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January 21, 2025

James Payne
Acting Administrator
Office of the Administrator
U.S. Environmental Protection Agency
Room 3000
WJC West Building
1200 Pennsylvania Ave., NW
Washington, D.C. 20460

Re: Request for an Administrative Stay Pending Judicial Review of the Final Trichloroethylene Regulation under the Toxic Substances Control Act; 89 Fed. Reg. 102568 (Dec. 17, 2024)

Dear Acting Administrator Payne:

On behalf of PPG Industries, Inc., ("PPG"), we request an immediate stay pending judicial review of the U.S. Environmental Protection Agency's ("EPA") tricholoroethylene ("TCE") final rule ("TCE Rule")[1] under the Toxic Substances Control Act ("TSCA"). PPG will also be filing a petition for judicial review of the TCE rule in the U.S. Court of Appeals for the Third Circuit on January 21, 2025.[2] Under the Administrative Procedure Act ("APA"), the EPA Administrator has authority to stay the effective date of a rule "when justice so requires."[3] As demonstrated below, an administrative stay is warranted here.

[1] 89 Fed. Reg. 102568 (Dec. 17, 2024).

[2] By submitting this petition to EPA, PPG satisfies its obligation under Fed. R. App. P. 18(a)(1) to move the agency for an administrative stay pending judicial review of the TCE Rule.

[3] 5 U.S.C. §705.

Background

Pursuant to TSCA Section 6(b), EPA published a risk evaluation for TCE in November 2020 and a supplemental risk evaluation in January 2023. 15 U.S.C. §2605(b). Both concluded that various TCE conditions of use present unreasonable risks. If EPA makes an unreasonable risk determination, as it did for TCE, EPA must then promulgate a risk management rule under Section 6(a) imposing requirements "to the extent necessary so that the chemical…no longer presents such risk." 15 U.S.C. §2605(a). EPA published a proposed risk management rule for TCE in October 2023, 88 Fed. Reg. 74712 (Oct. 31, 2023).

Of particular relevance to PPG, Section 6(g) of TSCA permits EPA to exempt a condition of use from a requirement in a risk management rule for a given period of time if one of several criteria are met. 15 U.S.C. §2605(g)(1)(A)-(B). These include whether the condition of use is a "critical or essential use for which no technically or economically feasible safer alternative is available" or where compliance with the restrictions would "significantly disrupt the national economy, national security, or critical infrastructure." *Id.* By its very nature, an exemption will necessarily allow activities that present some degree of unreasonable risk. When granting an exemption, therefore, EPA must engage in a balancing exercise in determining which risk mitigation conditions "are necessary to protect health and the environment while achieving the purposes of the exemption." *Id.* And finally, EPA must set forth its analysis in the final rule and describe how it was taken into account. 15 U.S.C. §2605(g)(2).

On June 29, 2022, PPG submitted to EPA a Section 6(g) exemption request for the use of TCE in the manufacture of *Teslin* substrate, a unique polymeric microporous sheet material that is a fundamental component of a wide range of products used in everyday life.[4] *Teslin* is manufactured in PPG's plant in Barberton, Ohio, the only facility in the world that produces *Teslin*. In its Section 6(g) exemption request, PPG relied on 15 U.S.C. §2605(g)(1)(A)-(B).

On October 31, 2023, as part of the proposed TCE rule, EPA proposed granting PPG's request for a Section 6(g) exemption. 88 Fed. Reg. at 74757-60. Specifically, PPG could continue its use of TCE in the manufacture of *Teslin* under a 15-year exemption pursuant to Section 6(g)(1)(A)-(B), with EPA finding that *Teslin's* various applications are "critical and essential uses for which no safer alternative is available," as well as "important for the national economy, national security, and critical infrastructure." *Id.* at 74757.

[4] *See* Exemption Request at EPA-HQ-OPPT-2020-0642-0098.

EPA also proposed an existing chemical exposure limit ("ECEL") of 0.0011 ppm as part of an overall workplace chemical control program ("WCPP") that PPG would have to implement during the exemption period. *Id.* at 74735-36. EPA recognized, however, that it would be infeasible for PPG to meet the ECEL through extensive use of respirators. Practical barriers and worker safety concerns would prevent full-time use. *Id.* at 74735-37; 74762. Nevertheless, EPA stated it "expects [PPG] to make appropriate changes to its worker exposure mitigation program to comply with the WCPP and attempt to meet the ECEL to the extent possible." *Id.* at 74757. Notably, EPA did not identify additional administrative and engineering controls that PPG could take to meet the 0.0011 ppm ECEL.

On December 15, 2023, PPG submitted extensive comments on EPA's proposal, which addressed three matters important to this request for an administrative stay.[5] First, given the 0.0011 ppm ECEL was based on a fetal cardiac defect endpoint to eliminate any unreasonable risk, PPG submitted comments and analysis demonstrating the ECEL was orders of magnitude below any unreasonable risk to human health or the environment. PPG submitted three extensive analyses showing: (i) the main study (Johnson, et al.) EPA relied upon suffered from critical deficiencies and weaknesses; (ii) EPA failed to adequately consider other studies representing the best available evidence (as required pursuant to 15 U.S.C. §2625(h)) indicating that developmental toxicity is not an appropriate endpoint; and (iii) EPA did not engage in an objective, systematic or reproducible weight of the evidence analysis (as required under 15 U.S.C. §2625(i)).

Second, PPG agreed with EPA it would not be feasible to require respirator use full-time to meet the ECEL. PPG stated that wearing PPE for entire shifts "would render performing work impossible." PPG identified numerous complications and hazards presented by such use, including reduced visibility and ability to communicate, tripping hazards, physiological and psychological stress, potential ergonomic injuries, and the need for extensive training and supervision. PPG therefore concluded respirators could only be used for short duration, high-risk, and/or non-routine tasks.

Third, PPG detailed its comprehensive industrial hygiene ("IH") processes that adequately protect workers at the Barberton plant under applicable TCE exposure limits. PPG noted, for example, that full shift TCE exposure monitoring results over the past five years have consistently been below PPG's TCE internal permissible exposure limit ("IPEL") of 5 ppm. In fact, these results are only a fraction of OSHA's and California OSHA's TCE PELs.

[5] *See* PPG Comments at EPA-HQ-OPPT-2020-0642-0315.

Finally, PPG indicated that it is not aware of any additional controls (absent full-time reliance on respirators) that would reduce exposures to the 0.0011 ppm ECEL or a proposed 0.036 ppm alternative interim ECEL.

TCE Final Risk Management Rule

The final risk management rule granted the 15-year Section 6(g) exemption for *Teslin*. EPA confirmed that such materials offer "critical and essential uses for which no technically and economically feasible alternative is available." 89 Fed. Reg. at 102587, 102610. However, EPA adopted a substantially different approach to the ECEL and occupational exposure limits.

Specifically, EPA abandoned the 0.0011 ppm ECEL which was based on eliminating all unreasonable risk (using developmental toxicity as the most sensitive endpoint). Instead, manufacturers, including PPG, will be required to meet a 0.20 ppm interim ECEL (with a 0.10 ppm action level) during the exemption period. *Id.* at 102580-81. Moreover, instead of only having to satisfy the ECEL "to the extent possible," manufacturers must always meet the standard and do so by September 15, 2025. *Id.* at 102600.

In the final rule, EPA discussed at length comments indicating that relying on PPE (i.e., respirators) full-time was not feasible. For example, commenters requested a higher ECEL to avoid an "unworkably burdensome level of PPE" and suggested levels such as 5 ppm (citing PPG's comments). Significantly, EPA stated it "acknowledges [high levels of PPE use] can represent an occupational hazard on its own" and cited hazards such as "communication problems, vision problems, worker fatigue, and reduced work efficiency among such challenges," ultimately "pos[ing] a risk to the wearer's safety or health." *Id.* at 102580 ("EPA recognizes the challenges of respiratory PPE."). In finalizing the 0.20 ppm ECEL, EPA claimed it was "based on feasibility considerations…Specifically, the interim ECEL takes into account significant challenges potentially exposed persons would experience from extensive respiratory PPE use in an occupational setting." *Id.*

But EPA had little to say as to whether manufacturers could satisfy the 0.20 ppm interim level through additional administrative and engineering controls, particularly without extensive PPE use. In conclusory fashion, EPA stated:

> EPA *expects* that the various industries subject to the interim ECEL can meet the interim ECEL with exposure controls that are feasible for owners and operators to implement for potentially exposed persons over a full shift, using engineering controls and in some instances, respiratory PPE. While certain supplied air respirators could be used to reduce exposures below the proposed exposure limit, these respirators are

> burdensome and EPA is not confident that they can be effectively and consistently implemented on an ongoing basis in a way that fully addresses the unreasonable risk…The interim ECEL allows for more robust use of the hierarchy of controls.

Id. at 102580-81 (emphasis added).

In fact, nowhere did EPA indicate that it engaged in a Section 6(g) balancing exercise. For example, EPA never pointed to record evidence showing there currently exist administrative and engineering controls that could feasibly be used to satisfy the 0.20 ppm standard without heavy reliance on respirators, whether by the compliance date or otherwise. Despite conceding that commenters, including PPG, indicated "they were not aware of any additional feasible engineering or administrative controls" to help meet low-ppm exposure levels without full-time use of PPE, *id.* at 102580, EPA just assumed such compliance was possible.

Even more concerning, EPA then reversed course and stated manufacturers would nevertheless have to rely on respirators to meet the interim ECEL where exposure levels exceeded 0.20 ppm and administrative and engineering controls were not sufficiently protective. *Id.* at 102603-04 ("If efforts of…engineering controls and administrative controls are not sufficient to reduce exposures to or below the interim ECEL for all potentially exposed persons in the workplace, EPA requires that the owner or operator…supplement these controls with respiratory protection and PPE as needed to achieve the interim ECEL"). *See also id.* at 102605 (prescribing various respirators for exposure levels above 0.20 ppm).

In the end, EPA did not indicate how 0.20 ppm would be protective of human health and permit PPG's continued use of TCE. To be sure, EPA stated the interim ECEL was supported by sound science in the record and the risk evaluation justifying the proposed 0.0011 ppm ECEL. *Id.* at 102580. But even if true, there was no discussion regarding how 0.20 ppm was balanced with Section 6(g)'s command that "critical and essential" TCE uses must be allowed until a safer alternative is found. Indeed, for manufacturers like PPG who cannot reduce TCE exposures to 0.20 ppm without extensive respirator use, the interim ECEL equates to an immediate ban and renders moot the Section 6(g) exemption.

PPG Is Likely To Succeed On The Merits

EPA must overcome a relatively high bar to adequately justify a risk management rule under TSCA's distinct version of the "substantial evidence" standard of review. 15 U.S.C. § 2618(c)(1)(B).

In *Ausimont U.S.A. Inc. v. EPA*, the Third Circuit stated that "this standard of review [is] more demanding than the arbitrary and capricious test often applied to administrative rulemaking." 838 F.2d 93, 96 (3d Cir. 1988). Indeed, the D.C. Circuit held in *Chem. Mfrs. Ass'n v. EPA* that Congress intended for courts under TSCA's "substantial evidence" standard to "engage in a *searching review* of [EPA's] reasons and explanations for [its] conclusions." 859 F.2d 977, 991 (D.C. Cir. 1988) ("*CMA*"). Citing to TSCA's legislative history, *CMA* held this standard is a "demanding one" and it is more "rigorous" than the deferential "arbitrary and capricious" review in APA cases. *Id.* at 991-92 (citing *Ausimont*). A reviewing court must ensure EPA has "identif[ied] the facts that underlie its determination" and that its action is "supported by [the] record" taken as a whole. *Id.* at 992.

Critically, under TSCA, EPA must "explain" its analysis; it cannot rely on "conclusory statements." *Vinyl Inst. Inc. v. EPA*, 106 F.4th 1118, 1128 (D.C. Cir. 2024). *See generally Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (agency must offer an explanation for its decision that does not "run[] counter to the evidence"); *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (An "agency cannot ignore evidence that undercuts its judgment; and it may not minimize such evidence without adequate explanation."). As discussed below, EPA utterly failed to meet this standard here.

EPA Failed to Support the TCE Rule with Substantial Evidence

EPA stated in the final rule that it "expects" PPG and others would be able to meet the interim ECEL of 0.20 ppm using "feasible" exposure controls, relying on additional engineering controls, and only using respiratory PPE in "some instances." But EPA did not cite to any record evidence indicating that a single manufacturing facility, whether PPG's or another plant, could modify their production processes to reduce exposures to 0.20 ppm without heavy reliance on respirators. EPA never explained why it believed manufacturers could "make significant, but feasible changes, from current practice." Instead, in only conclusory fashion, EPA assumed this would be possible.

In doing so, EPA contradicted its own repeated statements that full-time use of respirators would be infeasible. In the final rule, EPA "acknowledge[d]" respirator PPE presents occupational hazards, "recognize[d]" that respirators pose "challenges," and conceded respiratory protection should be a "last resort." Similarly, in the proposed rule, EPA found respirators "would be too difficult to implement over the long-term" and there was a "significant degree of uncertainty" whether manufacturers could control exposures without "relying primarily on the use of PPE." In fact, EPA ultimately banned TCE because it did not believe manufacturers could meet an ECEL indefinitely through extensive respirator use. Yet EPA never reconciled these statements with the practical reality that workers will need to wear respirators for an entire shift. EPA claimed the 0.20 ppm limit was "based on feasibility considerations" but never pointed to record evidence in support.

Perhaps most glaring is the absence of any analysis in the final rule explaining why EPA eventually discounted PPG's comments. PPG pointed to a litany of worker safety risks and barriers to full-time use, including limited visibility and communications, increased stress on the heart and lungs, adverse psychological impacts, and physical hazards. And EPA seemingly agreed that these warranted concern. But then EPA charged forward, essentially imposing a full-shift respirator requirement, while leaving wholly unresolved PPG's warnings. This alone justifies an administrative stay pending judicial review.

EPA Failed to Impose Conditions that Will Achieve the Purposes of the Section 6(g) Exemption

When granting a Section 6(g) exemption, EPA must engage in a balancing exercise by imposing conditions that "are necessary to protect health and the environment" while at the same time "achieving the purposes of the exemption." 15 U.S.C. §2605(g)(4). EPA may require inhalation controls provided they do not prevent the manufacturer from temporarily using a chemical where there is no substitute. 15 U.S.C. §2605(g). In other words, any controls must be feasible.

As noted above, in approving PPG's Section 6(g) exemption, EPA found that TCE was a "critical" and "essential" use in manufacturing *Teslin.* It also claimed record evidence supported the 0.20 ppm interim ECEL as substantially protecting workers from TCE inhalation exposures. But what EPA did not do is explain, despite a statutory obligation to do so, how manufacturers like PPG could comply with the interim limit and also continue operations. Given Section 6(g) permits a level of exposure that does not entirely eliminate unreasonable risk, it failed to weigh these factors and find a workable middle ground.

Consequently, EPA has effectively banned TCE as of September 2025 and therefore failed to achieve the purposes of Section 6(g). Indeed, PPG demonstrated it would be impossible to meet the 0.20 ppm limit with high levels of respirator use. PPG will have no choice but to cease all *Teslin* production by the compliance date. As such, EPA was obligated to consider a more feasible interim ECEL. For instance, PPG suggested 5 ppm, while others proposed 6 ppm. 89 Fed. Reg. at 102580. But there was no discussion why those limits would fail to represent an appropriate accommodation under Section 6(g).

The Interim ECEL Does Not Meet TSCA's Scientific Standards

When promulgating a risk management rule, EPA must base any controls on the "best available science" and the "weight of the scientific evidence." 15 U.S.C. §§2625(h)-(i). In the TCE Rule, EPA claimed the 0.20 ppm interim ECEL was justified by data presented in the risk evaluation used for the

proposed 0.0011 ppm limit. 89 Fed. Reg. 102580. However, PPG submitted comments, including three expert reports, showing the proposed ECEL did not meet TSCA's standards.

In particular, the 0.0011 ppm level, which was intended to protect against fetal cardiac defects, was based on a single study (Johnson, et al.). But this study was contradicted by numerous well-conducted studies showing no increase in such defects attributable to TCE exposures. EPA also failed to follow recommendations of the EPA Scientific Advisory Committee on Chemicals to consider a high-quality inhalation study showing TCE exposures as high as 600 ppm did not cause congenital heart defects. Indeed, EPA's interim ECEL is far below levels at which health effects have been observed and, in fact, are comparable to background residential indoor air concentrations.

To the extent the interim ECEL is based on Johnson, et al., it neither constitutes substantial evidence nor satisfies TSCA's scientific principles.

PPG Will Suffer Irreparable Harm

PPG will be irreparably harmed if the final TCE rule is not stayed. A petitioner suffers irreparable harm where, as here, the respondent has not waived sovereign immunity for money damages. *Cigar Ass'n of Am. v. City of Philadelphia*, 2021 WL 5505406, at *5 (3d Cir. 2021); *see Adams v. Freedom Forge Corp.*, 204 F.3d 475, 484-85 (3d Cir. 2000) ("The irreparable harm requirement is met if a plaintiff demonstrates a significant risk that he or she will experience harm that cannot adequately be compensated after the fact by money damages.").

Moreover, "[g]rounds for irreparable injury include loss of control of reputation, loss of trade, and loss of good will." *Guardian Life Ins. Co. of Am. v. Estate of Cerniglia*, 446 Fed. App'x. 453, 456 (3d Cir. 2011) (quoting *Kos Pharm., Inc. v. Andrx Corp.*, 359 F.3d 700, 726 (3d Cir. 2004)). Further, the "impending loss of key employees, as well as a decline in its customer base, sufficiently demonstrates the likelihood of irreparable harm." *Id.* at 456.

PPG will be forced to cease all *Teslin* operations as it would be completely infeasible to rely on full-time use of PPE respirators to satisfy the 0.20 ppm limit. Moreover, shutting down the *Teslin* production process will lead to substantial damages. PPG would lay off up to 100 employees, giving them notice in June 2025, and paying out severance packages. It would incur about $1 million to idle, decontaminate, and/or scrap manufacturing equipment. PPG would forego annual revenues in the triple digit millions of dollars, not to mention the hundreds of millions of dollars in economic impact that would be lost. And in addition to losing all of its *Teslin* customers, PPG would lose the good will and reputation it has built-up over many years as the world's only producer of the *Teslin* substrate.

PPG is also making every effort to comply with the TCE rule in the event EPA revisits the interim ECEL and eventually sets an achievable level. For instance, PPG has already retained a consultant to conduct a comprehensive review of the *Teslin* manufacturing process to identify further

administrative and engineering controls to lower TCE exposure levels from its current internal limit of 5 ppm. The consulting fees alone will total tens of thousands of dollars in the coming months. Further, over the next nine months (prior to the September 15, 2025 compliance date), PPG anticipates implementing some initial measures, like additional local ventilation, that could cost up to $800,000 and reduce exposures to the 4.0 ppm-4.5 ppm range. Going forward, more extensive modifications, such as enclosing the entire extraction process, would cost tens of millions of dollars, take up to 3-5 years to complete, and potentially reduce exposures to around 1.5 ppm-2.0 ppm.

The Public Interest and Balance of Harms Favor PPG

Granting an adminstrative stay would clearly be in the public interest. In granting the Section 6(g) exemption, EPA found *Teslin* is "critical" and "essential" to numerous products, including passports/e-passports and other credentials that protect national and global security, as well as commercial items like blood bags and chemical drums. Absent a stay, the Barberton facility would halt all *Teslin* production, and PPG's customers would be forced to develop and/or procure alternatives that may be less reliable and secure.

Moreover, during any stay, workers at the Barberton plant would still be protected by PPG's substantial industrial hygiene program. PPG's internal TCE exposure limits are orders of magnitude lower than current regulatory levels. Employees must wear respirators during short-term tasks with the potential for elevated TCE exposures. The facility is continuously monitored and alarmed to ensure levels do not exceed internal limits. And the extractor/dryer/oven area where TCE is used is fully enclosed and negatively pressurized so TCE vapors are drawn away from employees and filtered.

Finally, it is never in the public interest for a federal agency to violate the law. *R.J. Reynolds Vapor Co. v. FDA*, 65 F.4th 182, 191-92 (5th Cir. 2023). Here, EPA thoroughly defeated the purpose of PPG's 15-year Section 6(g) exemption by essentially banning the use of TCE now.

CONCLUSION

We request that EPA immediately stay the effective date of the TCE Rule because "justice so requires."[6]

[6] 5 U.S.C. §705.

Respectfully submitted,

Eric P. Gotting
Counsel for PPG Industries, Inc.