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By First-Class Mail and Email

Acting Administrator James Payne
U.S. Environmental Protection Agency
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, NW
Mail Code 1101A
Washington, DC 20460

Re: Renewed Request for Administrative Stay Pending Judicial Review of
Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA),
89 Fed. Reg. 102,568 (Dec. 17, 2024)

Dear Acting Administrator Payne,

I write on behalf of the Alliance for a Strong U.S. Battery Sector to renew our petition for an immediate stay of the effective date and of certain provisions of the above-captioned rule (the “Rule”) pending judicial review, pursuant to 5 U.S.C. § 705. The Alliance is a national trade association that seeks to strengthen national security and improve America’s energy independence by ensuring a robust domestic battery and battery component manufacturing sector. The Alliance is concerned that this Rule jeopardizes the viability of domestic battery-separator manufacturing by imposing unnecessary and excessive regulatory burdens that are wholly untethered from the record and sound science and that go beyond even the intrusive regulations imposed by the European Union. This regulatory overreach threatens to cause businesses to shut down, countless high-paying jobs to be lost, and nearly \$100 billion in harm to the battery industry and broader U.S. economy.

The Rule bans the chemical trichloroethylene (TCE) under the Toxic Substances Control Act (TSCA), which authorizes EPA “to regulate chemical substances... which present an unreasonable risk of injury to health or the environment.” 15 U.S.C. § 2601(b)(2). Battery separators are an essential component of the lead-acid batteries found in virtually all automobiles and much critical infrastructure and military hardware. Because there is no feasible alternative to TCE in manufacturing battery separators, EPA has determined that banning this use would “significantly disrupt national security and critical infrastructure.” 88 Fed. Reg. 74,712, 74,746 (Oct. 31, 2023). Accordingly, EPA has purported to grant U.S. battery-separator manufacturers a 20-year exemption from TCE’s ban. 89 Fed. Reg. at 102,572.

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That exemption, however, imposes such onerous conditions on battery separators that it effectively functions as a total ban. To continue using TCE, battery-separator manufacturers must comply with EPA's "Workplace Chemical Protection Program" (WCPP). That would require manufacturers to reduce TCE exposure levels to 0.2 parts per million (ppm)—a level more than 20 times below what is achievable using state-of-the-art engineering and administrative controls—or else equip exposed workers in stringent respiratory personal protective equipment (PPE) that EPA admits creates health and safety hazards and that the record demonstrates cannot feasibly be worn all day by employees in these manufacturing settings.

In imposing these conditions, EPA acted arbitrarily and capriciously. The Alliance therefore petitioned EPA to stay the Rule on January 10, 2025 and, three days later, moved in the U.S. Court of Appeals for the Fifth Circuit to stay certain provisions of the Rule pending review and to administratively stay the Rule's effective date. *See Alliance for a Strong U.S. Battery Sector v. EPA*, No. 25-60010 (5th Cir.), ECF No. 18. That same day, the Fifth Circuit entered a temporary administrative stay of the effective date of the Rule. *Id.* ECF No. 31 (Jan. 13, 2025). On January 14, pursuant to 28 U.S.C. § 2112(a)(3), the U.S. Judicial Panel on Multidistrict Litigation designated the U.S. Court of Appeals for the Third Circuit to hear the twelve consolidated petitions challenging the Rule. The Fifth Circuit transferred the proceedings the following day. ECF No. 36. On January 16, the Third Circuit issued an order confirming that the Fifth Circuit's stay remains in place until further order of the Court. *See Order, Alliance for a Strong U.S. Battery Sector v. EPA*, No. 25-1083 (3d Cir.), ECF No. 11 (Jan. 16, 2025).¹ That same day, EPA denied the Alliance's stay request. *See* Letter from Michal I. Freedhoff, Ph.D., Assistant Administrator of the Office of Chemical Safety and Pollution Prevention, EPA to Daniel J. Feith, Sidley Austin, Counsel for Alliance (Jan. 16, 2025) ("Denial Letter").

Given the Alliance's likelihood of success on the merits, a stay of the Rule's effective date and of the provisions imposing the WCPP on battery-separator manufacturers pending judicial review remains necessary to prevent irreparable harm and to protect the public interest. The Agency has ample authority to grant such a stay under 5 U.S.C. § 705 because the Third Circuit's judicial stay of the Rule's effective date means that the Rule has not yet taken effect.

The Agency also has ample justification to grant a stay under § 705. The APA empowers an agency to stay a Rule's effective date when "justice so requires." 5 U.S.C. § 705. It is particularly appropriate to stay a Rule under § 705 "to maintain the status quo in order to allow judicial review of the underlying regulation to proceed in a 'just' manner." *Bauer v. DeVos*, 325 F. Supp. 3d 74, 106–07 (D.D.C. 2018). As described below and in the Alliance's stay motion and supporting declarations in the Fifth Circuit, which the Alliance is attaching and incorporates by reference here, the TCE Rule meets this standard because (1) the Alliance is likely to succeed on

¹ The Third Circuit's order also directed any petitioners wishing to seek stays to file stay motions by January 21, 2025, and directed EPA to respond to any stay motions by January 28, 2025.

the merits of its arbitrary and capriciousness challenge and (2) a stay is necessary to preserve the status quo and protect battery-separator manufacturers and others from the irreparable harm of the Rule.

A. The TCE Rule Is Arbitrary and Capricious.

As an initial matter, the Alliance is likely to succeed on the merits because the Rule's requirement that battery-separator manufacturers comply with the infeasible ECEL and WCPP is arbitrary and capricious. The Administrative Procedure Act requires courts to "hold unlawful and set aside agency action[s]" that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); *see* 15 U.S.C. § 2618(c). EPA's Rule is arbitrary and capricious in several ways.

First, the Rule's WCPP is infeasible for battery-separator manufacturers, and EPA has offered no evidence or explanation showing otherwise. When EPA determines that an exemption from a TSCA risk management rule is warranted, EPA may impose only those conditions "necessary to protect health and the environment *while achieving the purposes of the exemption*." 15 U.S.C. § 2605(g)(4) (emphasis added). Thus, EPA must ensure that any conditions it imposes are feasible, lest the conditions make "achieving the purposes of the exemption" impossible. 89 Fed. Reg. at 102,581. Accordingly, in the Rule, EPA repeatedly stated that its WCPP is "feasible." 89 Fed. Reg. at 102,580.

EPA's assertion that the WCPP is feasible runs counter to the evidence in the record and to EPA's clear findings that it is *not feasible* for workers to work extensively in respiratory PPE. In the Rule, EPA specifically explained it had declined to adopt the proposed ECEL and corresponding PPE requirements because of "significant challenges" posed by "extensive respiratory PPE use in an occupational setting." 89 Fed. Reg. at 102,580. EPA acknowledged that respiratory PPE "can represent an occupational hazard on its own," causing "communication problems, vision problems, worker fatigue, and reduced work efficiency." *Id.* at 102,581.

The record makes clear that PAPRs present many of the same issues as the SCBAs and supplied-air respirators required under the proposed rule, particularly when worn at all times. Both types of respirators interfere with vision and communication by muffling voices and hiding essential visual cues. Both are known to inhibit breathing and increase the likelihood of worker fatigue, dizziness, overheating, and anxiety. And both pose maneuverability challenges as wearers cannot navigate many tight spaces or perform tasks that require flexibility while wearing these bulky devices. *See, e.g.,* ENTEK Comment at 23–25; *see also* Decl. of David Dodge ¶¶ 41–55² (detailing the similar risks posed by PAPRs and SCBAs).

² All citations to declarations are to declarations submitted in connection with the Alliance's stay motion in the Fifth Circuit.

EPA does not offer, and the record does not contain, any contrary information. It is unlawful under TSCA for EPA to impose infeasible conditions that will prevent battery-separator manufacturers from “achieving the purposes of the[ir] exemption.” 15 U.S.C. § 2605(g)(4). Moreover, EPA does not explain why it considers PAPRs feasible when their use presents the same concerns that led the agency to deem SCBA and supplied-air respirators infeasible. Such fundamental inconsistency within a rule is a hallmark of arbitrary and capricious agency action.

In the written denial of the Alliance’s first petition for stay, EPA tries to distinguish PAPRs from SCBAs by citing the fact that ENTEK employees use a “full facepiece breathing apparatus” for certain tasks. Denial Letter at 5. But this argument is flawed several times over. First, the respirators ENTEK generally uses are a level below PAPRs and do not pose many of the difficulties associated with PAPRs. *See* ENTEK Comment at 43 & Ex. D at 3. Second, and more importantly, ENTEK’s employees do not wear those respirators all day, every day, as the Rule would require. The fact that the Rule would require full-time use of PAPRs contributes significantly to its infeasibility. *See* Decl. of Bill Beadie ¶ 23 (explaining that full-time use of PAPRs is infeasible); Dodge Decl. ¶¶ 41–53. Finally, EPA’s response ignores the fundamental flaw in EPA’s reasoning: The record evidence uniformly demonstrates that PAPRs present the same concerns that led EPA to deem SCBAs to be infeasible. Indeed, the Denial Letter itself acknowledges that PAPRs “present a potential occupational hazard.” *Id.* at 5. EPA’s failure to explain why it considers PAPRs feasible when their use presents the same concerns that led the agency to deem SCBA infeasible is quintessentially arbitrary and capricious decisionmaking.

Further, EPA’s basic failure to explain *why* the WCPP is feasible is itself fatal. The agency offers no explanation of why the interim ECEL of 0.2 ppm and corresponding respiratory PPE requirements are feasible either in general or specifically for battery-separator manufacturers. EPA’s silence is especially striking given battery-separator manufacturers’ comments that they could not materially reduce plant-wide TCE exposure levels below current levels (which exceed 2 ppm) through administrative or engineering controls, making clear that workers would have to spend entire shifts in a powered air-purifying respirator (PAPR). *See* EPA, *Trichloroethylene (TCE); Revision to Toxic Substances Control Act (TSCA) Risk Determination: Response to Public Comments* (Nov. 20, 2024) at 91. This failure to consider a significant aspect of the rulemaking also renders the Rule unlawful.

EPA’s Denial Letter asserted that the respirator mandate is not infeasible because it applies only after regulated parties consider “engineering and administrative controls.” Denial Letter at 3. But battery-separator manufacturers submitted un rebutted evidence that they have already implemented state-of-the-art engineering and administrative controls and cannot further reduce TCE exposures by material amounts. *See, e.g.,* ENTEK Comment at 6, 17. Thus, they have no choice but to rely on full-shift respirator use to comply with the WCPP. For EPA to say

such reliance is not mandatory because other types of controls exist in theory blinks reality, contradicts the record, and is arbitrary.

Second, EPA did not consider viable alternative ECELS proposed by commenters. An agency may not simply acknowledge such alternatives but must consider them with “reasoned analysis.” *Wages & White Lion Investments, LLC v. FDA*, 16 F.4th 1130, 1139 (5th Cir. 2021). Here, although commenters proposed reasonable alternative ECELS, EPA offered no “reasoned analysis” for rejecting those alternatives in favor of the interim ECEL of 0.2 ppm. Multiple commenters, for example, proposed an ECEL of 6 ppm, which is the same limit allowed by European and British regulators implementing their analogues to TSCA. EPA, however, never addressed the 6 ppm alternative but rather focused exclusively on why 0.2 ppm is preferable to either of the proposed ECELS of 0.0011 ppm or 0.004 ppm. *See generally* 89 Fed. Reg. at 102,580–102,581. In its Denial Letter, EPA chronicled the alternatives it did consider. Denial at 5. Noticeably absent, however, is the 6 ppm limit validated by European regulators and proposed by multiple commenters.

Nor do EPA’s justifications for the 0.2 ppm ECEL indicate any basis for EPA’s choice. EPA claims it balanced several factors, including “significant feasibility challenges described by commenters,” *id.*, but EPA never explained why the optimum balance of these factors favors 0.2 ppm over 6 ppm (or any of the other proposed alternatives). This is particularly problematic because feasibility considerations strongly favor a higher ECEL. *See* ENTEK Comment at 19.

Third, the interim ECEL does not reflect the “best available science” and the “weight of the scientific evidence,” as TSCA requires. 15 U.S.C. § 2625(h)–(i). EPA did not even attempt to show that the interim ECEL of 0.2 ppm meets these standards, which alone is fatal to the Rule. To the extent the proposed ECEL of 0.0011 ppm drove EPA’s adoption of the interim ECEL, the proposed ECEL does not meet TSCA’s standards either. The proposed ECEL was based on a single study of rats, known as the “Johnson Study,” that found a link between fetal cardiac defects and TCE exposures above that level. 88 Fed. Reg. at 74,762. However, the Johnson Study was highly flawed and was not the best available science.

Commenters, including toxicologists, noted numerous problems with the Johnson Study, such as obvious failures to control key variables, failures to verify dosing, use of an unvalidated, non-standard technique to dissect rat hearts, and the failure of multiple studies to replicate its results. ENTEK Comment at 11-13; Chamber Comment at 10-13. Better-designed studies have repeatedly found no harmful health effects at 0.0011 ppm—or even at levels many orders of magnitude greater. ENTEK Comment 13–14. Thus, insofar as EPA derived the 0.2 ppm interim ECEL from the Johnson Study, the interim ECEL reflects bad science.

EPA’s response was to point to its prior risk evaluation of TCE. *See* RTC at 59; 89 Fed. Reg. at 102,617. EPA did the exact same in its Denial Letter. Denial at 5. But in that risk

evaluation, peer reviewers identified “several significant problems” in the Johnson Study’s design, noting that it “lacked credibility and should not be relied on,” and EPA acknowledged “the uncertainties associated with [the 0.0011] endpoint,” as compared to other endpoints. EPA, *Summary of External Peer Review and Public Comments*, 178. Thus, EPA’s only response to the criticism of the Johnson Study was to incorporate comments that recognized that the “best available science” did *not* support its ECEL.

Finally, the costs of the Rule outweigh its benefits. See 15 U.S.C. § 2605(c)(2)(A)(iv) (requiring EPA to consider the costs and benefits of risk management rules). A cost-benefit analysis “must identify benefits that ‘bear a rational relationship to the ... costs imposed.’” *Chamber of Com. of U.S. v. SEC*, 85 F.4th 760, 777 (5th Cir. 2023) (cleaned up). Here, the Rule’s purported benefits do not “bear a rational relationship” to its immense costs. In fact, even EPA’s grossly understated expected annual costs of the Rule (\$64.1 million) were nearly triple its expected annual benefits (\$22.9 million). 89 Fed. Reg. at 102,615; EPA, *Economic Analysis of the Regulation of Trichloroethylene Under TSCA Section 6(a)* (“EA”), 9-3. EPA’s use of “non-monetized benefits” to augment its total net benefits calculation “cannot. . . be used to effect a wholesale shift on the balance beam” towards a more favorable CBA. *Corrosion Proof Fittings v. E.P.A.*, 947 F.2d 1201, 1219 (5th Cir. 1991). The fact that EPA never explained why it never quantified the non-cancer effects, beyond lacking “sufficient information,” further precludes the agency from relying on them. See *id.*

This imbalance was made worse by EPA’s decision to leave important *costs* unquantified. See *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1153 (D.C. Cir. 2011). EPA’s cost figure omits the costs of installing many administrative or engineering controls required by the ECEL, of the Rule’s recycling and disposal mandates, of reduced worker productivity from the respirator mandate, and of wage effects. EA at 7-104-110. The Denial Letter appears to acknowledge that the Rule’s costs do not justify its benefits, explaining that the driving consideration in the Rule was to “mitigate[e] the unreasonable risk posed by TCE” without regard to cost. Denial Letter at 6.

And because EPA mistakenly assumed the WCPP is feasible for battery-separator manufacturers, EPA also ignored downstream costs from facility closures on regional economies and on the critical battery supply chain. See EA at 7-108. Alliance member ENTEK International LLC, the leading battery-separator manufacturer in the United States, included with its comment letter an economic analysis demonstrating that shutting down domestic battery-separator manufacturing could cause a cumulative shortage of approximately 270 million lead-acid batteries over a five-year period and trigger a wave of disruptions to U.S. supply chains, with expected economic impacts of at least \$14 billion in the battery sector alone and total economic losses of at least \$98 billion. See *generally* ENTEK Comment Ex. A., Att. A.

B. The Rule will cause immediate and irreparable harm to battery-separator manufacturers and is against the public interest.

Absent a stay of the Rule (specifically 40 C.F.R. § 751.325(b)(5)(iii)–(iv)), battery-separator manufacturers will suffer immediate irreparable harm, including substantial and unrecoverable financial losses, danger to employees’ safety and well-being, and even the potential loss of their U.S. businesses.

In view of the deadlines in the Rule, battery-separator manufacturers will need to begin incurring compliance-related expenditures as soon as the Rule goes into effect. At the outset, they will need to hire engineers and industrial hygienists to assess what, if any, additional administrative or engineering controls are feasible at their facilities. ENTEK estimates this alone will cost approximately \$1 million. *See* Decl. of Larry Keith ¶¶ 29–30. If additional controls are feasible, manufacturers must expend considerable resources to design those systems, seek applicable local and state permits, purchase necessary materials, construct any physical infrastructure, and then implement those systems. Completing all of this by mid-December 2025, as required by the Rule, if even possible, will require manufacturers like ENTEK immediately to begin work and incur costs. *See id.*

Preparations for compliance with the respirator mandate must also start as soon as the Rule goes into effect. Businesses like ENTEK with hundreds of employees will need to immediately begin incurring costs to complete these tasks on time. Such costs include purchasing respirators, reconstructing portions of their facilities to store and sanitize the respirators and to improve employees’ ability to move safely around the facility while wearing obstructive gear. For ENTEK, these costs would exceed \$4.5 million, none of which would be recoverable. *See id.* ¶¶ 27–28, 31–33.

In its Denial Letter, EPA seemingly suggests that battery-separator manufacturers will not face immediate compliance costs because they “have been aware of this upcoming Rule for years and have already begun measures to implement a hierarchy of controls.” Denial Letter at 8. This argument is baffling in multiple respects. For one thing, it appears that EPA does not understand its own regulation. The Rule does not permit manufacturers simply to assert that the status quo is good enough. Instead, as soon as the Rule goes into effect, manufacturers must assess what, if any, additional controls are feasible, implement any such controls, and explain to EPA’s satisfaction why other controls were not feasible. *See* 89 Fed. Reg. at 102,628 (to be codified at 40 C.F.R. § 751.315(c)(1)–(2)). This argument also flatly contradicts the administrative record, and goes to the heart of what is arbitrary and capricious about this Rule. While it is true that battery-separator manufacturers ENTEK and Microporous have installed state-of-the-art engineering and administrative controls, the record is clear that even with those controls, they do not come anywhere near meeting the exposure limit prescribed by the Rule. *See* ENTEK Comment Ex. D at 13. The record thus demonstrates that manufacturers will not be able

to rely on existing controls and will need to implement respirator programs, with all the associated, immediate costs that entails.

The Rule will also cause irreparable harm to battery-separator manufacturers' workforces. To meet the interim ECEL, nearly all of these manufacturers' production and maintenance employees and contractors will need to wear PAPRs all day, every day, indefinitely. As described above, these respirators are burdensome, hazardous, and ultimately infeasible for full-time use. The unredacted version of the Alliance's Fifth Circuit stay motion details the serious risks the infeasibility of the WCPP poses to battery-separator manufacturers and the broader economy. *See* Keith Decl. ¶¶ 35–44, 46–48.

EPA's suggestion that the Alliance's members do not need a stay "because the manufacturers have sufficient leeway to request to amend, modify, or extend a Section 6(g) exemption" is unavailing. Denial Letter at 8. Once the Rule takes effect, EPA could modify the exemption only through the rulemaking process. *See* 15 U.S.C. § 2605(g)(3) (noting modifications are to be promulgated "by rule"). EPA would not be able to complete the notice and comment process before the unrecoverable compliance costs start piling up. A stay is necessary precisely so that EPA can reconsider modifications to the Rule *without* causing irreparable harm to battery-separator manufacturers.

Lastly, both the balance of harms and the public interest decisively favor a stay. By EPA's own account, the public has a strong interest in domestic production of battery separators, which are "important for national security applications or for other critical needs." 88 Fed. Reg. at 74,716. If not stayed, the Rule's WCPP requirements could shut down U.S. battery separator production. This will harm the \$23 billion domestic battery manufacturing industry, which depends on domestically produced separators; imperil tens of thousands of jobs; and undermine national security by making manufacturers of military vehicles dependent on foreign sources of a critical input. As EPA itself summed up, such a shutdown will "significantly disrupt national security and critical infrastructure." *Id.* at 74,746; *see generally* Decl. of Roger Miksad ¶¶ 2–11 (describing the importance of domestic battery-separator manufacturing to the economy and national security); Decl. of Christopher E. Pruitt ¶¶ 4–9 (explaining the importance of a reliable domestic supply of battery separators to East Penn Manufacturing Co., which manufactures lead-acid batteries at facilities in Pennsylvania and Iowa); Decl. of Jeramy Lemieux ¶¶ 5–11 (explaining the importance of a reliable domestic supply of battery separators to Clarios International Inc., a leading battery manufacturer).

EPA should thus immediately stay the Rule, including the effective date and all deadlines applicable to battery-separator manufacturers under the WCPP, pending judicial review. *See* 89 Fed. Reg. at 102,634 (to be codified at 40 C.F.R. § 751.325(b)(5)(iii)–(iv)).

Thank you for your consideration.

Respectfully submitted,

/s/ Daniel J. Feith

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