BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

In re: **Exemption for Use of Trichloroethylene by U.S. Battery-Separator Manufacturers**	EPA Docket No. _____

Alliance for a Strong U.S. Battery Sector and Microporous, LLC's Petition for Reconsideration of Exemption Conditions in the Final Trichloroethylene Ban

Pursuant to 15 U.S.C. § 2620(a) and 5 U.S.C. § 553(e), the Alliance for a Strong U.S. Battery Sector ("Alliance") and Microporous, LLC (collectively, "Petitioners") respectfully submit this petition for reconsideration of and revisions to the U.S. Environmental Protection Agency ("EPA" or "Agency") final rule, *Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA)*, 89 Fed. Reg. 102,568 (Dec. 17, 2024) ("Final Rule"). The Final Rule includes a TSCA Section 6(g) exemption authorizing TCE's continued use as a processing aid in the manufacturing of lead-acid battery separators. That lead-acid battery separator manufacturing exemption includes specific conditions,[1] detailed below, that are the subject of this petition.[2]

As a national trade association dedicated to strengthening national security and energy independence through a robust domestic battery manufacturing sector, the Alliance represents the interests of manufacturers of batteries and battery components. The Alliance and its members play an integral role in ensuring American energy dominance by providing domestically manufactured energy storage options. The Alliance's members include ENTEK International LLC ("ENTEK"), one of only two domestic manufacturers of lead-acid battery separators, which are an essential component of every lead-acid battery. ENTEK produces approximately 80 percent of the domestic lead-acid battery separator supply.

Microporous, LLC ("Microporous") is the Nation's only other manufacturer of lead-acid battery separators. Microporous is a global company headquartered in Piney Flats, Tennessee. Microporous owns and operates three well-invested, world-class manufacturing facilities in the U.S. and Europe: two in Piney Flats and one in Austria. The Microporous facilities in Tennessee were built in 1971 and 2020. Microporous's and ENTEK's lead-acid battery separators are fundamental components in the lead-acid batteries used for passenger vehicles, semi-trucks, school

[1] As of the filing date of this petition, these conditions have not taken effect due to administrative actions by EPA postponing their effective date at least until June 20, 2025. *See* Delay of Effective Date for 4 Final Regulations Published by the Environmental Protection Agency Between November 29, 2024, and December 31, 2024, 90 Fed. Reg. 8,254 (Jan. 28, 2025) (delaying effective date of Final Rule to March 21, 2025); Postponement of Effectiveness for Certain Provisions of Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 90 Fed. Reg. 14,415 (Apr. 2, 2025) (delaying effective date of all conditions applicable to TSCA Section 6(g) exemptions under Final Rule to June 20, 2025).

[2] *See* 40 C.F.R. § 751.325(b)(5).

buses, public transportation, ambulances, fire trucks, and military vehicles, as well as other hardware used for national defense and critical infrastructure.

Petitioners respectfully seek reconsideration of the interim existing chemical exposure limit ("Interim ECEL") and certain elements of the Workplace Chemical Protection Program ("WCPP") applicable to the TSCA Section 6(g) exemption in the Final Rule authorizing continued use of TCE to manufacture lead-acid battery separators. As EPA has recognized, 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 lead-acid battery separators, EPA determined that banning this use would "significantly disrupt national security and critical infrastructure."[3] Accordingly, in the Final Rule, EPA purported to grant U.S. battery-separator manufacturers a 20-year exemption from the TCE ban (the "Battery Separator Exemption").[4]

The Battery Separator Exemption, however, includes such onerous conditions on the continued use of TCE that it effectively functions as a total ban. To continue using TCE, battery-separator manufacturers must comply with the WCPP set forth in the Final Rule. Under the WCPP, manufacturers must either reduce TCE exposure levels to the Interim ECEL of 0.2 parts per million ("ppm")—a level roughly 30 times below what European regulators allow and what can be achieved using state-of-the-art engineering and administrative controls—or else equip exposed workers in respiratory personal protective equipment ("PPE") that EPA admits creates health and safety hazards and that the record demonstrates cannot feasibly be worn all day, every day by employees in these manufacturing settings. These infeasible requirements violate TSCA because they are not based on the best available science and, more fundamentally, because they bring about the very result the Battery Separator Exemption is meant to avoid: [redacted].

As the Alliance and Microporous have demonstrated in prior submissions to both EPA and the U.S. Court of Appeals for the Third Circuit, the infeasible, unscientific, self-defeating nature of the conditions on the Battery Separator Exemption renders the exemption arbitrary, capricious, and contrary to law.[5] Petitioners therefore urge EPA to reconsider applying to battery-separator

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[3] Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 74,712, 74,746 (Oct. 31, 2023); *see also* 89 Fed. Reg. at 102,586 (explaining that "restrictions on the production of battery separators could critically impact the United States battery manufacturing supply chain and impede the expansion of domestic battery production capacity").

[4] 89 Fed. Reg. at 102,571; *see* 40 C.F.R. §§ 751.305(b)(9), 751.325(b)(5).

[5] *See All. for a Strong U.S. Battery Sector v. EPA*, No. 25-1083, Dkt. 15 (3d Cir. Jan. 21, 2025) (motion for stay pending judicial review) (attached hereto as Exhibit 1); 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) (attached hereto as Exhibit 2). Petitioners incorporate by reference the arguments set forth in these documents. Petitioners also incorporate by reference the comment letters submitted by Microporous and Alliance member ENTEK International LLC in the rulemaking proceeding that resulted in the Final Rule, attached hereto as Exhibits 3 ("Microporous Comment Letter") and 4 ("ENTEK Comment Letter").

manufacturers the specific problematic features of the WCPP—namely, the 0.2 ppm interim ECEL and the corresponding respiratory PPE requirements.

As explained below, Petitioners request that EPA revise the Final Rule to change two conditions applicable to the exemption for battery-separator manufacturers, as follows:

- Increase the interim ECEL for battery separator manufacturers to 6 ppm, in line with the levels permitted by European and British regulators under the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals ("REACH") and UK-REACH, respectively; and

- Extend the length of the duration from 20 to 25 years to account for the time required to research, develop, test, and obtain approvals for any alternative to TCE in battery-separator manufacturing.

Through these narrow but important changes, EPA can ensure that the WCPP applicable to the Battery Separator Exemption "protect[s] health and the environment while achieving the purposes of the exemption" by allowing this domestic industry essential to national security and critical infrastructure to continue operating.[6,7]

I. Background

A. TCE's use in battery separator manufacturing

TCE is a solvent used in industrial and commercial applications, including to produce lead-acid battery separators. Battery separators are highly-engineered, microporous membranes that provide the necessary separation and facilitate the flow of ions between a battery's electrodes. Battery separators are critical to the functioning of lead-acid batteries. As EPA succinctly put it, "separators are fundamental components in batteries that provide the necessary separation between the internal anode and cathode components that make batteries work."[8] Battery separators are inside all lead-acid batteries, which in turn are in virtually all automobiles, trucks, and emergency vehicles, as well as in military equipment (*e.g.*, tanks and submarines) and other critical infrastructure (*e.g.*, transportation and security systems).[9] TCE, in turn, is essential to manufacturing lead-acid battery separators. It serves as a high-performance solvent capable of

[6] 15 U.S.C. § 2605(g)(4).

[7] If EPA grants this petition and initiates a proceeding to amend the Final Rule, Petitioners respectfully request that EPA also (i) move to hold the Alliance's and Microporous's lawsuits challenging the Final Rule in abeyance until the conclusion of that proceeding, and (ii) further postpone the effective date of the conditions applicable to the Battery Separator Exemption until the conclusion of that proceeding.

[8] 89 Fed. Reg. at 102,586.

[9] *See* 88 Fed. Reg. at 74,745.

extracting oil from the separator, producing the required pore structure. As EPA has recognized, no viable substitute for TCE exists for this purpose.[10]

B. TSCA risk management rules and exemptions

TSCA authorizes EPA "to regulate chemical substances . . . which present an unreasonable risk of injury to health or the environment."[11] Under TSCA, if EPA determines that a chemical presents unreasonable risks under its "conditions of use," the Agency must issue a "risk management" rule to address those risks.[12] Such a rule may include banning a chemical's use.[13] EPA must base any rule on the "best available science" and "the weight of the scientific evidence."[14]

Congress nevertheless sought to avoid risk management rules with unduly disruptive consequences. TSCA Section 6(g) authorizes EPA to exempt a particular condition of use if it is "critical or essential" and "no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure," or if "compliance with the [general rule] . . . would significantly disrupt the national economy, national security, or critical infrastructure."[15] Section 6(g) further directs EPA to "include conditions" on exemptions if EPA "determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption."[16] EPA must also consider "the reasonably ascertainable economic consequences" of risk management rules and weigh their costs and benefits.[17]

C. The Final Rule and Battery Separator Exemption

EPA promulgated the Final Rule in December 2024, banning TCE in "a staggered compliance timeline throughout the supply chain."[18] For battery separators, EPA found that there is no feasible alternative to TCE in manufacturing battery separators and that banning this use would "significantly disrupt the national economy, national security, or critical infrastructure."[19]

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[10] 89 Fed. Reg. at 102,587.

[11] 15 U.S.C. § 2601(b)(2).

[12] *Id.* § 2605(a).

[13] *Id.*

[14] *Id.* § 2625(h)–(i).

[15] *Id.* § 2605(g)(1)(A)–(B).

[16] *Id.* § 2605(g)(4).

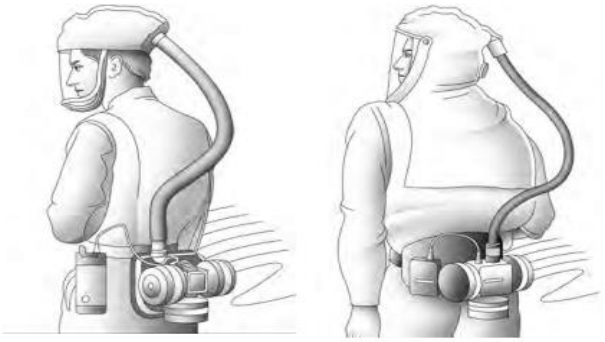
[17] *Id.* § 2605(c)(2)(A)–(C).

[18] 89 Fed. Reg. at 102,573.

[19] *Id.* at 102,572; *see also* 88 Fed. Reg. at 74,716 (recognizing that "battery separators are essential components of batteries that power vehicles and systems in the U.S. supply chain for multiple critical infrastructure sectors," including national defense, and "there are no feasible alternatives to TCE available" for manufacturing them).

Accordingly, EPA purported to grant U.S. battery-separator manufacturers a 20-year exemption from the TCE ban.[20]

As a condition of the exemption, however, the Final Rule requires battery-separator manufacturers to comply with a WCPP.[21] The WCPP requires manufacturers to reduce TCE exposure levels to 0.2 ppm—a level well below what is achievable using state-of-the-art engineering and administrative controls—or else equip exposed workers in constricting respiratory PPE. For example, for exposure levels of 2–10 ppm, workers must wear powered air-purifying respirators ("PAPRs") equipped with a helmet, hood, facepiece, or tight-fitting mask, depending on the precise exposure levels.[22] PAPRs use a battery-powered blower attached to the worker's back to force ambient air through air-purifying elements and to the worker, illustrated below:



PAPR[23]

II. Discussion

A. TSCA requires that exemptions be feasible and that risk management rules appropriately balance benefits and costs.

In TSCA, Congress recognized both the importance of regulations to address unreasonable health risks from toxic chemicals and the potential for such regulation to have burdensome and disruptive consequences. Under TSCA, if EPA determines that a chemical presents unreasonable risks of injury to health or the environment under its "conditions of use," EPA must issue a risk

[20] 89 Fed. Reg. at 102,571.

[21] *Id.* at 102,579.

[22] *Id.* at 102,605.

[23] This image is OSHA's official illustration of PAPRs. *See* OSHA, *Assigned Protection Factors for the Revised Respiratory Protection Standard*, at 5, OSHA 3352-02 2009, https://www.osha.gov/sites/default/files/publications/3352-APFrespirators.pdf.

management rule to address the risk.[24] Such a rule may include banning a chemical's use.[25] EPA must base any rule on the "best available science" and "the weight of the scientific evidence."[26]

At the same time, Congress directed EPA to avoid adopting risk management rules with unduly disruptive consequences. To begin with, EPA must consider "the reasonably ascertainable economic consequences" of its risk management rules and weigh their costs and benefits.[27] And, even where EPA finds a risk management rule to be justified *in general*, TSCA authorizes EPA to grant exemptions for a *particular* condition of use if that condition of use is "critical or essential" and "no technically and economically feasible safer alternative is available" or if "compliance with the [general rule] . . . would significantly disrupt the national economy, national security, or critical infrastructure."[28] In fashioning such exemptions, EPA must "include conditions" if it "determines the conditions are necessary to protect health and the environment *while achieving the purposes of the exemption*."[29] In other words, the conditions on an exemption cannot be so onerous that they defeat the exemption's purpose of allowing the condition of use to continue. They must, in short, be feasible.

Under this framework, EPA has rightly "recognize[d] that lead-acid . . . battery separators are essential components of batteries that power vehicles and systems in the U.S. supply chain for multiple critical infrastructure sectors within the national economy."[30] As EPA has explained, lead-acid batteries "are essential to serve critical infrastructure such as transportation systems, security systems, as well as to energize . . . the national defense base (*e.g.*, nuclear submarine batteries)."[31] Indeed, during the rulemaking process, several federal agencies warned EPA of "the potential adverse implications of banning or severely restricting use of TCE for battery separator production, as it would disrupt the supply chain and leave the U.S. reliant on foreign suppliers to the extent that they are available to support the national economy, national security, and critical infrastructure."[32] Several major battery manufacturers have likewise warned of the risks of depending on foreign sources—particularly sources in the People's Republic of China and other Foreign Entities of Concern—to supply such a vital component.[33]

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[24] 15 U.S.C. § 2605(a).

[25] *Id.*

[26] *Id.* § 2625(h)–(i).

[27] *Id.* § 2605(c)(2)(A)–(C).

[28] *Id.* § 2605(g)(1)(A)–(B).

[29] *Id.* § 2605(g)(4) (emphasis added).

[30] 88 Fed. Reg. at 74,716.

[31] *Id.* at 74,745.

[32] *Id.* at 74,744–45.

[33] *See, e.g.*, Decl. of Jeramy Lemieux, Vice President, Environmental Health and Safety, Clarios International Inc. ¶ 11. All cited declarations are included in the Alliance's motion for a stay pending judicial review filed in the Third Circuit, attached hereto as Exhibit 5.

EPA has also rightly recognized that alternatives to TCE "are not feasible for lead acid battery separator manufacturing."[34] Thus, a "restriction on TCE use for the production of battery separators would critically impact the U.S. battery manufacturing supply chain and impede the expansion of domestic battery production capacity."[35]

Based on these considerations, EPA soundly determined that an exemption from the TCE ban for lead-acid battery-separator manufacturers is warranted under TSCA § 6(g)(1)(B).[36] Nevertheless, as explained below, several conditions EPA attached to the exemption are so onerous and unworkable that the exemption exists in name only. In practice, the exemption is tantamount to a ban and would lead to the very harms EPA promulgated the exemption to avert.

B. EPA's conditions on the exemption for battery-separator manufacturers are infeasible and unlawful.

Under the Final Rule, the WCPP requires battery-separator manufacturers either to bring TCE exposure levels below an interim ECEL of 0.2 ppm using engineering and administrative controls, or to outfit workers exposed to levels above the interim ECEL in respiratory PPE.[37] As discussed in detail below, neither option is feasible. Battery-separator manufacturers cannot feasibly reduce exposures in their facilities to 0.2 ppm or anywhere close using engineering or administrative controls, nor can they feasibly require nearly all production and manufacturing workers to wear the called-for respiratory PPE all day, every day, indefinitely.

The Final Rule's application of the WCPP to battery-separator manufacturers should be reconsidered because it is arbitrary and capricious in numerous respects.[38] *First*, the record underlying the Final Rule demonstrates that the WCPP is infeasible for battery-separator manufacturers, and EPA has never even attempted to show otherwise. *Second*, the interim ECEL does not reflect the best available science or weight of the scientific evidence, as TSCA requires. And *third*, EPA failed to consider reasonable alternative ECELs. To address these concerns and prevent the WCPP from disrupting this critical industry, EPA should replace the unexplained, unscientific, and unworkable interim ECEL of 0.2 ppm applicable to battery-separator manufacturers with an interim ECEL of 6 ppm corresponding to the level of TCE exposure that is reasonably achievable and has been permitted by British and European regulators under REACH.

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[34] 89 Fed. Reg. at 102,587.

[35] 88 Fed. Reg. at 74,744; *accord* 89 Fed. Reg. at 102,586 (recognizing that "restrictions on the production of battery separators could critically impact the United States battery manufacturing supply chain and impede the expansion of domestic battery production capacity.").

[36] 15 U.S.C. § 2605(g)(1)(B); *see* 89 Fed. Reg. at 102,586–87.

[37] *See generally* 40 C.F.R. § 751.315.

[38] *See* 5 U.S.C. § 706(2)(A) (requiring courts to "hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law").

1. The WCPP is infeasible for battery-separator manufacturers, and EPA failed to justify its contrary conclusion.

In the Final Rule, EPA recognized that conditions on a TSCA § 6(g) exemption must permit "achieving the purposes of the exemption."[39] EPA therefore asserted that the key components of the WCPP, including the interim ECEL and corresponding respiratory PPE requirements, are "feasible."[40]

Yet EPA never justified that assertion. It provided no explanation of why the interim ECEL and corresponding respiratory PPE requirements are feasible either in general or specifically for battery-separator manufacturers. EPA's "unsupported" and "conclusory" assertions about the WCPP's feasibility[41] indicate that EPA "failed to consider an important aspect of the problem."[42] "Stating that a factor was considered . . . is not a substitute for considering it."[43] On this basis alone, reconsideration is warranted.

More fundamentally, the record demonstrates that, for battery-separator manufacturers, the WCPP's interim ECEL and respiratory PPE requirements are not feasible.[44] As to the interim ECEL, both ENTEK and Microporous—the only two domestic battery-separator manufacturers—have submitted unrebutted comments demonstrating that they have already implemented state-of-the-art engineering and administrative controls and cannot feasibly implement any further such controls to materially reduce their plant-wide TCE exposure levels, which exceed 2 ppm.[45] These comments made clear that for both manufacturers' production and maintenance workers, feasible TCE exposure levels would range from 2 to 10 ppm, a level at which the Final Rule would require such workers to wear PAPRs all day, every day.

Yet the record makes equally clear that outfitting workers in this manner is not feasible. PAPRs present a variety of feasibility concerns, especially when worn full time in the sort of conditions present at ENTEK's and Microporous's facilities, where workers need to maneuver in tight spaces among machinery and equipment, communicate amid high ambient noise, and work in high ambient heat.[46] As described at greater length in the industrial hygienist declaration attached to ENTEK's Comment Letter as Exhibit D, PAPRs interfere with vision and

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[39] 89 Fed. Reg. at 102,581 (quoting 15 U.S.C. § 2605(g)(4)).

[40] *E.g.*, *id.* at 102,580 (stating that the interim ECEL is "based on feasibility considerations" and that exempted users "can meet the interim ECEL with exposure controls that are feasible . . . over a full shift").

[41] *United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010).

[42] *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

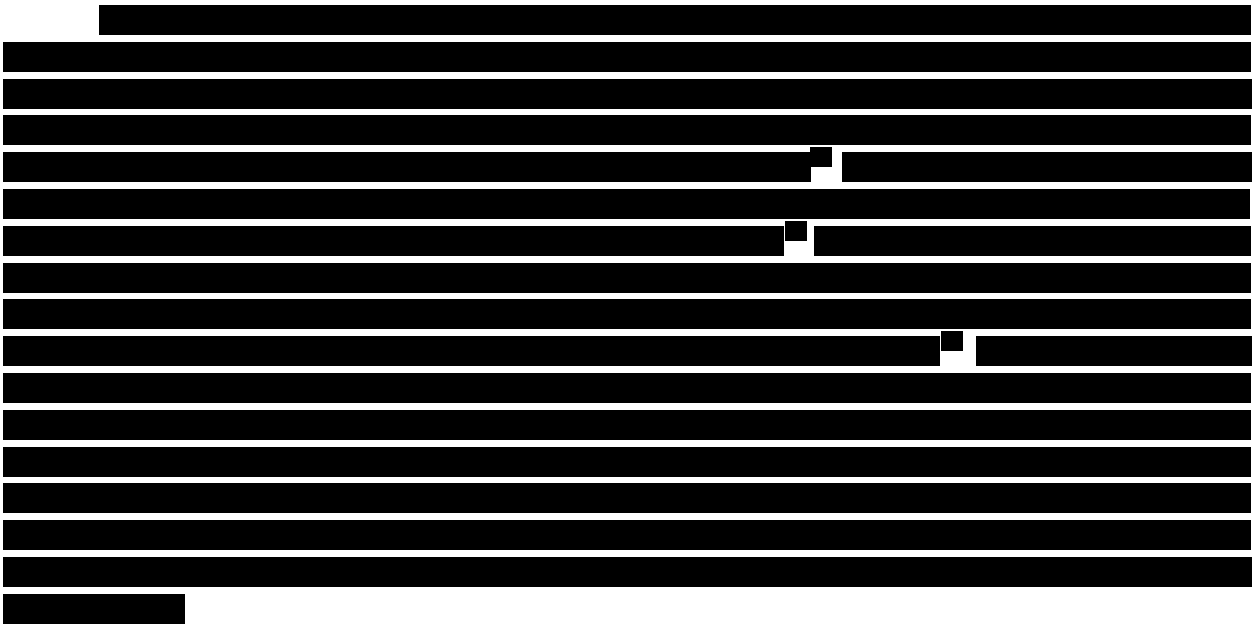
[43] *Getty v. Fed. Sav. & Loan Ins. Corp.*, 805 F.2d 1050, 1055 (D.C. Cir. 1986).

[44] *See State Farm*, 463 U.S. at 43 (explaining that a rule is arbitrary and capricious where there is no "rational connection between the facts found and the choice made").

[45] EPA-HQ-OPPT-2020-0642-0323 (ENTEK Comment) at 17–19; *id.* Ex. D at 13 (providing personal breathing zone monitoring data for production and maintenance personnel); EPA-HQ-OPPT-2020-0642-0300 (Microporous Comment) at 21–22.

[46] Decl. of David Dodge ¶ 55.

communication by muffling voices, impeding peripheral vision, and hiding essential visual cues.[47] They require wearers to exhale against high pressures, inhibiting breathing and risking fatigue, dizziness, and overheating.[48] They impair maneuverability because wearers must carry bulky power sources on their backs, making it difficult or unsafe to navigate tight spaces or perform tasks requiring flexibility.[49] They interfere "with feelings of well-being and cause anxieties (*e.g.*, claustrophobia) and discontent."[50] They can make "eating, drinking, face scratching, nose blowing, or eye rubbing" impossible "during working hours."[51] And they cannot be used by workers unable to pass fit tests or with certain medical or physical conditions, such as asthma or claustrophobia-related anxiety.[52] For these reasons, PAPRs are infeasible for systematic use among battery-separator manufacturing plant floor workers as an exposure control solution.[53]



Significantly, EPA cited similar concerns to those posed by PAPRs in jettisoning the proposed 0.0011 ppm ECEL (the "Proposed ECEL"), which would in practice have required

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[47] ENTEK Comment Letter Ex. D at 23–24.

[48] *Id.*

[49] *Id.*

[50] *Id.*

[51] ENTEK Comment Letter at 24.

[52] Decl. of Bill Beadie ¶ 18; Decl. of David Dodge ¶ 47.

[53] Decl. of David Dodge ¶ 7.

[54] *See* Decl. of Larry Keith ¶¶ 36–39; Decl. of Jeff Doyle ¶¶ 6–11; Decl. of David Pape ¶¶ 6–11.

[55] *See* Decl. of Larry Keith ¶¶ 40–41.

[56] *Id.* ¶ 40.

exempt workers to don full-facepiece self-contained breathing apparatus ("SCBA") or supplied-air respirators. As EPA explained in the Final Rule, such "extensive respiratory PPE use in an occupational setting" would pose "significant challenges."[57] Those challenges included "communication problems, vision problems, worker fatigue, and reduced work efficiency,"[58] as well as the fact that some "workers may not qualify for respirator use."[59]

Yet EPA did not (and could not) explain why it considered PAPRs feasible when their use presents the same health, safety, and workforce concerns that led the agency to deem SCBA and supplied-air respirators infeasible. Such "paradoxical action signals arbitrary and capricious agency action."[60] And, more fundamentally, it is unlawful under TSCA for EPA to impose an infeasible condition that will prevent battery-separator manufacturers from "achieving the purposes of the[ir] exemption."[61] These legal defects underscore the need to reconsider the WCPP applicable to the Battery Separator Exemption and adjust it so that it is feasible for battery-separator manufacturers.

2. The interim ECEL does not reflect the best available science or weight of the scientific evidence.

The interim ECEL also violates TSCA requirements designed to ensure that EPA's decisions reflect scientific rigor.

To begin with, TSCA requires EPA to base risk management decisions under § 2605 "on the weight of the scientific evidence."[62] Yet EPA did not even attempt to show that the interim ECEL of 0.2 ppm meets this standard. That alone is fatal and requires reconsideration.

Furthermore, to the extent the interim ECEL even has a putative scientific basis, that basis does not reflect the weight of scientific evidence. Although the Final Rule is somewhat unclear on this point, EPA appears to have set the interim ECEL as close as it believed was feasible to the Proposed ECEL of 0.0011 ppm, which EPA viewed as the proper "risk-based exposure limit,"[63]—*i.e.*, the limit that "would fully address the unreasonable risk."[64] If that was EPA's reasoning, it violates both TSCA's "weight of the scientific evidence" requirement and its separate requirement

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[57] 89 Fed. Reg. at 102,580.

[58] *Id.* at 102,581.

[59] EPA, *Trichloroethylene (TCE); Regulation Under the Toxic Substances Control Act (TSCA); Final Rule, Response to Public Comments*, at 91 (Nov. 20, 2024) (hereinafter "RTC"); *see also* 88 Fed. Reg. at 74,764–65 (acknowledging that "[i]ndividuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator.").

[60] *Sw. Elec. Power Co. v. EPA*, 920 F.3d 999, 1016 (5th Cir. 2019).

[61] 15 U.S.C. § 2605(g)(4).

[62] 15 U.S.C. § 2625(i).

[63] 89 Fed. Reg. at 102,580

[64] RTC 6.

to "use scientific information . . . consistent with the best available science."[65] EPA itself has acknowledged that the Proposed ECEL, which is based on a developmental endpoint of congenital heart defects, does not reflect "the best available science" or "weight of the scientific evidence."[66]

EPA based the Proposed ECEL on a single study of rats, known as the "Johnson Study," that reported an increased incidence of cardiac malformations in the developing fetuses of pregnant rats orally exposed to TCE in drinking water.[67] The Johnson Study, however, has been widely and deservedly criticized in the literature due to numerous defects.[68] These criticisms were described extensively in reports by ToxStrategies and Gradient, both submitted by ENTEK as attachments to its comments on the proposed rule and are summarized below.[69]

First, the Johnson Study reports results using pooled experimental data sets from different experiments conducted over a 6-year period—a methodology that introduces significant uncertainty in interpreting the study's results.[70] As ToxStrategies explained, the purpose of testing all animal groups at the same time is to minimize the impact that factors other than the test chemical will have on the results. In the Johnson Study, however, there is clear documentation in the methods that water sources used in the earlier and later TCE dose groups across the 6-year period were not the same, raising the likelihood that some animals were exposed to unknown drinking water contaminants. Furthermore, given the poor documentation of the studies,[71] it is likely that there were other environmental and experimental inconsistencies in the conduct of the Johnson lab experiments that went unreported that may have also influenced their results.[72]

Second, rather than testing control groups concurrently with the associated exposure groups, the Johnson Study inappropriately pooled negative control group data from the same set of different experiments spanning six years. Again, this approach makes the study's results susceptible to undocumented differences in the environmental conditions, which were likely magnified in the Johnson laboratory over the extensive testing period. The combination of the

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[65] 15 U.S.C. § 2625(h).

[66] EPA, Risk Evaluation for Trichloroethylene § 4.5.2.1 (Nov. 2020) ("2020 Risk Evaluation").

[67] *See id.* § 3.2.5.1.6, App'x F § F.1.1.

[68] *See, e.g.*, EPA, Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE): Response to Support Risk Evaluation of Trichloroethylene (TCE) at 178 (Nov. 2020) (noting that multiple SACC members stated that the Johnson Study "lacked credibility and should not be relied on by EPA," noting that the study "reported adverse cardiac effects at TCE exposure levels that were orders of magnitude lower than no-effect levels of other investigators").

[69] *See generally* ENTEK Comment Letter Ex. E, ToxStrategies Report; *id.* Ex. D, Gradient Report § 4.

[70] *Contra* 15 U.S.C. § 2625(h)(1), (4).

[71] *See* erratum by Johnson *et al.*, 2014.

[72] *See generally* ENTEK Comment Letter Ex. E, ToxStrategies Report § 5; *id.* Ex. D, Gradient Report § 4.1.

different, variously sized control groups from across the different experiments also artificially inflates the statistical power of the study.[73]

Third, the Johnson Study's conclusions are based on TCE exposure groups that were poorly spaced and lack a meaningful dose-response relationship. As detailed in the Gradient Report, in one phase of the Johnson Study, there was no statistical difference in the rate of cardiac abnormalities between two exposure groups, despite a 733-fold difference in the TCE exposure concentrations between the groups. Similarly, for rats dosed only during the pregnancy period, there was no statistical difference between one exposure group and the controls. And the pooled data overall lack an interpretable dose-response relationship.[74]

Fourth, the levels of TCE in the drinking water used in the Johnson Study were not analytically verified. TCE has a high propensity to volatilize into the air, which makes maintaining consistent target concentrations of TCE in drinking water solutions particularly challenging. Without analytical verification, accurate dose and exposure information cannot be obtained, significantly reducing the "degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information [in the Johnson Study] are documented."[75] The design of the Johnson Study exacerbated this problem because animals in the study were group-housed, with multiple dams drinking from the same bottle, further reducing the precision of dose calculations.[76]

Fifth, the Johnson Study's conclusions regarding congenital heart defects were based on a non-standard, unvalidated fetal heart dissection technique. As ToxStrategies explained, in all of the scientific literature, only one other peer-reviewed published study has employed the same dissection technique to evaluate chemical toxicology, and that group of investigators (which included Dr. Johnson) found no statistically significant increase in fetal heart malformations in rats exposed to TCE via drinking water.[77]

Finally, and most significantly, the Johnson Study's results have never been reproduced, despite multiple attempts. Two high-quality Good Laboratory Practice (GLP)-compliant rat oral exposure studies, Fisher *et al.*, 2001 and DeSesso *et al.*, 2019, were specifically designed to reproduce the findings of the Johnson Study. Neither found evidence of an association between TCE exposure and congenital heart defects.[78]

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[73] *See* ENTEK Comment Letter Ex. D, Gradient Report § 4.1. As the Gradient Report explains, the Johnson Study also deviated from standard practice in developmental toxicology studies by failing to provide information to appropriately analyze the incidence of congenital heart defects per litter compared to time-matched concurrent controls, or to match individual fetus data to a particular dam. *See id.*

[74] *See id.*

[75] 15 U.S.C. § 2625(h)(3).

[76] *See* ENTEK Comment Letter Ex. E, ToxStrategies Report § 5; *id.* Ex. D, Gradient Report § 4.1.

[77] *See* Fisher *et al.*, 2001.

[78] *See* ENTEK Comment Letter Ex. E, ToxStrategies Report § 5.

Indeed, among 13 developmental toxicology studies reported in the published literature that investigated TCE's potential effects on fetal development in pregnant animals, the Johnson Study is the *only* one to report an association between exposure to low levels of TCE and congenital heart defects. All other studies—including all inhalation studies, which EPA's Science Advisory Committee on Chemicals ("SACC") has stated represent the most relevant route of exposure for human occupational exposure[79]—demonstrate a lack of association between *in utero* TCE exposure and fetal cardiac defects.[80] Given TSCA's express requirement that EPA consider "the extent of independent verification" of the information on which it bases any scientific determinations related to risk management rules,[81] the failure of any studies—particularly those reflecting more relevant exposure routes—to replicate the Johnson Study's results is a major problem.

One inhalation study in particular, Carney *et al.*, 2006 (the "Carney Study"), highlights the degree to which the Johnson Study's results are unreliable. In the Carney Study, no fetal cardiac malformations were observed in animals in any of the dose groups, which were exposed to up to 600 ppm TCE—more than *500,000 times higher than the Proposed ECEL*—during gestation.[82] The SACC expressly recommended that "Trichloroethylene inhalation studies, notably that of Carney *et al.*, 2006, should receive greater attention."[83] Using the Risk of Bias tool developed by the National Toxicology Program's Office of Health Assessment and Translation, a systematic review by Wikoff *et al.*, 2018 similarly found that the inhalation studies overall had lower Risk of Bias than the oral studies and that the Johnson Study had the highest Risk of Bias of all animal studies due to the defects identified above.[84] Despite the SACC's recommendation, EPA did not reconsider the Carney Study in the final TCE Risk Evaluation's weight of evidence assessment, nor did it ever explain why it scored the Johnson and Carney Studies as having equal relevance.

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[79] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2020-4, Recommendation 70 (Mar. 24–27, 2020) (hereinafter "SACC Report") (observing that "[c]ardiac developmental anomalies have not been described in any of six [TCE] inhalation studies in rodents," and "data for the inhalation route would be preferred [to data from drinking-water studies] because inhalation exposures are most relevant to [the conditions of use].").

[80] *See* ENTEK Comment Letter Ex. E, ToxStrategies Report § 5; *id.* Ex. D, Gradient Report § 4.1.

[81] 15 U.S.C. § 2625(h)(5).

[82] *See* ENTEK Comment Letter Ex. E, ToxStrategies Report § 5; *see also* SACC Report at 19 ("The cardiac effects reported by Johnson et al., seen at trichloroethylene exposure levels that are orders of magnitude lower than no-effects levels of other studies, have not been seen even at much higher doses in other investigations of trichloroethylene where heart effects were also examined.").

[83] SACC Report at 19; *see also id.* Recommendation 70 ("Particular attention should be paid to the study by Carney et al. (2006) that reported no evidence of heart defects in progeny of dams exposed to as high as 600 ppm trichloroethylene vapor 6 hours/day, 7 days/week during gestation. . . . For this Evaluation, it appears data for the inhalation route would be preferred because inhalation exposures are most relevant to COUs. As a result, findings from studies based on the inhalation route of exposure offer less uncertainty on POD estimates.").

[84] *See* ENTEK Comment Letter Ex. E, ToxStrategies Report § 6.

None of the other evidence for the developmental endpoint adduced by EPA compensated for the Johnson Study's unreliability. EPA attempted to bolster its reliance on the Johnson Study with epidemiological studies, but as ToxStrategies and Gradient explained, those studies have critical limitations that preclude them from supporting conclusions regarding the association between TCE exposure in humans and the incidence of fetal heart defects. For example, none of the studies directly evaluated quantitative exposure to TCE, resulting in a high potential for exposure misclassification. Furthermore, the studies lack controls for important confounding factors, such as preexisting maternal illness, infections during pregnancy, alcohol and drug use, and existing chemical co-exposures.[85] Based on these limitations, SACC members commented that the studies provided only "weak" evidence for the association between TCE and congenital heart defects and urged EPA to "[r]econsider the scores assigned to the epidemiological evidence"[86]—a suggestion EPA wrongly declined to follow.

More recent studies further undercut reliance on those epidemiological studies. For example, in Liu *et al*., 2021, a multicenter case-control epidemiological study that directly evaluated TCE exposure in the study population by measuring urinary TCE concentrations, the authors concluded that maternal TCE exposure was not associated with the occurrence of fetal cardiac defects. Further, Urban *et al*., 2020, a recent systematic review integrating the human and animal evidence streams with available mechanistic data, concluded that "the totality of evidence does not support CHDs as a critical effect in TCE human health risk assessment."[87]

EPA also relied on mechanistic studies. But, as ToxStrategies detailed, there are substantial limitations to these studies, and the evidence base is quite limited when scrutinized through a systematic review process. Urban *et al.*, 2020 found that the majority of the TCE-CHD mechanistic studies fail to meet study quality standards for inclusion in risk assessment, with the most common issues being the inadequate reporting of test article and solution information, data analysis, and the failure to test for potential cytotoxicity at the tested TCE concentrations (which can result in false positives). Based on their systematic review of the mechanistic evidence base, Urban *et al.*, 2020 concluded that the available mechanistic data could not be developed into any coherent mechanistic or adverse outcome pathway ("AOP") that might provide biologically plausible support for the TCE-CHD hypothesis. The SACC offered a similar criticism, noting that EPA's risk evaluation "did not integrate and organize the mechanistic data into a coherent causal pathway from initial exposure to adverse outcome," and describing the mechanistic studies as of "limit[ed] . . . relevance."[88] These criticisms cast serious doubt on EPA's view that the mechanistic data are stronger and more reliable than either animal or human databases.[89]

For all these reasons, the Proposed ECEL did not reflect the best available science and should not have been used to derive the interim ECEL. Under each of the factors EPA must

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[85] *See id.*; ENTEK Comment Letter Ex. D, Gradient Report § 4.1.

[86] SACC Report Recommendation 71.

[87] *See* ENTEK Comment Letter Ex. D, Gradient Report § 4.1.

[88] SACC Report Recommendation 72.

[89] *See* 2020 Risk Evaluation App'x F § F.3.2 at tbl. Appx. F-13.

consider to ensure it is following the "best available science," the evidence underlying the Proposed ECEL falls short.[90] Crucially, since issuing the 2020 Risk Evaluation, EPA has never argued, let alone attempted to show, that the developmental endpoint reflects the best available science. It did not address the issue at all in the Revised Final Risk Evaluation, and in the Proposed Rule, its only justification for relying on that endpoint was that comments led to "concerns pertaining to political interference and scientific integrity, among other issues."[91] EPA has never acknowledged or addressed the well-documented scientific flaws and uncertainties that have been published in the peer-reviewed literature, nor has it addressed the SACC's concerns with the use of this endpoint as the basis of a quantitative risk assessment. And regardless of the vague concerns EPA identified, nothing has prevented EPA from attempting to show that the developmental endpoint reflects the best available science and is supported by the weight of scientific evidence. EPA's failure to do so is plainly contrary to TSCA's requirements. Thus, to the extent EPA based the interim ECEL on the Proposed ECEL, that reliance was improper and should be reconsidered.

3. EPA failed to consider reasonable alternative ECELs, including one supported by multiple comments and analogous regulatory schemes.

Finally, reconsideration of the interim ECEL as it applies to the Battery Separator Exemption is needed because EPA failed to consider reasonable alternatives to its approach. Although commenters proposed viable alternative ECELs, EPA offered no reasoned analysis for rejecting those alternatives in favor of the interim ECEL of 0.2 ppm.

In particular, some commenters, including battery-separator manufacturer ENTEK, proposed an ECEL of 6 ppm.[92] A 6 ppm ECEL is supported by a survey of occupational exposure limits from 28 national bodies worldwide that found that equivalent TCE limits ranged from 6 to 50 ppm.[93] Moreover, as ENTEK and other commenters attested, this ECEL is also feasible for battery-separator manufacturers and other exempted uses, and matches the exposure level permitted at ENTEK's European facilities under the European Union's analogue to TSCA, the REACH law and, after Brexit, under UK-REACH.[94]

Yet EPA never addressed that alternative. Rather, its justifications for the interim ECEL focused exclusively on why EPA preferred 0.2 ppm to the proposed ECELs of 0.0011 ppm or

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[90] *See* 15 U.S.C. § 2625(h)(1)–(5).

[91] 88 Fed. Reg. at 74,723.

[92] *See*, *e.g.*, ENTEK Comment Letter at 19; EPA-HQ-OPPT-2020-0642-0285 (Alliance for Chemical Distribution Comment) at 4.

[93] EPA-HQ-OPPT-2020-0642-0320 (American Chemistry Council Comment) at 6.

[94] *See*, *e,g.*, ENTEK Comment Letter at 19 (explaining that under REACH and UK-REACH, regulators can authorize use of an otherwise restricted or banned substance if "it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies"); EPA-HQ-OPPT-2020-0642-0272 (SAFECHEM Comment).

0.004 ppm.[95] EPA's unlawful failure to address the 6 ppm alternative underscores the need for reconsideration of the interim ECEL, at least as applied to the exemption for battery-separator manufacturers.[96]

4. EPA should adopt an interim ECEL of 6 ppm for the Battery Separator Exemption.

EPA should address the foregoing concerns by resetting the interim ECEL from 0.2 ppm to 6 ppm for purposes of the Battery Separator Exemption.

As discussed above, a 6 ppm exposure limit reflects the lowest end among current occupational exposure limits from 28 national bodies worldwide and is the exposure limit permitted of battery-separator manufacturers by European and British regulators under the REACH and UK-REACH regimes. The REACH and UK-REACH authorizations, in particular, ought to heavily inform EPA's approach here. Similar to the TSCA § 6(g) framework, REACH and UK-REACH authorize regulators to permit use of otherwise restricted or banned chemicals when the "socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies."[97] Using that authority, the European Chemical Agency ("ECHA") and the Agency for UK REACH have each determined that 6 ppm expressed as an 8-hour time-weighted average, and measured *after* taking into account the effectiveness of respiratory PPE, is the proper "benchmark for exposure" from TCE inhalation in ENTEK's battery-separator manufacturing facilities.[98] That 6 ppm benchmark reflects the agencies' judgment as to the "risk to human health" from increasing levels of exposure. With respect to the risks to human health, both agencies rely on an assessment performed by ECHA's Committee on Risk Assessment ("RAC").[99] After a thorough literature review, RAC determined that the cytotoxic risk of occupational exposures only starts to rise in any meaningful sense once the dose exceeds 6 ppm.[100] In more technical terms, 6 ppm marks the "knee" in the dose-response curve.

Crucially, an interim ECEL of 6 ppm is also feasible for battery-separator manufacturers. As the Agency for UK Reach has stated, a TCE exposure level of 6 ppm would indicate "that the

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[95] *See* 89 Fed. Reg. at 102,580–81.

[96] *See Int'l Ladies' Garment Workers Union v. Donovan*, 722 F.2d 795, 817 (D.C. Cir. 1983) (explaining that the "APA demands an adequate explanation when these alternatives are rejected.").

[97] Regulation (EC) No 1907/2006 of the European Parliament of the Council, Art. 60(4) ("REACH") (adopted as UK law through the European Union (Withdrawal) Act 2018).

[98] ECHA RAC, Opinion on an Application for Authorisation for Trichloroethylene as an extraction solvent for removal of process oil and formation of the porous structure in polyethylene based separators used in lead-acid batteries (2015) at 5, 9; Ex. I, UK REACH Opinion, at 4–5, 7, 65, 96.

[99] ECHA, Committee on Risk Assessment, Application for Authorisation: Establishing a Reference Dose Response Relationship for Carcinogenicity of Trichlorethylene. RAC/28/2014/07 rev 2 Final (April 10, 2014).

[100] *Id.* at 6.

TCE exposures are reduced to as low a level as is technically and practically possible."[101] Furthermore, given achievable exposure levels at their facilities, battery-separator manufacturers could comply with a 6 ppm interim ECEL without having to outfit workers in PAPRs full-time, thereby resolving another infeasible aspect of the current Final Rule.

Thus, an interim ECEL of 6 ppm would reflect the lowest exposure level that is both feasible and scientifically sound and that therefore meets the requirements of TSCA § 6(g).

C. EPA should extend the length of the exemption for battery-separator manufacturers to 25 years.

EPA should also reconsider and extend the duration of the exemption for battery-separator manufacturers. Despite a consensus among battery industry commenters that a 25-year exemption is necessary given the numerous hurdles to developing and deploying an alternative to TCE, the Final Rule limited the Battery Separator Exemption to just 20 years.[102] That 20-year term lacks support in the record and is insufficient from a technical perspective.

1. The record provides no support for a 20-year exemption.

EPA's decision to limit the exemption to only 20 years is not supported by the record. In the proposed rule, EPA acknowledged "aware[ness] that some U.S. battery separator manufacturers continue to rely on TCE to manufacture specialty separator materials of lead-acid and lithium batteries."[103] The agency discussed several industry comments it received (following the 2020 Risk Evaluation for TCE) that requested 25-year exemptions, but EPA proposed a 10-year exemption to "align with the EU and UK approaches."[104] The proposed rule sought public input on this issue.[105]

Public comments, including those submitted by Microporous and ENTEK, were overwhelmingly in favor of a 25-year exemption for TCE use in battery separator manufacturing.[106] And while some commenters urged EPA to adopt an exemption of longer than

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[101] *Id.* at 29, 72–73.

[102] 89 Fed. Reg. at 102,586.

[103] 88 Fed. Reg. at 74,744.

[104] *Id.* at 74,746.

[105] *Id.*

[106] The following comments expressly requested an exemption period of 25 years or more: EPA-HQ-OPPT-2020-0642-0299 (Battery Council International); EPA-HQ-OPPT-2020-0642-0262 (Surrette Battery Company Limited); EPA-HQ-OPPT-2020-0642-0236 (Superior Battery Mfg. Co., Inc.); EPA-HQ-OPPT-2020-0642-0260 (GS Yuasa Corporation); EPA-HQ-OPPT-2020-0642-0267 (Clarios International Inc.); EPA-HQ-OPPT-2020-0642-0265 (EnerSys Delaware Inc.); EPA-HQ-OPPT-2020-0642-0242 (East Penn Manufacturing Co.); EPA-HQ-OPPT-2020-0642-0302 (Stryten Energy LLC); EPA-HQ-OPPT-2020-0642-0289 (Alliance for Automotive Innovation); EPA-HQ-OPPT-2020-0642-0300 (Microporous, LLC); EPA-HQ-OPPT-2020-0642-0240 (Concorde Battery Corporation); EPA-HQ-OPPT-2020-0642-0323 (ENTEK).

10 years without specifying a duration,[107] and a very small number of commenters recommended exemptions of 10 years or less,[108] not a single public comment requested an exemption period of 20 years. The record provides no insight on how EPA arrived at a 20-year exemption. EPA never proposed it; no party requested it; and EPA's response to public comments and the Final Rule shed little light on its reasoning.

In fact, in EPA's response to public comments, the Agency stated that it would be instituting a *15*-year exemption and provided cursory explanation:

> Based on the comments, EPA believes that extending the TSCA section 6(g)(3) period for exemption to 15 years for the use of TCE in lead-acid battery separator manufacturing is reasonable to allow for more time for manufacturers to develop substitutes to TCE. However, EPA does not believe that a longer exemption is

[107] *See* EPA-HQ-OPPT-2020-0642-0296 (Halogenated Solvents Industry Alliance, Inc.; "EPA's proposed exemption for battery separator manufacturing is too short and imposes unreasonable and infeasible conditions—not required by TSCA—that function to ban or severely constrain this essential TCE use."); EPA-HQ-OPPT-2020-0642-0310 (The Trichloroethylene Panel of the American Chemistry Council; "ACC's TCE Panel is concerned that the 10-year phaseout does not provide sufficient time for the industry to identify and implement an alternative chemistry or process. We encourage EPA to allow as long a phaseout period as reasonably possible for this important application."); EPA-HQ-OPPT-2020-0642-0298 (The Rechargeable Battery Association; "PRBA requests that EPA extend the 10-year exemption proposed to a timeframe that aligns with the information in the rulemaking record from industry."); EPA-HQ-OPPT-2020-0642-0313 (National Association of Manufacturers; "However, the EPA's proposed exemption for battery separator manufacturing is too short and creates a de facto ban on an essential TCE use. A ten-year exemption is insufficient to adequately protect the nation's access to battery separators.").

[108] Notably, the few commenters who argued for an exemption of 10 years or less either based their arguments on circumstances that no longer exist or failed to offer any evidence that 10 years was adequate for battery-separator manufacturers to find a substitute for TCE. For example, the American Federation of Labor and Congress of Industrial Organizations argued for a 10-year exemption because one battery-separator manufacturer at the time did not use TCE. *See* EPA-HQ-OPPT-2020-0642-0286. As other public comments noted, however, that manufacturer used the solvent hexane, an explosive, volatile, highly flammable neuro- and reproductive toxin, and its process did not allow for reliable manufacturing of 9–12 micrometer separators. *See* Microporous Comment Letter at 8. Moreover, that manufacturer's domestic facility suffered a major fire in December 2023 and has been shut down. *See* John Kirkpatrick, *Daramic closes local manufacturing facility, union responds*, Owensboro Times (July 9, 2024), https://www.owensborotimes.com/news/2024/07/daramic-closes-owensboro-manufacturing-facility-local-union-responds/; Ryan Richardson, *No injuries in overnight fire at Daramic, officials say*, Owensboro Times (Dec. 30, 2023), https://www.owensborotimes.com/news/2023/12/no-injuries-in-overnight-fire-at-daramic-officials-say/. Other commenters provided no basis to conclude 10 years or less is adequate. *See* EPA-HQ-OPPT-2020-0642-0281 (Nuclear Energy Institute; providing no support for the Institute's position that ten years is an adequate exemption period, beyond an isolated reference to the Institute's "preliminary determination" on this issue); EPA-HQ-OPPT-2020-0642-0312 (Environmental Defense Fund; failing to tie any of arguments about the duration of the exemption to potential exposure from domestic battery-separator manufacturers specifically).

> reasonable at this time, given the need for the industry to transition away from TCE as quickly as possible.[109]

EPA offered no other explanation.

Then, upon publication of the Final Rule, EPA revealed that the exemption period would instead be 20 years.[110] EPA justified this decision by claiming that in comment letters and during meetings with the agency, industry members supposedly agreed that "20 years would be the minimum timeframe needed."[111] But the comment letters and meeting records EPA cited simply do not support this conclusion. In its public comment, Microporous specifically requested 25 years, while noting that "a reasonable range for the exemption is 22 to 30 years."[112] EPA's notes from a February 2024 meeting with Microporous state that the discussion "indicat[ed] that the shortest possible timeframe to transition away from TCE would be 15 years," but it is not the case that Microporous agreed this timeframe is adequate.[113] The American Chemistry Council's comment, which EPA also cited, did not even address the length of the lead-acid battery exemption.[114] And as for EPA's citation to a February 2024 meeting with ENTEK, EPA's own meeting notes indicate that "ENTEK repeated information in their public comment, including that the proposed exemption under TSCA section 6(g) for the use of TCE in manufacturing battery separators be lengthened to at least **25 years**."[115] Other than these inapposite citations, EPA offers no substantive discussion of the basis for its claim that industry agreed 20 years was sufficient.

2. A 25-year exemption is needed to have adequate time to research, develop, test, and obtain approvals for a TCE alternative in battery-separator manufacturing.

As numerous battery industry stakeholders explained in their comment letters, a 25-year exemption is necessary given the numerous hurdles battery-separator manufacturers must clear before they can shift lead-acid battery separator production away from TCE.

To begin with, a technically feasible alternative to TCE must be identified; today, despite more than a decade of research into more than a dozen potential alternatives, none exists.[116] Then, once that alternative is identified, it must undergo rigorous, multi-stage, multi-year testing. As

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[109] *See* EPA-HQ-OPPT-2020-0642-0726 (EPA Response to Public Comments) at 110.

[110] 89 Fed. Reg. at 102,586.

[111] *Id.*

[112] Microporous Comment Letter at 6–7.

[113] *See* EPA-HQ-OPPT-2020-0642-0688.

[114] *See* EPA-HQ-OPPT-2020-0642-0320.

[115] *See* EPA-HQ-OPPT-2020-0642-0687.

[116] *See* ENTEK Comment Letter at 34. As ENTEK noted in its comment letter, EPA could require manufacturers to provide the agency with periodic reports—for example, every five years—on the status of their efforts to identify and assess feasible alternatives to TCE. This way, EPA will have current information on ongoing alternatives analyses.

ENTEK explained in its comment letter, battery separator customers and end users require compliance with strict performance testing before any new separator is accepted. These testing processes are particularly stringent and time-consuming in national defense and other transportation-related applications, typically taking several years to complete.[117] This testing includes completion—and passage—of not only component-level production part approval processes ("PPAP") and testing of the separator itself, but also battery-level PPAP and testing, and in some applications also requires vehicle-level testing at the original equipment manufacturers.[118] Once testing is successfully completed, manufacturers must retrofit their facilities and/or build out new production lines to manufacture the battery separators at scale; alternative solvents cannot simply be dropped-in to existing equipment. This is a multi-year process as well. In addition, research to date[119] indicates that any new alternative substance would quite likely be a "new chemical" subject to the requirements of TSCA § 5, which would take even more time to receive approval.[120] Thus, even if a technically feasible alternative did become available in the next decade, it would take many years beyond that to confirm the technical, economic, and commercial feasibility of the non-TCE separators. Given that lengthy process, and given the need of battery-separator manufacturers to attract the financial capital to continue to invest in research and development of potential alternatives to TCE, a 25-year exemption is essential.

III. Conclusion

EPA has correctly recognized that an exemption for use of TCE as a processing aid in the manufacture of lead-acid battery separators is necessary to avoid significant disruptions to national security and critical infrastructure. Nevertheless, the Final Rule conditions the Battery Separator Exemption on an infeasible, unscientific, and unexplained interim ECEL that forces unworkable respiratory PPE requirements on employees, and limits the exemption to an unsupported, unrealistically short period of time. Accordingly, for the reasons set forth above, Petitioners respectfully ask that EPA reconsider these features of the Battery Separator Exemption, adjust the interim ECEL applicable to battery-separator manufacturers to 6 ppm, and extend the length of the exemption to 25 years, as set forth in Exhibit A.

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[117] *See* ENTEK Comment Letter Ex. B, Attach. C, ENTEK Letter to EPA re ENTEK Request for Section 6(g) Exemption Duration Supplement (Dec. 15, 2021) at 2–3; *see also* ENTEK Comment Letter Ex. A, Attach. A, eftec Report.

[118] *See* ENTEK Comment Letter Ex. A, Attach. A, eftec Report at 36–37.

[119] *See* ENTEK Comment Letter Ex. A, Att. A, eftec Report, Sec. 5, Appx. A–B.

[120] *See* 15 U.S.C. § 2604.

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