COU where the final risk evaluation modeled exposures assuming non-use of PPE, it also modeled those exposures using assumptions of PPE use, and in every one of those case, the result was at least one exposure above the benchmark margin of exposure of 30, indicating unreasonable risk.[21] So eliminating all assumption of PPE use in the Final Risk Evaluation would make no difference for any of the COUs, assuming no other changes to the risk evaluation. The discussion of this issue on pp. 7-8 of the draft revised risk determination never acknowledges this point. It should be revised accordingly. Indeed, because EPA's PPE assumptions made no difference in the case of PV29, the draft's entire discussion of that issue is irrelevant and could simply become a footnote that notes EPA's policy as a matter of completeness.

D. Estimating Risk Assuming a Range of Worker Protections Informs Risk Management

Even if EPA assumes non-use of PPE (or other worker protections) in making unreasonable risk determinations, it would also be wise for EPA to estimate risk *assuming* use of those protections as a tool for informing a subsequent risk management rulemaking. Such estimates enable EPA to determine with precision which risk management actions are the minimum "necessary so that the chemical substance . . . no longer presents such risk."[22] EPA recognizes this point on page 7 of the draft revised risk determination, and CPMA supports it.

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[19] Revised Draft Risk Evaluation at 89-90. *See also* letter from Aaron Schulenberg, Executive Director of the Society of Collision Repair Specialists, to Lanelle Wiggins, U.S. Small Business Administration (Feb. 8, 2022), at 4-6 (describing how air exposures at auto refinishing shops are controlled, including by use of positive pressure spray booths and use of supplied air hoods).

[20] 87 Fed. Reg. 12691.

[21] *See* Final Risk Evaluation at 79-80, 86-87, and 90-97.

[22] 15 U.S.C. § 2605(a).

III. The PV29 Risk Management Rule Cannot Impose Requirements Where No Unreasonable Risk Is Occurring

As CMPA explained in our December 15, 2021 submission,[23] CPMA retained Ramboll US Consulting to conduct a study of airborne particulates at the Bushy Park, South Carolina facility that is the sole U.S. facility manufacturing PV29. The study focused on the PV29 grind and blend packout process, which is the final stage in the batch production of this material and the one most likely to generate the highest concentrations, and smallest particle size, of PV29.

For purposes of the upcoming PV29 risk management rule, the most important finding of the study was that "airborne [ultrafine particulates (UFP)] were not generated as part of the PV29 grind and blend pack-out process."[24] The study observed that "[a]irborne ultrafine particle concentrations decreased throughout the monitoring period with a mean concentration [that] was less than the mean background concentration [that] was measured prior to handling PV29."[25] Also, the concentrations of UFP did not increase during activities and events involving handling of PV29. By contrast, measurements of larger particle sizes demonstrated lower background concentrations and clear increases that corresponded closely with tasks performed during bag filling, including overfilling bags, wiping down surfaces and the "shake down" task that occurred at the end of the bag filling process. This correlation was particularly pronounced in the 1.0-3.0 µm size range, the bin that encompasses the most likely average particle size observed during the study (estimated to be approximately 2.5 µm, or more than 50 times larger than the size found to give rise to unreasonable risk). As Ramboll concluded, "[t]hese results demonstrate that airborne PV29 particulate was not generated at the size used by USEPA in their risk evaluation."[26] Rather, under "real-world manufacturing conditions," primary "particulates . . . form larger agglomerates."[27]

TSCA Section 6(a) requires that, where a risk evaluation finds unreasonable risk under a condition of use, EPA issue a risk management rule "to the extent necessary so that the chemical substance . . . no longer presents such unreasonable risk."[28] Section 26 requires risk management rulemakings to be based on the best available science and the weight of the scientific evidence.[29] The Ramboll study "is relevant for the Administrator's use in making a decision" regarding unreasonable risk,[30] and shows definitively that workers and occupational non-users at the Bushy Park facility are not exposed to PV29 particles in the ultrafine range that EPA found to present health hazards. In the final PV29 risk evaluation, EPA noted that it "may make a determination of no unreasonable risk for conditions of use where the substance's hazard and exposure potential, or where the risk-related factors described previously, lead the Agency to determine that the risks are not unreasonable."[31] Such a circumstance exists here. Based on the

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[23] *See* note 9 *supra*.
[24] Ramboll US Consulting, "Airborne Particle Size Characterization of C.I. Pigment Violet 29 (PV29)" (Dec. 2021), at 10.
[25] *Id*. at 2.
[26] *Id.*
[27] *Id.* at 1.
[28] 15 U.S.C. § 2605(a).
[29] 15 U.S.C. § 2625(h), (i).
[30] *Id*. § 2605(h)(2).
[31] Risk Evaluation at 87 (emphasis added).

scientific information now available to EPA regarding exposures to PV29 at particle sizes of concern, EPA can (indeed, must) conclude that PV29 "no longer presents [an] unreasonable risk" at the Bushy Park facility. Accordingly, no additional risk management requirements are required (or authorized) for the manufacturing condition of use.

CPMA believes that similar circumstances would exist at processing conditions of use involving PV29 (e.g., incorporation into plastic pellets, paints and inks), given our understanding of the processes they use to transfer PV29 particles from bags into process equipment. We believe it would be appropriate for EPA to conclude that no unreasonable risk exists at any such downstream use of PV29 unless such uses involve agitation and dispersion of PV29 particles in a way absent at the Bushy Park facility. Alternatively, EPA could encourage representatives of these downstream industries to conduct similar ultrafine particle monitoring at representative workplaces and provide the Agency with the results.

At an absolute minimum, the proposed risk management rule should provide facilities with the option of conducting initial monitoring at appropriate locations, comparable to that conducted by Ramboll, to determine whether ultrafine particles are observed to fluctuate in ways that correspond to activities involving PV29. Where no such correlation is observed, facilities would have no further obligations under the rule. Retesting could be required where processes are changed in significant ways that could reasonably be expected to create exposures to ultrafine particles of PV29.

IV. EPA is Improperly Reopening the Risk Evaluation

CPMA's December 15 submission noted that we did not seek to reopen the risk evaluation to incorporate the Ramboll study, so long as EPA takes that study into account in the risk management rulemaking, and evaluates the actual potential for unreasonable risk to occur from any given COU in light of that study, as just discussed.

The draft revised risk determination says: "With respect to the C.I. Pigment Violet 29 risk evaluation, EPA does not intend to amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation."[32] In the next paragraph, however, the draft opines that alveolar hyperplasia is an "irreversible" effect, without any discussion of the issue. In fact, the final risk evaluation does not use that or any similar word and says nothing about whether that or other "non-carcinogenic effects" observed in rodent studies of carbon black are reversible in rodents or humans.[33] In fact, the scientific

[32] Draft for Public Comment at 2.
[33] *See, e.g.,* Final Risk Evaluation at 76.

literature indicates that evidence indicates that alveolar hyperplasia, both in humans[34] and rodents,[35] *can* be reversed.

Moreover, articles discussing alveolar hyperplasia as an adverse health effect regard it as a precursor to cancer,[36] but the final risk evaluation describes alveolar hyperplasia as a *non-cancer* health effect, and says "EPA determined that [PV29] is not likely to be carcinogenic."[37] (CPMA agrees with that determination.) The risk evaluation does not, however, explain what adverse, non-cancer human effect alveolar hyperplasia would be an irreversible precursor *of*. It cites EPA's 2019 Integrated Science Assessment for Particulate Matter for the proposition that alveolar hyperplasia is relevant to humans,[38] but the only discussion that document contains speaks merely of "evidence of mild morphologic changes, such as hyperplasia of the bronchoalveolar duct (Batalha et al., 2002) and changes in the mucus content of the nasal epithelium (Yoshizaki et al., 2016), that could be downstream effects of inflammation following inhalation of PM2.5."[39]

If EPA wants to supplement the final risk evaluation to further address this issue, it needs to reopen the risk evaluation for public comment.

V. EPA Needs to Integrate Section 5 with the Balance of the Risk Evaluation

For the most part, the draft revised risk determination reads as if it were a drop-in replacement for existing Section 5 of the final risk evaluation. However, in other instances, it talks about "revisions" that "would be" made to Section 5.[40] Even more problematic, it also says at one point that--

> The discussion of the issues in this draft revision to the risk determination would supersede any conflicting statements in the prior C.I. Pigment Violet 29 risk evaluation (January 2021) and the response to comments document . . . .[41]

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[34] *See* K.M. Kerr, "Pulmonary Preinvasive Neoplasia," 54 J. CLIN. PATHOL. 257 (2001) ("The recently published WHO lung tumour classification defines three separate lesions that are regarded as preinvasive neoplasia. These are (1) squamous dysplasia and carcinoma in situ (SD/CIS), (2) atypical adenomatous hyperplasia (AAH), and (3) diffuse idiopathic pulmonary neuroendocrine cell hyperplasia (DIPNECH). . . . It may take between one and 10 years for invasion to occur, yet the lesion(s) may be reversible if carcinogen exposure ceases.").

[35] *See* Masanao Yokohira et al., "Validating the Use of Napsin A as a Marker for Identifying Tumorigenic Potential of Lung Brochiolo-Alveolar Hyperplasia in Rodents," 69 EXP. TOXICOL. PATHOL. 637 (2017) ("There are two types of bronchiolo-alveolar hyperplasia (hyperplasia) in rodent lungs. The first is "inflammatory hyperplasia" that retains its ability to revert to normal epithelia upon removal of the stimulating insult. The second is "latent tumorigenic hyperplasia", which is irreversible and causes independent preneoplastic lesions that can progress to bronchiolo-alveolar adenocarcinoma."); Roger Renne et al., "Proliferative and Nonproliferative Lesions of the Rat and Mouse Respiratory Tract," 37 TOXICOLOGIC PATHOLOGY 5S, 5S-6S (2009) ("Cellular damage from repeated exposure to toxicants induces a repair process in which the damaged tissue may proliferate (hyperplasia) and/or undergo metaplasia to a different, more resistant cell type if return to normal morphology is not complete.").

[36] *See* previous two footnotes.

[37] Final Risk Evaluation at 14.

[38] *Id.* at 76.

[39] EPA/600/R-19/188, "Integrated Science Assessment for Particulate Matter" (Dec. 2019) at 5-6.

[40] Draft for Public Comment at 3.

[41] *Id*.

This is not an acceptable approach to drafting documents with legal effect that the public will rely on. EPA needs to integrate Section 5 into what would become a revised final risk evaluation so that it is complete and internally consistent. This may require revising other sections of the document as well.

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We very much appreciate the opportunity to submit these comments on EPA's draft revised risk determination for PV29. If you have any questions regarding the matters discussed here, please do not hesitate to contact me at 571-348-5106 or davidwawer@cpma.com.

Sincerely,

David Wawer
Executive Director