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Gabriela Rossner
Existing Chemicals Risk Management Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW, Washington DC 20460-0001

Re: Microporous, LLC Comments on EPA's TSCA Trichloroethylene Proposed Rule, Docket No. EPA-HQ-OPPT-2020-0642

Dear Ms. Rossner:

By way of this letter and enclosures, we submit on behalf of Microporous, LLC the following comments regarding the U.S. Environmental Protection Agency's ("EPA") October 31, 2023 proposed rule entitled "Trichloroethylene ["TCE"]; Regulation under the Toxic Substances Control Act ["TSCA"]," 88 Fed. Reg. 74,712 (Oct. 31, 2023) (the "Proposed Rule").

I. Inappropriately Short Comment Period.

At the outset, please note that these comments are Microporous' attempt, under an unnecessarily truncated comment period, to address some of EPA's sixty or so specific requests for comment on much of the Proposed Rule. (*See* 88 Fed. Reg. at 74,775-79) On November 8, 2023, Microporous submitted to EPA a request for a brief 45-day extension of the comment period through and including January 29, 2024. EPA summarily denied Microporous' request. Other commentors similarly sought extensions but all were denied. This limited comment period did not give Microporous a sufficient opportunity to develop necessary data and information to respond fully. Without sufficient time on an extremely complex and lengthy Proposed Rule, Microporous has done what it could to evaluate and comment on EPA's Proposed Rule. However, these comments do not represent Microporous' full analysis and comment. What is particularly troubling is that many of EPA's requests invite interested parties to undertake scientific and technical analyses and develop new data to address EPA's scientific framework fully (*see, e.g.*, 88 Fed. Reg. at 74,775-79), but then EPA does not give parties a sufficient opportunity to develop

that data. Microporous still believes that an extension of time is warranted and requests that EPA reopen the comment period so Microporous and others may evaluate the Proposed Rule fully.

II. Background of Microporous in the Battery Separator Industry.

TCE is the primary solvent used in the manufacture of battery separators. Battery separators are essential, irreplaceable components for all rechargeable batteries in the U.S. and around the world. Battery separators provide the necessary separation between the internal anode and cathode components that make all batteries work, and separators hold the electrolyte in the proper location. TCE is a necessary solvent for the manufacture of the majority of separator materials required to produce lead batteries. Further, many separator materials used in lithium-ion and other chemistries are manufactured utilizing processes that require TCE.

Microporous is one of the nation's largest manufacturers 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 Feistritz, Austria. The Microporous facilities in Tennessee were built in 1971 and 2020. The Tennessee facility that was built in 1971, underwent an expansion in 2000, and now employs 190 people.

Microporous' battery separators are critical and essential to the national economy and infrastructure, particularly the manufacturing, energy, transportation, and defense sectors. Microporous' battery separators are essential in gasoline and electric-powered commercial vehicles, emergency response and military vehicles, marine engines, nuclear power providers, and they are used in many other business sectors.

Microporous manufactures rubber and polyethylene ("PE") plate separators used by others in commercial wet cell batteries. The Piney Flats site comprises approximately 31.5 acres and is developed with one approximately 147,000-square-foot building (the "Eastern Building") and one approximately 36,000-square-foot building (the "Western Building). The Eastern Building contains multiple manufacturing lines in two distinct areas, the "rubber side" and the "PE side". The rubber side of the Eastern Building was built in 1971. The PE side of the Eastern Building was built in 2000 to facilitate Microporous' entry into the polyethylene separator market. The Western Building was constructed in 2020, and it is used for the manufacture of PE plate separators. TCE is used exclusively on the PE side of the process, in the southwestern portion of the Eastern Building (called "PE Building 1") and in the Western Building (called "PE Building 2").

III. Microporous' Use of TCE to Manufacture Battery Separators.

Microporous' separator manufacturing process requires a high-performance process solvent with unique properties. Microporous' lead-acid battery separators are made of silica, process oil, and polyethylene resin, a unique polymer that is extruded into sheet form using the process oil. The mixture is fed into an extruder that heats and pushes the molten material through

a die to generate a sheet. Much of the process oil used in the extrusion process must be removed from the separator sheets using a solvent. The sheet is run through a set of calendaring rollers that imprint a pattern, then the sheet enters an oil-extraction process that employs TCE to extract the oil, reducing the oil content within the sheet from approximately 60% - 65% to just 20% - 25%. The extracted oil and 99.7% of the TCE are captured and reused in the process. The oil-extraction process occurs inside an entirely enclosed structure within the process area that is in-line with the extruder. The enclosure is maintained under negative pressure, and makeup air enters through louvres in the ceiling of the enclosure. Air from inside the enclosure is vented to a series of carbon beds. Once the solvent has removed the precise amount of oil from the separator, the solvent is evaporated/removed from the separator to yield the required porosity to allow ion flow in the finished battery.

The process solvent Microporous uses, TCE, is essential to Microporous' separator manufacturing process. TCE has a unique combination of chemical properties that facilitate the controlled removal of process oil while allowing Microporous to recover and recycle previously-used TCE efficiently for reuse in the battery separator production processes in a manner that minimizes worker exposure while resulting in a product with the characteristics required by battery producers. TCE possesses the following properties critical to Microporous' use and reuse:

- TCE is non-flammable;
- TCE rapidly extracts process oil;
- TCE is compatible with the metallurgy of the process equipment;
- TCE is easily distilled from the process oil for recovery and reuse of each component;
- TCE has low water solubility and a higher density, thereby allowing for water capping of the holding vessels to prevent exposure (including vapor);
- TCE has a vapor pressure that allows for evaporation, yet can be condensed from a steam atmosphere using cooling coils (allowing for liquid phase separation and recycling of the TCE from a water-solvent mixture); and
- TCE in its vapor form can be efficiently recovered via Microporous' on-site carbon beds thereby minimizing emissions to atmosphere and maximizing solvent recovery.

As detailed below, there is no other chemical alternative suitable or available to replace TCE in Microporous' process at present, or on the horizon. Microporous has researched, developed, and implemented sophisticated control measures to minimize employee TCE exposure at its Piney Flats, Tennessee plant and to maximize recovery and reuse of TCE. These efforts and control measures are described more fully below.

IV. The Battery Separator Exemption and its Shortcomings.

Under TSCA Section 6(g)(1), EPA has the authority to exempt specific uses of TCE from EPA's risk management rules when the statutory criteria are met. EPA concluded that restricting certain conditions of use ("COUs") in certain industrial sectors in which there is no feasible

alternative would "disrupt the supply chain and leave the U.S. reliant on foreign suppliers to the extent they are available to support the national economy, national security, and critical infrastructure." (88 Fed. Reg. at 74,745) Battery separator manufacturing is one of those exempt industrial sectors.

Microporous agrees with and fully supports EPA's conclusions that banning Microporous' use of TCE at this time would "significantly disrupt national security and critical infrastructure," and that prohibiting TCE use for battery separator production would "disrupt national security priorities of reducing supply chain risks by building a robust domestic renewable power sector and transitioning to a clean energy-based economy." (88 Fed. Reg. at 74,746) Microporous appreciates that EPA has recognized the significant negative impact to national security, the national economy, and critical infrastructure of banning the use of TCE for battery separator manufacturing.

Further, Microporous fully supports EPA's proposal to issue a TSCA Section 6(g) exemption for industrial and commercial use of TCE as a processing aid for battery separator manufacturing, called "Industrial and Commercial Use of TCE as a Processing Aid for Battery Separator Manufacturing (Lead-Acid And Lithium Battery Separators)," set forth at proposed 40 C.F.R. § 751.317(c)(1) (the "Battery Separator Exemption" or "Exemption"). (*See* 88 Fed. Reg. at 74,744) EPA has met the statutory factors for issuing such an exemption pursuant to TSCA Section 6(g)(1)(B), 15 U.S.C. § 2605(g)(1)(B), concluding that the Battery Separator Exemption is necessary to preserve national security, the national economy, and critical infrastructure. As an aside, Microporous also believes its operations warrant an exemption under 15 U.S.C. § 2605(g)(1)(A) and (C).

While the Battery Separator Exemption is a good first step, it does not go nearly far enough, and, as a practical matter, really amounts to no exemption at all in the manner proposed. All that EPA purports to give in the Battery Separator Exemption itself, EPA takes away in the conditions on that Exemption. These comments address the following aspects of the Battery Separator Exemption: (1) the 10-year period of the Battery Separator Exemption; (2) the unachieveable existing chemical exposure limit ("ECEL") and unwieldy workplace chemical protection program ("WCPP"); (3) the ban on disposal of TCE in wastewater to publicly owned treatment works ("POTWs"), and (4) the apparent prohibition on trace TCE in finished battery separator products in commerce.

V. Executive Summary.

A. Microporous needs a 25-year exemption. The proposed 10-year term for the Battery Separator Exemption is unreasonable and unrealistic. Under TSCA, EPA must adopt "reasonable" durations for exemptions under Section 6(g). To be reasonable, an exemption must remain in place as long as necessary to fulfill the exemption's purposes. EPA recognizes that there are no feasible alternatives to TCE at present, and none are on the horizon as is evident based on Microporous' research and recent developments related to per- and polyfluorinated substances ("PFAS"). Furthermore, even if Microporous is able to identify an alternative in fewer than 10

years (which does not appear to be possible), 10 years is insufficient time to build the necessary production infrastructure and allow the alternative to undergo the strict performance testing required for commercial use for national defense and other transportation customers. Thus, Microporous again requests that EPA adopt Microporous' proposed 25-year term, which would ensure adequate time to test, build the required production infrastructure, and obtain any necessary regulatory approvals for any alternatives to TCE.

B. The ECEL and WCPP need to be reasonable, or the exemption operates as a practical ban. EPA may impose conditions on an exemption under Section 6(g), while still allowing the exempt party to achieve the purposes of the exemption. (*See* 15 U.S.C. § 2605(g)(4)) The Battery Separator Exemption falls well short. EPA's proposed ECEL is not based on good science and cannot be implemented as a practical matter. EPA has recognized the uncertainties in the science that purports to support the ECEL, and for good reason. Included with its comments, Microporous provides two supplemental toxicological reports that lay bare the flaws in EPA's scientific underpinning. The fact is that nearly all relevant published studies have found no harmful health effects at levels anywhere near the level of the proposed ECEL. Further, there are no feasible engineering or administrative controls that Microporous could implement to meet the proposed ECEL, which is well below exposure limits set by another long-established federal agency, the Occupational Safety and Health Administration ("OSHA"). These shortcomings also apply to EPA's primary alternative ECEL that attempts to go at the toxicological analysis a different way, but equally as flawed.

Because Microporous cannot meet the proposed ECEL or primary alternative ECEL, the only option to meet the proposed WCPP respirator plan would require Microporous to equip all plant workers with self-contained breathing apparatuses ("SCBAs") or supplied-air respirators at all times, despite EPA's acknowledgement that long-term use of such devices does not make sense, and may do more harm than good. The WCPP's monitoring requirements also do not make sense. EPA has recognized that it is not possible to measure TCE reliably at the levels of the proposed ECEL or primary alternative ECEL. Moreover, under the Proposed Rule, Microporous would need to conduct expensive personal breathing zone monitoring every three months. Compliance with such a requirements simply is not possible.

C. A ban on TCE in wastewater discharges is not appropriate and is contrary to the well-established regulatory framework for wastewater discharges under the Clean Water Act ("CWA"). The proposed ban on disposal of TCE in wastewater also is unworkable and unlawful. Microporous discharges process wastewater to a POTW pursuant to a wastewater discharge permit. The proposed wastewater disposal ban preempts Microporous' validly-issued permit, leaving Microporous no discharge alternative other than to transport its wastewater off-site for disposal and with it enormous environmental costs from the associated emissions and other risks to human health and the environment.

D. Finished battery separator products with incidental TCE are not banned TCE-containing articles. EPA also should clarify that finished battery separators with incidental amounts of TCE are not TCE-containing articles subject to any ban. The Proposed Rule could be read to ban the processing of TCE to incorporate it into an article such that it "becomes an integral component of an article distributed for industrial, commercial, or consumer use." (88 Fed. Reg. at 74,726) Trace amounts of TCE remain in finished battery separators but are not intentionally incorporated into it or integral to its function. Accordingly, EPA should make clear in the final rule that battery separators do not fall within the proposed ban. Alternatively, EPA should allow the Battery Separator Exemption to extend to trace levels of TCE retained within the finished products.

VI. Microporous Continues to Request a 25-Year Exemption, with an Extending Term, Authorizing Its Continued Use of TCE Until a Safer, Feasible Alternative Is Available.

TSCA Section 6(g) directs EPA to establish a "time limit" for each exemption, the duration of which is "to be determined ... as reasonable on a case-by-case basis." (15 U.S.C. § 2605(g)(3)) Based on the critical nature of Microporous' use and the current lack of any technically safer or economically feasible alternative, Microporous requested that EPA establish an initial 25-year period of exemption that renews for a progressive term until a safer and economically feasible TCE alternative is available for manufacturing battery separators.

While EPA's general concerns regarding the use of TCE in the U.S. certainly are understandable, the U.S. battery separator manufacturing industry, and Microporous specifically, have extensive safety and exposure control protocols in place to maximize plant safety for employees. The effectiveness of these protocols is supported by robust data. Accordingly, accounting for all available information related to the use of TCE in the manufacture of battery separators, its importance to the national economy and defense, the lack of viable alternatives, and the extensive workplace safety controls, Microporous initially requested an exemption under TSCA Section 6(g)(1) for the continued and limited use of TCE in the manufacture of battery separators for a period of not less than 25 years. Microporous renews this request for the reasons set forth in its prior comments dated August 10, 2022, that are included with these comments behind **Tab A**. Microporous also provides letters submitted to EPA by its customers underscoring the need for a 25-year exemption period and modifications to the proposed conditions for the 10-year exemption behind **Tab B.**

As discussed below, the term of the exemption is justified, as highlighted by very recent developments regarding PFAS. The battery separator industry, including Microporous, has been searching for a viable alternative to TCE since 2014. In those nine years, Microporous has invested more than $2 million in this research and still has not found a safer alternative solvent with the necessary properties for use in its battery separators. Microporous and others have evaluated more than a dozen potential alternatives without identifying one feasible alternative. Many of these candidates did not meet oil extraction needs, were not as easily recovered for re-use, were flammable, would require complete redesign and construction of manufacturing processes, or

would need to be blended with other chemicals that are being phased out or subject to restrictive regulation such as materials that EPA has categorized as PFAS. Most recently, Microporous was pursuing a potential alternative by a major supplier, 3M. The potential alternative contained raw materials that EPA has defined as PFAS. 3M recently announced that it is removing PFAS from all its products, thereby making this potential alternative unavailable.

It is a reasonable estimation that it will be another four to six years before a suitable alternative is identified. Once that alternative is identified, the period for trial use, customer vetting and approval, and construction of a new manufacturing plant is expected to last at least fifteen to twenty years. This means that a reasonable range for the exemption is 22 to 30 years.

The effects of the proposed rulemaking potentially prohibiting the use of TCE in the manufacture of battery separators are a significant concern. The continued use of TCE in the manufacture of battery separators aligns directly with President Biden's February 24, 2021 Executive Order to strengthen critical supply chains by revitalizing domestic manufacturing and research and development. Likewise, the erosion of the U.S. battery industry is contrary to the Administration's national security priorities – specifically, the reduction of supply chain risks by building a robust domestic renewable power sector, transitioning to a clean energy-based economy, growing a mature and competitive high-capacity battery industry, and leading global innovation and production in high-technology products through a strong domestic manufacturing base.

A. EPA has recognized that Microporous' TCE use qualifies for the Section 6(g)(1)(A) exemption because Microporous' TCE use is critical and essential, with no available technically and economically feasible safer alternative.

Under TSCA Section 6(g)(1)(A), EPA may exempt uses that are critical or essential that have no technically and economically feasible safer alternative available, taking into consideration hazard and exposure. Microporous' conditions of use meet these criteria and EPA has recognized this fact by granting the Battery Separator Exemption in the Proposed Rule. Microporous' critical and essential use of TCE bears repeating because it is integral to the 25-year exemption.

1. Microporous' TCE use is critical and essential.

As described above, Microporous' manufacture of battery separators is both a "critical" and "essential" use, and the only proven alternative presents an extreme explosive hazard. Every single heavy-duty vehicle and every mass-market passenger vehicle—including electric vehicles—relies on one or more lead acid batteries that are critical to the operation of the vehicle. Lead acid batteries also provide critical back-up emergency power to nearly all data centers, telecommunications centers, and other essential assets. Both lead acid and lithium-ion batteries require battery separators for operation. Of the battery separator market, 80% is supplied by batteries utilizing TCE. In fact, all battery separator manufacturing plants constructed over the past 40 years have been based on TCE technology, supporting the notion that this technology is the most effective and efficient process aid.

Absent battery separators manufactured with TCE, domestic battery manufacturers would have few, if any, means to obtain these critical components. Theoretically, they would have two options: (1) purchase domestic-made separators made without TCE (the current supply of which would likely support less than half of the U.S. battery production need); or (2) import foreign battery separators made with TCE, hexane (lead-acid), or methylene chloride (lithium).

With respect to the first option, only one domestic lead-acid battery separator manufacturer does not use TCE. That producer uses the solvent hexane, an explosive, volatile, highly flammable neuro- and reproductive toxin, the use of which also presents significant human health risks. (*See* **Tab A**) Other domestic producers would not be able to meet the displaced lead-acid battery separator demand if the use of TCE in battery separator manufacturing was prohibited. For lithium battery separators, only one domestic manufacturer does not use TCE, and its "dry process" separator manufacturing process does not allow it to produce reliably the 9-12 micrometer (um) separators of choice for electric vehicle applications.

Therefore, the only potential alternative is to import "wet process," non-TCE alternative separators that are produced using methylene chloride, a suspected carcinogen and cause of significant non-cancer health risks, for which EPA also is engaging in TSCA risk management rulemaking and which likely will be subject to future restrictions.[1]

With respect to the second option, forcing domestic battery manufacturers to rely on imported separators not only imposes significant new financial, logistical, and administrative costs on these entities, but also raises grave national security and energy independence concerns. Again, based on Microporous' projections, it is unlikely there is enough global supply to support the full demand of the domestic battery manufacturing sector.

2. No technically and economically feasible safer alternative to TCE is available for Microporous' use.

Microporous' ongoing research and development analyses have repeatedly found there is no alternative solvent currently available that is technically and economically feasible or safer than TCE in Microporous' process. Thus far, no such alternative solvent or solvent-free process exists, but Microporous continues to research alternatives to TCE and ways to transition to other solvents or to eliminate solvent use altogether.

Microporous uses TCE at its Piney Flats, Tennessee facility because of TCE's ability to solubilize contaminants such as oil, and because TCE is non-flammable with a high boiling point and therefore less of an explosion hazard. Hexane, the alternative solvent, has an extremely low flashpoint and tends to evaporate readily at room temperature, and chronic exposure to hexane can have detrimental effects on peripheral neurons. Therefore, Microporous considers hexane to be more of a safety hazard than TCE and therefore unsuitable for use as a regrettable TCE alternative.

[1] See EPA, Risk Evaluation for Methylene Chloride (Dichloromethane , DCM) CASRN: 75-09-2, § 5.2.1.30, at 753 (June 2020).

Microporous has been working with three suppliers, 3M, ExxonMobile, and MicroCare, to identify potential options such as trans-1,2-dichloroethene azeotrope alternatives that utilize PFAS and petroleum based alternatives. One supplier is conducting pilot scale studies to evaluate the effectiveness of its products further under facility-specific applications, such as steaming of the carbon beds and air stripping. However, thus far, no suitable TCE alternative has been identified. As noted above, the 3M product was a potential alternative but it contains what EPA has defined as PFAS compounds. 3M announced that it no longer will be offering PFAS-containing products, so this no longer is a viable alternative. Another potential candidate also contains PFAS. Finally, the petroleum candidate's extraction rate is many times lower than TCE.

Microporous' ongoing alternatives analyses also are evidenced in Microporous' submissions under Europe's analogue to TSCA, the Registration, Evaluation, Authorization and Restriction of Chemicals program ("REACH"). As part of Microporous' most recent REACH Authorization application seeking to authorize TCE use at Microporous' plant in Feistritz, Austria, Microporous prepared a robust alternatives analysis, a copy of which Microporous provided in its August 10, 2022 exemption request letter attached behind **Tab A**. The European Chemicals Agency has authorized Microporous' continued TCE use at the Austria plant until at least 2035, with an option for a 12-year extension of the authorization, for a total of 25 years.

Once Microporous identifies a suitable TCE alternative, it must initiate and complete the capital expenditure process to modify or replace the existing process equipment in the Piney Flats facility. The design, testing, procuring, installation, and start-up process would take five years or longer, depending on today's equipment availability.

Moreover, before utilizing a new separator product manufactured with an alternative to TCE, battery manufacturers must initiate and complete new product testing and approval processes. Industry testing requirements restrict and delay the practical availability of any alternative solvents by two to three years depending on the number of interations requiring evaluation. Before any alternative solvent could be brought online on a commercial scale, separators produced with the alternative solvent would need to be qualified through a formal customer approval process, including rigorous field testing and performance analysis. Over the past nine years, few alternative candidates have been identified, and to date, none have moved past a feasibility evaluation, through the qualification process, and to completion of the design and build of the new manufacturing process. Given this history, the identification of a suitable solvent through Microporous' research initiatives and the subsequent negotiated commercialization with a company such as 3M (absent PFAS) could take 15 years or more to complete.

In addition, once an alternative solvent has been commercialized, Microporous' battery manufacturer customers have indicated that battery separators produced under changed processes (*i.e.*, with a new solvent) would need to be tested internally for a period of approximately two years. After internal testing, the battery manufacturers' customers would then need to test each product individually, which likely would span another year for aftermarket applications and two years for original equipment manufacturer ("OEM") applications, after some waiting period to advance through the testing queue. That queue could extend up to two years because battery

manufacturers typically wait to approach their customers to test a new product until there are multiple, accumulated changes ready to be approved. Thus, any single change, such as a separator made with a new extraction solvent, could face a significant potential waiting period before the approval process could begin, as reflected in **Table 1** below (which assumes a single alternative is commercially available). In addition, battery manufacturing customers have informed Microporous that new products must be gradually phased into the market (as there would not be an instant substitute/swap) over a period of at least two to four years, as the product would have to establish its reputation on the market in terms of cost effectiveness and durability. In the end, the entire implementation process for a TCE alternative likely could take well more than 25 years to complete. EPA's proposed 10 year exemption period simply is not long enough.

Table 1

Action	Time Period
Evaluation of Reasonable Alternatives	4-6 Years
Sample Trials	2-3 Years
Lab Battery Test	2-4 Years
Customer Trials	2-3 Years
Equipment Sourcing/Engineering/Installation	3-5 Years
Scale up/Process Validation	2-3 Years
Customer Samples Validation	3-4 Years
End Use Customer Validation and PPAP	2-3 Years

3. Microporous' sophisticated control measures minimize TCE hazard and exposure.

Microporous understands the potential human health risks of TCE and has developed a robust suite of control measures to protect employees at its Piney Flats plant from the reported dangers of exposure to TCE, including sophisticated engineering controls, training, and personal protective equipment ("PPE"). Microporous installed a new line in 2021 using the newest, best-in-class technology to minimize employee exposure to TCE. The attached Ramboll Report (**Tab C**) describes Microporous' control measures.

Employees at the Piney Flats plant receive hazard communication training and an initial, one-time safety and environmental orientation training upon hiring. Many topics are covered during each orientation, including TCE usage and management. During the safety orientation, the presenter discusses the safety aspects of TCE, such as what PPE to wear and the health effects and

symptoms of short and long-term exposure. The environmental orientation covers aspects such as cleaning up spills, keeping TCE inside containment and out of soil and groundwater, and proper disposal practices. Additionally, employees within the facility who work with solvents of any kind, receive an additional training called *Working Safely with Solvents* that covers topics such as the general physical and health hazards of solvents as a group, general labeling, first aid, PPE, fire prevention, spill cleanup, environmental damage, and how to obtain additional information from safety data sheets.

Microporous institutes administrative controls to minimize employee exposure to TCE, including limiting the time personnel are allowed to enter spaces where they could be potentially exposed. Microporous also has a series of work instructions for various employee positions that identify PPE to be worn by employees, including chemical-resistant gloves, chemical-resistant aprons, goggles, and face shields if splash hazards exist. Employees working in the TCE process areas receive respiratory protection training and are assigned either a half-face or full-face air purifying respirator. Any entry inside the extraction enclosure requires the use of an air purifying respirator, regardless of the duration of the entry. Facility policy is to limit entry into the enclosure to 15 minutes at a time. Further, ambient air from inside the extraction enclosure is vented to the carbon beds to capture TCE vapor.

As a discharger to a POTW, Microporous already has invested in controls to minimize the amount of TCE discharged in its wastewater. TCE is used to remove process oil used in the extrusion process and the amount of residual oil allowed to remain is per client specifications and is quite low. The extracted oil and 99.7% of the TCE are captured and reused in the extraction process utilizing condensation and distillation units.[2] Once the solvent has removed the oil from the separator as per specification, the solvent is removed from the separator through a drying oven for TCE removal. *See id.* The TCE-laden air from the dryers is primarily handled by a condensation system that produces a TCE condensate. *See id.* Since the dryer is maintained under negative pressure, this process introduces ambient moisture from the humid air. *See id.* The air stream and remaining uncondensed TCE then are sent to the carbon beds that are re-activated using steam. *See id.* The comingled water/residual TCE then is sent through an air stripper before being sent to the boiler used for the steam as make-up water. *See id.*

Trace amounts of TCE in the wastewater are from the distillation process. *See id.* The distillation of oil and TCE from the extraction process leaves residual TCE in the oil. *See id.* When the oil is re-used in the process as part of the "mix" sent to the extruders, it contains residual TCE, some moisture and some low-boiling point oil components. *See id.* The gases from the heated extruder are captured in a vacuum system with emissions to an air stripper. *See id.* Even though the vast majority of the TCE is recovered, this process results in wastewater containing trace TCE concentrations. *See id.*

[2] *See* **Tab D**, Ramboll Report § 3.1.3.

A summary of Microporous' TCE exposure control efforts is included in the *Evaluation of the Use, Storage, and Management Practices Related to Trichloroethylene (TCE) at the Microporous, LLC Facility* report prepared by ERM, provided with Microporous' August 10, 2022 exemption request letter that is attached as **Tab A.**

EPA has been tasked with evaluating the "unreasonable risks of injury to health" associated with the use of TCE under TSCA. EPA has indicated that the risks from workplace exposure are a significant factor in its review of the continued use of TCE. Understanding this risk, Microporous focuses significant resources on minimizing workplace exposure and emissions of TCE. Microporous has implemented administrative and engineering controls to protect its workers from unnecessary exposure to TCE and minimize chemical losses from the manufacturing process. Microporous utilizes a closed loop process and regenerative carbon beds to minimize TCE losses and employee exposure points. Microporous limits the amount of time personnel spend in places of potential exposure and conducts exposure monitoring with lab analysis for time weighted average indicators. These employee protection measures are vitally important to Microporous. However, they become irrelevant when faced with EPA's proposed ECEL and WCPP requirements, discussed further below.

In the end, Microporous firmly believes that the Battery Separator Exemption must be for 25 years. Any shorter timeframe is a death-knell for the battery separator industry as it exists today, including Microporous.

B. Anything short of a 25-year exemption would significantly disrupt the national economy, national security, and critical infrastructure.

Under TSCA Section 6(g)(1)(B), EPA may exempt a specific condition of use if requiring compliance with the otherwise applicable risk management requirements for the use would significantly disrupt the national economy, national security, or critical infrastructure.

As discussed above, TCE is essential to Microporous' production process, and there is no safer technically and economically feasible alternative to TCE currently available for Microporous' use. The cost and time required to reconfigure the plant to replace TCE with another solvent would force, at minimum, an indefinite plant closure, and more likely, a complete shutdown. In short, any ban or substantive restriction on Microporous' TCE use would force the PE portion of the Piney Flats, Tennessee plant to cease operations**.**

Further, nearly the entire U.S. economy is dependent on lead acid and lithium-ion batteries manufactured using TCE, so prohibiting its use in the manufacture of battery separators would "significantly disrupt the national economy, national security, or critical infrastructure." Our national defense, transportation, and communication sectors, among many others, are dependent on battery separators manufactured with TCE (at least 80%). If the use of TCE in the U.S. is prohibited by the Proposed Rule, the U.S. will be forced to depend on foreign suppliers for its batteries, harming the U.S. economy and risking national security. The downstream effects of any such disruption would ripple through the national economy, including within multiple critical

infrastructure sectors, and render the U.S. dangerously reliant on foreign separator suppliers to the extent adequate foreign supplies can even be made available.

The Biden Administration has prioritized not only protecting but *strengthening* these critical industry sectors and supply chains, calling on the Secretary of Energy to evaluate and report on risks in the supply chain for "high-capacity batteries, including electric vehicle batteries" and to provide "policy recommendations to address these risks."[3] The Administration aims to improve the U.S.'s role "in the supply chain associated with electric battery production," including by "better leverag[ing] our ... manufacturing know-how to expand domestic battery production."[4] The President's American Jobs Plan furthers this priority by seeking to "reinvigorat[e]" domestic battery manufacturing capacity by scaling operations[5] to create a "reliable and independent battery supply chain."[6] A 2021 100-Day Report on these efforts focuses on lithium battery supply chains and expressly highlights that "separators ... represent a battery supply chain stage where the United States currently relies on foreign imports due to limited domestic manufacturing capacity."[7] Accordingly, a key goal of the U.S. Department of Energy's National Blueprint for Lithium Batteries (2021-2030) is to support the growth of midstream lithium battery manufacturing (which includes separator manufacturing) to meet domestic economic and defense demands.[8] The Inflation Reduction Act of 2022 provides tax incentives and funding for the U.S. manufacture of batteries, energy storage, and electric and other clean energy vehicles, all of which require battery separators.[9] In fact, nearly all sources of clean energy require batteries to operate. Without an exemption allowing the continued use of TCE in battery separator manufacturing, the Biden Administration cannot meet its goals to expand domestic battery manufacturing or transition to a clean energy economy.

[3] Exec. Order No.14017, 86 Fed. Reg. 11849-50 (2021).
[4] See Office of President Biden, "Fact Sheet: Securing America's Critical Supply Chains" (Feb. 24, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/fact-sheet-securing-americas-critical-supply-chains/.
[5] Office of President Biden, "Fact Sheet: The American Jobs Plan Supercharges the Future of Transportation and Manufacturing" (May 18, 2021), https://www.whitehouse.gov/briefing-room/statements-releases/2021/05/18/fact-sheet-the-american-jobs-plan-supercharges-the-future-of-transportation-and-manufacturing/.
[6] Andy Colthorpe, Energy Storage News, "Biden's US$2 trillion American Jobs Plan for infrastructure 'prioritises energy storage'" (Apr. 1, 2021), https://www.energy-storage.news/bidens-us2-trillion-american-jobs-plan-for-infrastructure-prioritises-energy-storage/.
[7] Office of President Biden, "Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-Based Growth, 100-Day Reviews Under Executive Order 14017," 112 (June 2021), https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.
[8] U.S. Department of Energy, Federal Consortium for Advanced Batteries "Executive Summary: National Blueprint for Lithium Batteries 2021-2030," 19 (June 2021), https://www.energy.gov/sites/default/files/2021-06/FCAB%20National%20Blueprint%20Lithium%20Batteries%200621_0.pdf.
[9] See United States Senate, "Summary of the Energy Security and Climate Change Investments in the Inflation Reduction Act of 2022" (July 28, 2022), https://www.democrats.senate.gov/imo/media/doc/summary_of_the_energy_security_and_climate_change_investments_in_the_inflation_reduction_act_of_2022.pdf.

C. Microporous' TCE use qualifies for a 25-year exemption because the condition of use of TCE for the manufacture of battery separators, as compared to the lack of reasonably available alternatives, "provides a substantial benefit to health, the environment, or public safety."

The condition of use of TCE for the manufacture of battery separators, as compared to the lack of reasonably available alternatives, "provides a substantial benefit to health, the environment, or public safety." At this time, hexane is the only proven alternative to TCE for use in the manufacture of battery separators. Hexane, however, is a highly flammable neurotoxin and reproductive toxin that presents a significant explosive hazard. The risks of using hexane greatly outweigh those of TCE. While hexane technically is an alternative, it is not practical, and quite possibly presents a significantly greater acute risk profile. It simply does not make sense to replace one solvent (TCE) with a regrettable alternative (hexane) that does not provide additional benefit to health, the environment, or public safety, and actually increases the risk of harm.

Additionally, Microporous began researching alternatives to TCE use in its battery separators in 2014 in an effort to eliminate the TCE-related exposure risks to its employees. Unfortunately, to date, after many years and significant financial investment in research, no viable alternative has been identified. Considerate of the regulatory and safety concerns surrounding the continued use of TCE in its process and consumer products, Microporous continues to invest resources into identifying and validating alternative solvents for use in its battery separators.

VII. EPA's Conditions Imposed as Part of the Battery Separator Exemption are not Based on Good Science and are Unworkable as a Practical Matter.

In granting a TSCA Section 6(g) exemption, EPA may impose conditions if "necessary to protect health and the environment while achieving the purposes of the exemption." The purpose of these conditions is to "protect health and the environment *to the extent feasible*, recognizing that, by its nature, an exemption will allow for activities that present some degree of unreasonable risk."

The fundamental problem with the proposed Battery Separator Exemption is that it is subject to a set of unworkable conditions that would prevent Microporous from continuing operations as a practical matter. Although EPA has recognized that the Battery Separator Exemption is needed to protect the economy, national security, and critical infrastructure, it has proposed subjecting the exemption to an ECEL and WCPP conditions that, together, effectively ban any realistic use of TCE by battery separator manufacturers. Thus, if these proposed conditions remain in the final rule, the impact on the battery separator industry will be fatal, causing an inevitable shut down of battery separator manufacturers. This result is the very consequence that the Battery Separator Exemption is supposed to prevent, that is a significant disruption to the national economy, national security, and critical infrastructure, all of which depend on battery separators.

A. The ECEL and WCPP conditions are unreasonable and unworkable.

The Proposed Rule imposes conditions that must be met to qualify for the Battery Separator Exemption, including an ECEL and corresponding WCPP. While TSCA allows EPA to impose reasonable conditions, EPA has not done so here. The proposed ECEL and primary alternative ECEL are scientifically unsound. To make matters worse, the WCPP's respiratory protection and monitoring requirements are unreasonable and unworkable. In fact, in some cases (such as the respiratory protection condition) actually cause more harm than good. The practical impact of these conditions is an outright ban because no battery separator manufacturer can comply and stay in business.

1. The proposed and primary alternative ECELs are scientifically unsound.

The proposed Battery Separator Exemption mandates a Proposed ECEL of 0.0011 ppm (1.1 ppb) as an 8-hour time-weighted average ("TWA"). (88 Fed. Reg. at 74,764) The Proposed ECEL is based on a developmental endpoint of congenital heart defects ("CHD"). (88 Fed. Reg. at 74,731) EPA also considered a primary alternative ECEL of 0.004 ppm (4 ppb) as an 8-hour TWA, reflecting an immunotoxicity endpoint. (*Id.*) The attached reports from ToxStrategies (**D**) and Gradient (**Tab E**) explain in detail the scientific shortcomings in EPA's purported scientific basis for the proposed and primary alternative ECEL. These reports are summarized briefly below. Given the weight of evidence detailed in these reports, and given the importance of battery separator manufacturing to the national economy, national security, and critical infrastructure, Microporous respectfully requests that EPA reconsider conditioning the Battery Separator Exemption on either the proposed or primary alternative ECELs.

(a) EPA should not adopt the Proposed ECEL.

TSCA provides that in carrying out its Section 6 authority, "to the extent that [EPA] makes a decision based on best available science," EPA shall: (1) "use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science" (15 U.S.C. § 2625(h)); and (2) "make decisions under [Section 6] … based on the weight of the scientific evidence." (15 U.S.C. § 2625(i)) Yet, by EPA's own admission, the Proposed ECEL fails to meet either of these standards. In the 2020 Risk Evaluation, EPA acknowledged that "there is lower confidence in the dose-response and extrapolation of results" from the studies supporting the developmental endpoint, "resulting in uncertainty surrounding the precision of the derived [points of departure] for th[at] endpoint[]."[10] Based on that uncertainty, EPA concluded that the developmental endpoint does not reflect "the best available science" or "weight of the scientific evidence."[11]

EPA's conclusions regarding the uncertain state of the science are correct. The Proposed ECEL rests primarily on a single study, Johnson et al. 2003 (the "Johnson Study"), that reported

[10] 2020 Risk Evaluation § 4.5.2.1.
[11] *Id.*

an increased incidence of cardiac malformations in the developing fetuses of pregnant rats orally exposed to TCE in drinking water.[12] The Johnson Study, however, has been widely criticized in the literature due to numerous defects,[13] as explained in the attached reports from Gradient and ToxStrategies, and summarized briefly below.

First, the Johnston 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. (*Contra* 15 U.S.C. 2625(h)(1), (4)) As ToxStrategies explains, 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 (*see* erratum by Johnson et al., 2014), it is likely that there were other environmental and experimental inconsistencies in the conduct of the Johnson Study lab experiments that went unreported that may also have influenced their results.[14]

Second, rather than testing control groups concurrently with the associated exposure groups, the Johnson Study inappropriately pooled negative control group data in the same set of different experiments spanning six years. Again, this approach makes the study's results sU.S.C.eptible to undocumented differences in the environmental conditions, which were likely magnified in the Johnson Study laboratory over the extensive testing period. The combination of the different, variously sized control groups from across the different experiments also artificially inflates the statistical power of the study.[15]

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. Also, the pooled data overall lack an interpretable dose-response relationship.[16]

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[12] *See* 2020 Risk Evaluation § 3.2.5.1.6, App'x F § F.1.1.

[13] *See, e.g.*, Summary of External Peer Review and Public Comments and Disposition for Trichloroethylene (TCE): Response to Support Risk Evaluation of Trichloroethylene (TCE) at 178 (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").

[14] *See generally* **Tab D**, ToxStrategies Report § 5; **Tab E**, Gradient Report § 42.1.

[15] *See* **Tab E**, 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.*

[16] *See id*.

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." (15 U.S.C. 2625(h)(3)) The design of the Johnson Study exacerbated this problem because animals in the study were group-housed, with multiple rats drinking from the same bottle, further reducing the precision of dose calculations.[17]

Fifth, the Johnson Study's conclusions regarding congenital heart defects were based on a non-standard, unvalidated fetal heart dissection technique. As ToxStrategies explains, in all of the scientific literature, only one other peer-reviewed published study (Fisher et al., 2001) 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.

Last, 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. Importantly, neither found evidence of an association between TCE exposure and congenital heart defects.[18]

In fact, among 13 developmental toxicology studies reported in the published literature that investigated the potential effects of TCE 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, with the other studies demonstrating a lack of association between *in utero* TCE exposure and fetal cardiac defects. This includes all inhalation studies, which represent the most relevant route of exposure for human occupational exposure.[19] As the Science Advisory Committee on Chemicals ("SACC") observed, "cardiac 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]."[20] 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,[21] the failure of any studies 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

[17] *See* **Tab D**, ToxStrategies Report § 5; **Tab E**, Gradient Report § 2.1.
[18] *See* **Tab D**, ToxStrategies Report § 5.
[19] *See* **Tab D**, ToxStrategies Report § 5; **Tab E**, Gradient Report § 2.1.
[20] TSCA Science Advisory Committee on Chemicals Meeting Minutes and Final Report No. 2020-4, Recommendation 70 at 64 (Mar. 24-27, 2020) (hereinafter SACC Report).
[21] 15 USC 2625(h)(5).

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.[22] The SACC expressly recommended that "trichloroethylene inhalation studies, notably that of Carney et al. (2006), should receive greater attention."[23] A systematic review by Wikoff et al. (2018) similarly found that the inhalation studies overall had lower Risk of Bias than the oral studies, using the Risk of Bias tool developed by the National Toxicology Program's Office of Health Assessment and Translation, and that the Johnson Study had the highest Risk of Bias of all animal studies due to the defects identified above.[24] Despite the SACC's recommendation, however, EPA did not reconsider the Carney Study in the weight of the evidence assessment included in the final TCE Risk Evaluation, nor did it ever explain why it scored the Johnson and Carney Studies as having equal relevance.

None of the other evidence for the developmental endpoint adduced by EPA compensated for the Johnson Study's unreliability. EPA has attempted to bolster its reliance on the Johnston Study with epidemiological studies, but as ToxStrategies and Gradient explain, 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.[25] 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"[26]—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) (the "Urban Study"), a recent systematic review integrating the human and animal evidence streams with available mechanistic data, concluded

[22] *See* **Tab D**, 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.").
[23] SACC Report at 19.Recommendation 70 at 64 ("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.").
[24] *See* **Tab D**, ToxStrategies Report § 6.
[25] *See* **Tab E**, Gradient Report § 2.1.
[26] SACC Report Recommendation 71 at 65.

that "the totality of evidence does not support CHDs as a critical effect in TCE human health risk assessment."[27]

EPA also relied on mechanistic studies. But, as ToxStrategies details, there are substantial limitations to these studies, and the evidence base is quite limited when scrutinized through a systematic review process. The Urban Study 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, the Urban Study 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."[28] These criticisms cast serious doubt on EPA's view that the mechanistic data are stronger and more reliable than either animal or human databases.[29]

For these reasons, EPA lacks a basis to adopt the proposed ECEL. Importantly, since issuing the 2020 Risk Evaluation, EPA has never argued, let alone attempted to show, that the developmental endpoint reflects the best available science. The Agency did not address the issue at all in the Revised Final Risk Evaluation. In the Proposed Rule, EPA's only justification for relying on that endpoint was that comments led to "concerns pertaining to political interference and scientific integrity, among other issues." (88 Fed. Reg. at 74,723) EPA does not acknowledge or address the well-documented scientific flaws and uncertainties that have been published in the peer-reviewed literature and does not address the SACC's concerns with the use of this endpoint as the basis of a quantitative risk assessment. Even granting the vague concerns EPA identified, nothing prevents 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.

(b) EPA should not adopt the Primary Alternative ECEL.

EPA also lacks a scientifically sound basis to adopt the primary alternative ECEL. The primary alternative ECEL is based largely on a study by Keil et al. (2009) (the "Keil Study"). As the SACC observed, however, the Keil Study has multiple significant limitations, including the lack of a consistent dose-response relationship, lack of precise exposure information such as analytical verification of exposure dose, lack of a plausible reason why the autoimmune-prone strain of mice did not show evidence of increased biomarker response or disease progression, lack of confirmation of an adverse effect in other organs and tissues, and lack of adequate dose groups

[27] *See* **Tab E**, Gradient Report § 2.1.
[28] SACC Report Recommendation 72.
[29] *See* 2020 Risk Evaluation App'x F § F.3.2 tbl. Apx F-13.

for dose-response modeling.[30] EPA has failed to respond adequately to the SACC's recommendations.

As Gradient and ToxStrategies explain, the autoimmune related antibodies reported in the Keil Study represent serum biomarkers related to autoimmunity and do not indicate the presence of actual autoimmune disease. Thus, the resulting point of departure ("POD") does not represent an adverse effect, is much lower than levels where actual immunological effects have been reported, and has a high level of uncertainty. The Keil Study states that TCE exposure at the two concentrations studied (1,400 and 14,000 ppb) did not alter NK cell activity, or T- and B-cell proliferation in either strain of mice and was not associated with the development of autoimmune disease in either strain. Further, the biomarkers studied in the Keil Studycan be caused by a variety of transient conditions and thus have been recognized as having low positive predictive value for immunotoxicity diagnosis. On these grounds, the Agency for Toxic Substances and Disease Registry concluded, with respect to the immune response, that "reliable biomarkers of effect are not available for trichloroethylene [TCE]." (ATSDR, 2019) As such, EPA's use of these autoimmune biomarkers from the Keil Study for estimation of human health risk is not appropriate and does not represent the best available science as mandated by TSCA for chemical risk evaluations.[31]

The Gradient Report further explains that, in a prior study, EPA itself has recognized that the reported increases in the antibodies reported in the Keil Study were not accompanied by evidence of inflammation or autoimmune-related nephritis in a similar dose- and time-dependent manner, or the progression or initiation of autoimmune disease.[32] Additionally, a National Toxicology Program ("NTP") study using the same strain of mice (B6C3F1) found no evidence of autoimmune disease associated with chronic TCE exposure. Recent studies in autoimmune-prone and non-autoimmune-prone mice also have reported no development of autoimmune disease despite expression of autoimmune-related biomarkers and exposure to TCE at significantly greater concentrations than those used in the Keil Study. Taken together, the changes in autoantibody levels from the Keil Study represent a highly uncertain endpoint with regard to potential adverse effect and thus should not be used as the basis of human health risk conclusions. Importantly, while EPA classified the Keil Study as "high quality," it was graded as an "unreliable" study by the U.S. Army Public Health Center ("APHC") according to the APHC's systematic study quality and relevance scoring tool.[33] Ultimately, because the immunotoxicity POD is based only on biomarkers related to autoimmunity rather than actual autoimmune disease, it has a high level of uncertainty and is therefore inappropriate as the basis of EPA's Primary Alternative ECEL.

[30] *See* **Tab E**, Gradient Report § 2.2; *see also* **Tab D**, ToxStrategies Report § 8.
[31] *See Id.*
[32] *See* **Tab E**, Gradient Report § 2.2.
[33] See *id.*

2. Compliance with the ECEL as a condition of the Battery Separator Exemption would be unreasonable and unworkable.

EPA proposes that each user's WCPP address unreasonable TCE risk to achieve the ECEL "to the extent possible," (88 Fed. Reg. 74,764) with exposure monitoring required to identify a user's "lowest achievable exposure level" relative to the ECEL. (88 Fed. Reg. at 74,743) Under the WCPP, in workplaces where reducing TCE to the lowest achievable exposure level does not lead to exposures at or below the ECEL, EPA proposes that exposed persons be required to wear respirators as a supplement to other feasible exposure controls "whenever TCE exposures exceed or can reasonably be expected to exceed the ECEL." (88 Fed. Reg. at 74,741) The type of respirator required would be based on OSHA's regulations at 29 C.F.R. § 1910.134(d)(1) and on an exposure concentration scale for the minimum required respirator protection. (*See* 88 Fed. Reg. at 74,741-42) For example, if monitored exposure concentrations are measured greater than 1.1 ppm, exposed persons would need to be equipped with a National Institute for Occupational Safety and Health ("NIOSH")-certified SCBA or supplied air respirator equipped with a full facepiece and operated in a pressure demand or other positive pressure mode (to achieve an assigned protection factor ("APF") of 10,000). (*See* 88 Fed. Reg. at 74,742)

Additionally, monitoring frequencies would be tied to air concentration conditions. For example, if monitoring indicates that airborne exposure is above the ECEL, then periodic exposure monitoring would be required within three months. (*See* 88 Fed. Reg. at 74,739) Thus, for facilities that consistently exceed the ECEL, monitoring would be required at least every three months for the duration of the exemption period. Under these requirements, if Microporous "cannot demonstrate exposure below the ECEL or exposure at the lowest achievable level for the facility, including through the use of engineering controls or work practices," and cannot "demonstrate[] that it has supplemented feasible exposure controls with respiratory protection," this would constitute a failure to comply with the ECEL. (88 Fed. Reg. at 74,790)

Despite the robust engineering and administrative controls in place at Microporous' Piney Flats plants explained above, it is not possible to meet the currently proposed ECEL. Microporous already has implemented robust engineering and administrative controls at its Piney Flats, Tennessee plants, including installing a new line in 2021 using the newest, best-in-class technology, and Microporous knows of no additional feasible engineering or administrative controls that would enable Microporous to avoid the proposed WCPP's mandate that workplaces exceeding the ECEL must have employees wear SCBAs or supplied-air respirators at all times. As detailed below, the constant use of such respirators is simply unreasonable and would pose a significant risk to Microporous workers.[34]

These infeasibility conclusions are consistent with the EPA's own findings. EPA itself acknowledges that compliance with the ECEL will be unachievable by administrative and engineering controls. In its recent webinar on the Proposed Rule, EPA rightly noted that "[m]eeting the ECEL presents significant challenges" and "[c]annot be achieved just through engineering and administrative controls: would require workers to be in PPE of Assigned

[34] *See* **Tab C**, Ramboll Report § 2.2.2.

Protective Factor (APF) 10,000 or above, which is not feasible long term."[35] (Emphasis added) In the preamble to the Proposed Rule, EPA specifies that the agency "believes that the extremely low ppm level of the ECEL . . . will be infeasible for industry to reliably meet due to the need for a combination of engineering, administrative controls, and full-face, self-contained, air-supplied respirators." (88 Fed. Reg. at 74,762) EPA thus requests comment on "the feasibility of controlling worker exposures to TCE at or below the proposed ECEL, and the accuracy of measurements at this level," recognizing potential detectability problems as well. (*See* 88 Fed. Reg. 74,737) Such feedback, EPA notes, is "important for determining whether there are realistic and effective exposure controls that can be used by industry for effectively controlling exposures to levels at or below the ECEL." (88 Fed. Reg. at 74,737)

In stark contrast to EPA's Proposed ECEL of **0.0011 ppm** for an 8-hour time-weighted average, OSHA has set the Permissible Exposure Limit ("PEL") at **100 ppm** for the same 8-hour time-weighted average. Additionally the NIOSH 8-hour TWA standard is 50 ppm, and the American Conference of Governmental Industrial Hygienists ("ACGIH") 8-hour TWA standard is 10 ppm. OSHA has determined that the 100 ppm exposure limit "most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." (29 U.S.C. § 655(b)(5)) As discussed below, the same feasibility considerations must inform EPA's determination of what conditions to impose on an exemption under TSCA Section 6(g).

3. The WCPP respirator requirements proposed as a condition of the proposed Battery Separator Exemption are infeasible and unreasonable.

Because the ECEL will be unachievable for Microporous to attain using feasible engineering and administrative controls, under the proposed WCPP, the natural result is that all Microporous plant workers would need to be equipped with SCBAs or supplied-air respirators at all times.[36] Such a mandate in an industrial setting like Microporous would be wholly unprecedented in U.S. industry, to Microporous' knowledge.

EPA, however, has specifically acknowledged that its respirator requirements are infeasible and not a "long-term ... feasible means of addressing unreasonable risk." (88 Fed. Reg. at 74,766) In a recent webinar on the Proposed Rule, EPA explained that "[u]ncertainty about WCPP implementation is a driving factor" behind its decision to propose an outright ban of TCE rather than permit its use subject to implementation of a WCPP.[37] In particular, EPA has recognized that the "complexity and burden of wearing respirators increases with increasing APF." (88 Fed. Reg. at 74,764) Therefore, "[g]iven the high APF of respirators that are likely needed to

[35] November 2023 EPA Webinar, Slide 17.
[36] *See* proposed 40 C.F.R. § 751.311(3)(iii)(G), at 88 Fed. Reg. 74,791; *see* **Tab C**, Ramboll Report § 2.2.2.
[37] November 2023 EPA Webinar, Slide 16.

reach the ECEL, EPA recognizes that this equipment and its programmatic maintenance could be highly burdensome." (*Id.*)

OSHA's respirator standards unquestionably are onerous and generally do not accommodate or contemplate respirator use by all employees working at a large-scale industrial plant. Among other standards, 29 C.F.R. § 1910.134 requires a medical evaluation and respirator fit testing for each employee donning a respirator. (29 C.F.R. §1910.134(e), (f)) Individuals who fail either of these qualifying tests cannot wear a respirator, nor can employees with facial hair or any other condition that interferes with the face-to-facepiece seal or valve function. (29 C.F.R. §1910.134(e), (f), (g)(1)) Furthermore, all respirators used must be managed under frequent disassembly, disinfection, and inspection protocols (including a requirement that unless each employee is provided his or her own exclusive respirator, each respirator must be fully disinfected between wears) and prescriptive storage requirements. (29 C.F.R. § 1910.134(h)(1), (2))

The WCPP's respirator requirements are technically and operationally infeasible when applied to Microporous' operations for the following reasons, among others explained in the attached reports:

- Microporous would only be able to employ those people who could pass a medical evaluation and respirator fit test. EPA has acknowledged that "not all workers may be able to wear respirators. Individuals with impaired lung function due to asthma, emphysema, or chronic obstructive pulmonary disease, for example, may be physically unable to wear a respirator." (88 Fed. Reg. at 74,764-65) With respect to the latter, that is because, as EPA explains, "[i]ndividuals with facial hair, such as beards or sideburns that interfere with a proper face-to-respirator seal, cannot wear tight fitting respirators."[38] Thus, implementation of the WCPP effectively means Microporous would have to significantly reduce its workforce, then seek to replace all of those employees.

- For those workers able to wear respirators, the costs in time of frequently switching out SCBA tanks over a 12-hour shift would be enormous and crippling to sustained facility operations. Additionally, bearing the additional load of a SCBA tank is a substantial physical burden for a person, as SCBAs typically weigh 30 lbs or more.[39]

- As EPA has indicated, mandating respirators for all employees in and around the plant poses serious safety and access hazards. Among the numerous risks posed are the following, which are present at the Microporus plants:

[38] *Id*.
[39] *See* **Tab E**, Gradient Report § 3.2 at 12. (""SCBA respirators are heavy, weighing 30 pounds or more").

- Employees' vision and hearing will be impaired, reducing their situational awareness and ability to identify dangerous conditions putting their safety in jeopardy.[40]

- Use of respirators presents problems with maneuverability and with the ability to perform basic tasks. At Microporous, due to the configuration of the workspaces and the high density of machinery, respirator units and hoses could easily become caught on objects, particularly when working in narrow areas.

- Employees occasionally need to climb ladders in the multi-level plants, which would be dangerous to do wearing respirator equipment. Access may in fact not be feasible, as these are often caged ladders for fall protection without space for respirators.

- Respirators greatly increase the risk of heat exhaustion during spring and summer months (particularly in Tennessee) by stifling air flow and body heat escapement. Microporous' process equipment adds to the heat issues, posing potential risks of both worker heat stress and potential melting of respirator tank and hose equipment. Moreover, maintenance workers have to access certain enclosures at Microporous where the temperatures range from 90-110° F, adding to the fatigue and risks of heat stress.

- Microporous maintenance employees must perform electrical testing, which will become challenging if not impossible for workers wearing respirators. Electrical testers must wear arc flash-protectant shirts, gloves, and hoods, which do not also accommodate full- or half-face respirators. Microporous and its experts (Gradient and Ramboll) know of no commercially available SCBAs or supplied-air respirators rated to provide arc flash protection. Failure to use rated clothing and equipment increases the risk of electrical burns and injuries from arc flash.

- Microporous' plant would have to be substantially, if not entirely, reengineered and reconstructed to provide the requisite storage for the respirator equipment. Under pressurized air safety considerations, storage areas would need to be dry, well-ventilated, without temperature extremes, protected from physical impacts, with valve caps, and away from flammable materials and sources of heat. The program here would require Microporous to procure and store hundreds of respirator units, requiring significant space to safely store such equipment. With about 50 employees working at the plant during any given shift, and with each employee needing to change their air tanks every 30-minutes, Microporous would need to construct and accommodate at minimum around 45 separate refilling stations to

[40] *Id.* at 13. ("Respirators can interfere with vision, communication, worker activities, and interations with the head.")

ensure adequate and safe air supply and refilling access. Similar engineering, physical, and operational challenges prevent Microporous' plant from being reconfigured to accommodate supplied air lines for all plant employees. Microporous' plant simply cannot accommodate the requirements necessary to provide supplied air from respirators to all employees at all times and maintain its separator production at any meaningful rate.

- The program entails logistical impracticalities and dangers. For example, vendors, contractors, and other visitors would have to obtain medical and fit-test clearance to wear SCBA prior to even entering the building to perform inspections, conduct tours, or provide emergency response efforts.

- As noted above, a supplied air system would be similarly infeasible for many of the same reasons. Again, the entire plant would need to be substantially, if not entirely, rebuilt to ensure that all plant workers were provided safe and reliable supplied air.

These WCPP components also are infeasible from an employment perspective, as "worker acceptability" – the willingness to comply with this extraordinarily burdensome requirement – would be a significant problem. This is well established by the literature.[41] Many workers simply may find the requirement unacceptable, leading to employees leaving or simply being unable to comply. Piney Flats, Tennessee is a small, rural town. As a practical matter, finding and retaining enough technologically skilled workers to staff our sophisticated plant is already a challenge. Subjecting all of those employees to full-time respirator use and frequent personal breathing zone monitoring protocols simply will likely not be accepted by Microporous' workforce. Even beyond the problems detailed above, on a fundamental level, wearing these respirators during all hours of all shifts would make working at Microporous an intolerable experience. Microporous retention and recruitment, as well as employee autonomy and quality of life will be severely compromised under the WCPP. This, too, undermines the exemption's protection and purpose. Microporous is not aware of <u>any</u> manufacturing workplace where, in the normal course, employees are expected to wear full SCBA or supplied air respirators for full 8-hour shifts, let along 12-hour shifts, every day for the duration of their employment.

Fortunately, TSCA Section 6(g) does not require all day every day WCPP or respiratory protection as a condition on exempt uses. EPA has recognized its ability to relax infeasible conditions for exempt uses, as it did so in the perchloroethylene ("PCE") TSCA risk management rulemaking. There, EPA proposed a Section 6(g) exemption for NASA's use of the chemical in human space flight, under which NASA must comply with the WCPP only "to the extent technically feasible." (88 Fed. Reg. 39,682) To exempt NASA's use from full WCPP compliance, while requiring such compliance for Microporous' use, which is critical to the nation's everyday functioning, is counter to the purpose of TSCA Section 6(g). Given the extreme infeasibility of the WCPP's respirator requirements in Microporous' use, they are unreasonable and violative of

[41] *Id.* at 14 ("the willingness to wear and make proper use of respirators is a significant problem").

TSCA § 6(g)(4). Accordingly, the Battery Separator Exemption must not subject exempt TCE users to the requirements, as proposed.

4. The WCPP's proposed monitoring requirements also are infeasible and unreasonable.

The proposed monitoring requirements also are infeasible and unworkable. As discussed above, if the proposed WCPP were applied to Microporous' plant, exposure monitoring would be required every three months on an ongoing basis for the duration of the exemption.

EPA has acknowledged the burden of this proposed monitoring scheme, noting it "may be difficult to operationalize routine use of these [monitoring] methods for detection at the low levels needed for the TCE ECEL and ECEL action level." (88 Fed. Reg. at 74,737) EPA also has recognized detection limitations, noting that neither EPA nor the regulated community can "reliably monitor to [an] ECEL of 0.0011 ppm, or to action level."[42] Accordingly, EPA has requested specific comment on "personal air sampling devices that are capable of detecting indoor air TCE concentrations at or below the ECEL action level … with the requisite precision and accuracy" and whether it should instead "require compliance with an interim exposure level based on the limit of detection of established analytical methods." (88 Fed. Reg. at 74,737)

As Microporous' toxicology experts have concluded, the lowest feasible detection limit for TCE from exposure monitoring is 0.018 ppm for a 12-hour sample, which is *16 times higher* than EPA's proposed ECEL of 0.0011 ppm, 33 times higher than the proposed action level of 0.00055 ppm, and 4.5 times higher than EPA's proposed alternative ECEL of 0.004 ppm.[43] Moreover, methods facilitating lower detection limits in the range of the proposed ECEL are unconventional and would be too cumbersome for personal breathing zone ("PBZ") sampling. They also would be unreliable and therefore too difficult to meet on a routine basis pending further advances in analytical capabilities.[44]

Again, TSCA Section 6 does not require a prescriptive monitoring scheme for exempt uses. Accordingly, in at least the PCE rule, EPA imposed relaxed monitoring and reporting requirements for an exempt use, allowing the user, NASA, to comply with the WCPP only "to the extent technically feasible" in certain situations. (*See* 88 Fed. Reg. at 39,682) The same outcome is needed here to ensure the exemption's intent is realized.

5. EPA failed to coordinate with OSHA as required by TSCA § 9(a).

TSCA Section 9(a) requires that EPA consult and coordinate with the heads of other appropriate federal executive departments or agencies to achieve maximum enforcement of TSCA while imposing the least burden of duplicative requirements. (*See* 15 U.S.C. 2608(a)) As EPA has put it, "[i]f risk is already managed effectively under a different statute, regulation under TSCA

[42] November 2023 EPA Webinar, Slide 17.
[43] **Tab E**, Gradient Report, § 3.1.
[44] *Id.* For example, use of a 6-liter Summa canister and analysis by TO-15 could achieve a detection limit less than the action level, but the canister is too heavy to feasibly be worn on the belt of a worker.

is not necessary."[45] With regard to statutes administered by other federal agencies, Section 9 directs that if EPA has reasonable basis to conclude that a chemical's use presents, or will present, an unreasonable risk of injury to health or the environment and that such risk may be sufficiently prevented or reduced by another agency under another federal law, EPA "shall" submit to that agency a report describing the risk and requesting that the other agency determine if the risk may indeed be sufficiently prevented or reduced under that law. (15 U.S.C. § 2608(a)(1)) If so, EPA "shall" also request from that agency an order declaring whether or not the use presents such risk. (*Id.*)

EPA in the Proposed Rule preamble explains that Administrator Regan performed this Section 9(a) analysis (*see* 88 Fed. Reg. at 74730), but ultimately chose "to exercise his discretion not to determine that the unreasonable risk from TCE under the conditions of use may be prevented or reduced to a sufficient extent by an action taken under a Federal law not administered by EPA." (88 Fed. Reg. at 74,773) EPA notes in particular that OSHA "may set exposure limits for workers, but its authority is limited to the workplace and does not extend to consumer uses of hazardous chemicals." (88 Fed. Reg. at 74,774) EPA states it "has and continues to coordinate with" various agencies including OSHA. (88 Fed. Reg. at 74,773) But it is unclear from the preamble or materials within the rulemaking docket what, if any, specific OSHA coordination occurred. Still, EPA seeks comment on "the sufficiency of an action taken under a Federal law not administered by EPA." (88 Fed. Reg. at 74,774)

Based on the Proposed Rule's preamble and available record materials, EPA has not reasonably exercised its discretion under Section 6(a) here. EPA concluded—seemingly without any substantive coordination—that risk from TCE in the workplace could not be prevented or reduced to a sufficient extent by action taken by OSHA, even though protecting against such risks is OSHA's prime directive and authority. (29 U.S.C. § 651)

VIII. A Ban of TCE in Wastewater Discharges is Not Feasible, and is Contrary to the Well-Established Regulatory Framework for Wastewater Discharges.

EPA's proposed wastewater discharge ban also does not satisfy TSCA Section 9(b), requiring EPA to "coordinate actions taken under [TSCA] with actions taken under other federal laws administered in whole or in part by [EPA]." (15 U.S.C. § 2608(b)(1)) If EPA decides to deviate from this mandate, EPA must do so only if it "determines … that it is in the public interest" to do so. (*Id.*) For EPA to invoke TSCA to preempt or supersede another regulatory scheme, EPA must first find either that "a risk to health or the environment" associated with TCE cannot "be eliminated or reduced to a sufficient extent" under another of EPA's authorities or that supplemental regulation through TSCA is "in the public interest."

Here, EPA has not complied with TSCA Section 9(b) because another long-established federal statutory scheme—the Clean Water Act—governs wastewater discharges to industrial pre-

[45] EPA, *TSCA Section 9 Relationship to Other Federal Laws*, Assessing and Managing Risks under TSCA, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-9-relationship-other-federal-laws (last accessed Dec. 14, 2023).

treatment, industrial treatment, and POTWs. In its Proposed Rule, EPA makes no finding as to whether regulation under the CWA could eliminate or sufficiently reduce the risks associated with discharges of TCE. Instead, and insufficiently, the Proposed Rule only references statutes like the CWA in passing. Other EPA statutes, like the CWA, "have been used to limit TCE exposure," those limitations "largely regulate releases to the environment," and management under TSCA is "also appropriate" to prevent "occupational and consumer exposures and in some cases can provide upstream protections that would prevent the need for release restrictions required by other EPA statutes." (88 Fed. Reg. at 74,774) That gets the required analysis backward, however. Under Section 9(b), EPA must first determine whether the CWA reduces the risk from TCE "to a sufficient extent." Instead, the Proposed Rule justified invoking TSCA for the purpose of averting "the need for release restrictions required by other EPA statutes," such as the CWA. Section 9(b) directs EPA to treat TSCA as a gap-filler, not as the primary source of regulation.

The closest EPA comes to identifying the need to supersede the CWA is its assertion that regulation under the CWA would not "address the direct human exposure to consumers, bystanders, workers, and [occupational non-users] ONUs from the conditions of use evaluated in the 2020 Risk Evaluation for TCE."[46] But EPA has not explained how or why the CWA's existing regulation of TCE in wastewater is insufficient to protect against these exposures. And no reason exists. As the Supreme Court has recognized, the CWA ensures "comprehensive regulation of water pollution."[47] State and local discharge permit terms, like those in place at Microporous, are derived from federal ambient water quality criteria for TCE, which EPA establishes to protect the public health and welfare and that states like Tennessee must use to set water quality standards and permit limits.

Nor is the wastewater POTW disposal ban an example of an "upstream protection" referenced in EPA's justification. A system like Microporous' is a closed process, and EPA has offered no data or other information to support the need for "upstream protection" due to exposures from TCE present in wastewater prior to discharge. Nor has EPA made the "public interest" determination expressly required by TSCA Section 9(b) to regulate wastewater under TSCA. The record lacks any reasoned consideration of the risk from continuing to discharge TCE or any comparison of the estimated costs and efficiencies of the Proposed Rule, when compared against maintaining the current discharge.

As noted above, the preamble language, or rationale that EPA presents for the prohibition, ignores the CWA and its supporting regulations, in particular the 1978 adoption of the General Pretreatment regulations [40 C.F.R. Part 403] to control industrial dischargers to POTWs. There are approximately 1,600 POTWs that have local pretreatment programs.[48] Thirty-six states are authorized to act as the approval authority for POTWs in their state and the EPA Regions authorize pretreatment programs in other states or issue the pretreatment permits themselves.[49] Certain

[46] *See id.* at 74,774-75 (explaining that the CWA cannot "address exposures to workers and ONUs related to the specific activities that result in occupational exposures").
[47] *Int'l Paper Co. v. Oullette*, 479 U.S. 481, 500 (1987).
[48] **Tab C**, Ramboll Report § 3.1.2.
[49] https://www.epa.gov/npdes/national-pretreatment-program-implementation#:~:text=In%20a%20traditional%20pretreatment%20program,act%20as%20the%20approval%20authority

battery separator manufacturers are a federal categorical industry or considered a significant industrial user, hence subject to the pretreatment program of their POTW, whether connected via sewers or hauling in wastewater. Specific to worker safety, the pretreatment program addresses protection from acute effects and chronic effects.[50]

Attempting to regulate overlapping aspects of a chemical's use under both TSCA and another statute administered by EPA also poses significant administrative and legal problems.[51] EPA itself recognizes that its wastewater ban may target activities not constituting disposal under RCRA and the CWA, which poses a huge potential for administrative and enforcement confusion. (*See* 88 Fed. Reg. at 74,729)

Absent further justification and support, EPA has fallen short of Section 9(b)'s directive to manage TCE risks from wastewater under other existing laws as opposed to under TSCA.

IX. Finished Battery Separator Products with Incidental TCE are not Banned TCE-containing Articles.

To enable those companies subject to the Battery Separator Exemption to operate within the confines of the Exemption, EPA must clarify the Proposed Rule to make plain that finished battery separators that retain trace amounts of TCE are not banned. Though there may be some question, it appears that the Proposed Rule would ban the processing of TCE to incorporate it into an article, such that it "becomes an integral component of an article distributed for industrial, commercial, or consumer use." (88 Fed. Reg. at 74,726) A trace amount of residual TCE remains in finished battery separators after manufacturing and must remain to obtain the necessary amount of process oil, which protects the separator from oxidation within a battery's harsh environment. This trace amount of TCE is in the final product but is not intentionally incorporated into the finished product or integral to its function. Therefore, battery separators are not articles that incorporate TCE as contemplated by the Proposed Rule.

EPA has recognized that the separator itself is the "fundamental component[]" of a battery that must be protected under the exemption. (88 Fed. Reg. at 74,744) Microporous requests that EPA clarify the Proposed Rule to confirm that the exemption covers TCE retained within finished battery separators. If such clarification is not issued, the entire Battery Separator Exemption would be meaningless because the separators themselves—the key assets protected by the exemption—could constitute prohibited articles. Consequently, no downstream use of the separators could occur and the national economy and critical infrastructure sectors would suffer accordingly. Alternatively, EPA should expressly exempt *de minimis* levels of TCE—*i.e.*, any incidental TCE in battery separator products —from regulation under the final rule.

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[50] *See* **Tab C**, Ramboll Report § 3.1.2.

[51] *See, e.g., N. Y. Cmtys. for Change v. N.Y.C. Dep't of Educ.*, No. 11 CV 3494 SJ, 2012 WL 7807955, at *33 (E.D.N.Y. Aug. 29, 2012), report and recommendation adopted, No. 11CV3494 SJ CLP, 2013 WL 1232244 (E.D.N.Y. Mar. 26, 2013) (court "acknowledge[ed] the difficulty in merging the regulatory aspects of TSCA and RCRA" when considering whether TSCA's regulation of PCBs precluded PCB enforcement action under RCRA).

X. Conclusion

Microporous appreciates the opportunity to provide these comments to EPA and appreciates EPA's recognition of the national importance of Microporous' battery separator production and related Battery Separator Exemption. As discussed above, a potential collapse of the U.S. lead acid and lithium-ion battery industry would jeopardize U.S. national security interests, eliminate thousands of jobs, cause billions of dollars in revenue losses for the U.S. economy, and increase U.S. dependence on foreign supply of batteries. Therefore, Microporous respectfully reiterates its request that EPA grant a TSCA Section 6(g) exemption for TCE use in the manufacture of battery separators for a period of not less than 25 years. Microporous further requests that EPA recognize the fundamental flaws with EPA's proposed Battery Separator Exemption, namely the non-scientific based ECEL, the unwieldy respirator and monitoring requirements of the WCPP, wastewater ban, and article ban. Microporous requests the changes to the Proposed Rule discussed herein. With those changes, Microporous' continued use of TCE for the 25-year exemption period will remain protective of human health and the environment while preserving national security, the economy and critical infrastructure.

Please feel free to contact me should you have questions or need additional information.

With best regards,

John Reeves
Chief Executive Officer, Microporous, LLC